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Case studies in ethics and public health

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Case studies in ethics and public health

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INTRODUCTION

If there is one area of health that should be a focus of interest, analysis and a desire to promote participation in decision-making, it is public health. Public health refers to the protection and monitoring of health at the populational level, and for this reason public health activities should reflect the highest possible degree of consensus between politicians and citizens in order to ensure effective, fair health prevention measures, designed not just to prevent specific problems but also to contribute to the sustainability of the public health system.

We all know that medicine is not an exact science, and even less so where disease prevention policies are concerned. Although the notion that "prevention is better than cure" is a generally accepted piece of folk wisdom, it is far less clear what such prevention should consist of, to what degree it is acceptable to seek to modify people's lifestyles, and what the most appropriate and fairest way of doing this is. The spirit of an illegitimate paternalism hovers threateningly over the autonomy that individuals demand for themselves and for their way of life. John Stuart Mill, perhaps the most renowned critic of paternalism, argued that, "The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not sufficient warrant."

Mill's statement would appear to brook no doubt. The individual is sovereign over his or her health, and the authorities are only authorized to interfere with the individual's liberty in order to prevent harm being done to others. However, the problem lies in the fact that, if medicine is not an exact science, then neither is the meaning of expressions such as "harm to others" or "against his will" straightforward and above dispute. What may or may not harm others in the short, medium or long term is subject to differing interpretations. And our wishes are themselves subject to the actions of different social agents, who seek to influence them through a variety of means, many of which are extremely subtle. We need think no further than the power and

influence of advertising, publicity and fashion. As a result, it is hard to know when opposition to a legislative proposal reflects individual wishes or is actually the expression of other motives, which may be more or less conscious.

These reasons, and others too numerous to list, lead us to conclude that, of all areas of healthcare, public health is one of those where it is most important to analyse, discuss and consider the issues before taking any decisions. Or, to put it another way, it is impossible to pursue public health objectives in a democracy without also engaging in careful ethical consideration of all decisions and the arguments upon which they are based.

Echoing this belief, Andreu Segura, as spokesperson for the Spanish Society for Public Health and Health Administration (SESPAS), sought the collaboration of the Víctor Grífols i Lucas Foundation in forming a working group that would reflect on some of the most pressing and controversial issues in public health, and would draw up a series of documents and guides to good practice designed to contribute to the development of ethics in this sphere of health protection. This initiative led to three series of meetings, each of which generated publications, the last of which is the one published here. This addresses three very different case studies, each with wider relevance to today's society: 1) management of the swine flu pandemic; 2) possible conflicts of interest regarding the adoption of public health measures; 3) the scope and limits of functional foods. Both the presentations that set the scene for the discussion sessions and the contributions of participants to these debates have been the source of material that we hope will be useful as a teaching resource and for future reflections on public health.

Effective recognition of the right to health protection, through a public healthcare system guaranteed by the state, has inculcated in citizens the belief that health is a right that cannot be renounced under any circumstances. This conviction is firmly held and forms part of the core of basic needs that must be met regardless of the economic circumstances. However, with people's desire to preserve their health comes a set of duties. The notion of public health brings together perhaps more clearly than anywhere else the rights and duties to which the individual is subject, to the extent that health is seen not just as the right to receive health care, but also as an obligation to the

community, expressed in the form of vaccination programmes, lifestyle advice and hygiene precautions. Public health objectives do not involve individuals in isolation, but rather within the context of their relations to others. For this reason, the ethical dimension is of particular importance and cannot be ignored. This is the conviction that underpins this project and this publication.

Victoria Camps President

Introduction

Ethics and public health: a working group, a working dynamic

The Ethics and Public Health Group: origins and purpose

The Ethics and Public Health Group is a working group of the Spanish Society for Public Health and Health Administration (SESPAS) whose principal purpose is to promote the application of ethical discussion within the sphere of public health, both in professional practice and in social programmes and interventions.

The group came into being during the seminar on 'Maleficence in prevention programmes', which took place in April 2010 and was organized jointly by the Institute for Health Studies (IES) in Barcelona and the Víctor Grífols i Lucas Foundation. The proceedings of this seminar were published as part of the Foundation's collection of monographs¹. In July 2011, the Víctor Grífols i Lucas Foundation and SESPAS signed an agreement to promote cooperation between public health practitioners (members of SESPAS and affiliated bodies) and experts in ethics. In September, the first ethics and public health meeting was held in Menorca, within the framework of the Public Health Summer School, and this led to the foundation of a working group, open to participants who were not necessarily linked to SESPAS or the Foundation, and coordinated by Andreu Segura. The proceedings of this meeting in Menorca were published in the monograph *Ethics and public health*².

During 2012 the group expanded, and a forum was created on the SESPAS website on which participants engaged in ethical discussion of the three public health case studies chosen for consideration at the second meeting on ethics and public health at the Menorca Summer School. These studies are included in this document.

The Ethics and Public Health Group: second meeting

On 17 and 18 September 2012, with the support of the Víctor Grífols i Lucas Foundation, the second meeting of the Menorca Public Health Summer School (EVSP), on the Lazareto island in Mahón, discussed the topic "Ethics and public health. Putting public health into practice." As suggested at the first meeting, the aim this time round was to present, analyse and debate real ethical dilemmas faced by public health professionals in their daily practice, with the aim of compiling a set of case studies to serve as a tool for reflection and training in this field. The meeting was attended by public health practitioners and specialists in ethics^a, all of whom contributed to and enriched the discussion.

The situations chosen were the management of the flu pandemic, possible conflicts of interest between different areas of the public health services, and functional foods. The case studies were chosen in an email survey that asked members of the group which case studies or issues they wanted to discuss. For each case study, an individual with academic or professional experience in the area, combined with ethical awareness was chosen; this person – the moderator – was then responsible for preparing the material, chairing the debate, and writing up the case study afterwards. The task of preparing these case studies began some months before the meeting, through online discussion forums led by the case study moderators.

The first day in Mahón began with a plenary session at which the three case studies were introduced, and three groups created to analyse and discuss each of the topics. To provide a variety of perspectives and to ensure that the discussion would be as wide-ranging as possible, participants were allocated to groups on a multidisciplinary basis. During the next session, the moderators led group discussion of the individual case studies.

During the second day, the moderator of each group presented the provisional conclusions of their discussions to a plenary session, and these were

then debated by all the participants. Following the meeting, a first draft of the key ideas and the group's conclusions regarding each case study was distributed to all participants. All 25 participants had the opportunity of contributing and making suggestions regarding the wording and content of the case studies. After compiling all the revisions, reviewing the suggested bibliography, and summarizing the ideas and conclusions from the discussions, the moderator, coordinator and secretary of each group wrote up the case studies presented here.

This new monograph, then, is the product of the analysis, debate and consensus of experts in public health and ethics. The scope of the conclusions of these three case studies goes beyond the specific situations they describe and can be extrapolated to many other similar situations that frequently arise in the field of public health.

The group will continue to operate and is keen to encourage the participation of new members, who can email us at gteticaysaludpublica@sespas.es.

It would not have been possible to produce this document without the support of the Víctor Grífols i Lucas Foundation. We would also like to thank all of the members of the group for their contributions, which reflect many hours of analysis and collaborative effort.

Coordinators Andreu Segura Andrea Burón José Miguel Carrasco

a. See list on page 90

Notes

- 1. *Maleficence in prevention programmes*. Barcelona: Fundació Víctor Grífols i Lucas, 2010.
- 2. Ethics and public health. Barcelona: Fundació Víctor Grífols i Lucas, 2011.

CASE STUDIES

Case study 1:
The flu pandemic
Jordi Delclòs

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1. Case description

In March 2009 an outbreak of swine flu in Mexico attracted attention both because it was unseasonal and because it was caused by a new strain of the H1N1 virus. Soon after identification of the first cases, deaths occurred, giving rise to fears that the world was on the brink of a particularly deadly pandemic. Another unusual feature of the outbreak was the fact that the deaths had occurred in atypical groups: young people with no risk factors, including pregnant women. Within a few days the cases spread to the United States and Canada, leading the Centers for Disease Control and Prevention (CDC) in the United States to issue recommendations for the prevention and control of cases. Despite this, the number of cases continued to rise and, in 2009, the first cases appeared in the southern hemisphere, although these did not appear to exhibit the very high mortality rates initially feared. However, given the increasingly broad geographic spread of cases, the World Health Organization (WHO) declared a pandemic (level 6) in June 2009, and proposed a series of containment measures that were rapidly adopted by the majority of member states, including Spain. The recommendations included the identification of specific risk groups, based on the profile of existing cases (e.g., pregnant women) or because of their contact with the general public (health staff or teachers). The strict measures remained in place throughout the summer, despite the growing evidence that this new swine flu (H1N1) was proving to be less deadly than had been expected and was, indeed, less lethal than ordinary seasonal flu. During the autumn, together with the vaccine for seasonal flu, a specific vaccine for the new swine flu (H1N1) was being marketed, accompanied by vaccination campaigns. The take-up rate for this vaccine, however, was fairly low. Cases of the new flu strain peaked in Spain and Europe in November 2009, falling from that point onwards, although the WHO maintained a state of pandemic until August 2010. When it finally declared an end to the pandemic, the WHO recognized that it had been milder than originally predicted. Table 1 summarizes how the key events unfolded.

Table 1. Chronology of events associated with the flu pandemic of 2009-2010.

Date	Event	Comments
March 2009	Initial outbreak (Mexico)	Initial containment measures
April 2009	Transmission to USA and Canada	CDC broadens measures
May 2009	Transmission to southern hemisphere	Low mortality?
June 2009	WHO declares pandemic (level 6)	Measures proposed by WHO and adopted by governments
Summer 2009	Evidence of lower than expected mortality	Recommendations not modified
September 2009	Seasonal vaccine	
October 2009	H1N1 vaccine	EU ≈ 10%. Spain ≈ 6%
November 2009	Cases peak in Europe	

2. Main dilemmas and ethical principles involved, potential conflicts of interest, and foreseeable or actual consequences

During the weeks prior to the workshop on Menorca, four background documents were distributed: Gérvas and Hernández, 2012; Stern and Markel, 2008; Berlinguer and Moses, 2006; and Torá *et al.*, 2012 (listed in the bibliography below). An internet discussion forum was then created, and participants were encouraged to identify the key ethical dilemmas raised by the

global and local reaction to the pandemic that might benefit from more detailed analysis at the meeting. Table 2 summarizes the issues raised in the forum, and identifies the possible consequences of a failure to fully consider the ethical implications.

Table 2. Summary of main ethical issues relating to the flu pandemic of 2009, identified on the forum and proposed for discussion.

Ethical dilemma	Consequence	
Situations that compromise the principle of autonomy	Loss of individual rights and freedoms.	
Use of precautionary principle to justify responses	Decisions taken on the basis of scant scientific evidence.	
The ethics of the unknown	Having to act in the absence of solid scientific evidence.	
Limited capacity for adaptation	Loss of criterion of proportionality. Decisions that do not reflect reality.	
Lack of transparency in decision-making	Paternalism, undermines citizens' trust in public bodies, loss of moral authority. Failure to comply with recommendations.	
Potential conflicts of interest for experts	Abuse of trust, biased decisions or decisions that benefit some at the expense of others.	
Action focused solely on preventing cases and reducing deaths	Loss of principle of equity and distributive justice.	
Lack of self-criticism and accountability	Repetition of errors in future crises.	
Role of professionals and professional bodies	Can help to ensure transparency if they involve the different stakeholders. Otherwise, there is a danger that some perspectives will take priority over others.	

In addition, a number of key ethical principles, values and duties were identified, with the aim of focusing the discussion on the ethical dilemmas listed in the table above, on the basis of the recommendations of the Hastings Center (see bibliography). These included the fundamental ethical *principles* of autonomy, beneficence and non-maleficence; the *values* of reciprocity, transparency, social accountability, and the reduction of social inequalities in health, with particular attention to the most vulnerable groups; and the *duty* to plan, formulating rules and developing tools to support fair decisions, and seeking to ensure the proportionality of responses. And all of this must occur within the framework of respect for civil rights and procedural guarantees, and with effective communication methods.

3. Some reflections as a basis for addressing or resolving each of the dilemmas identified, from the perspective of ethics and public health

After the material had been presented, the pandemic flu working group organized its discussion of these issues along three major lines:

- a) planning responses to a pandemic in a context of transparency and effective communication
- b) the common good versus individual autonomy and freedom
- c) the proportionality of responses versus the precautionary principle

a) Planning in a context of transparency and effective communication

 Planning should be an essential, organizational component of the response to pandemics and other dynamic situations. And it must be incorporated from the start of the response process.

- Planning is an ongoing process that combines prior planning, the flexibility to adapt to changing situations, self-criticism and accountability.
- Good planning should include not just specialists but also representatives from the world of bioethics, the media, professional bodies and other stakeholders.
- Planning must be subject to the oversight of potential conflicts of interests between the different stakeholders.
- Planning should include public education regarding risk.
- The leaders of the planning process should not look down on the general public, members of which are generally able to understand clear communication from reliable sources that transmit transparent messages, even when these messages are not encouraging.

A central objective of the planning process is to help create an informed society and to enable it to participate in and assume responsibility for the process, seeking to counteract the phenomenon of the 'society of fear' and to generate trust in communication so that it has moral authority.

b) The common good versus individual autonomy and freedom

In this area, the discussion gave rise both to questions and to specific observations:

- What is the common good and how do we define it?
- Alternatively, perhaps we should define the limit of the 'common evil'.
- How and when is this autonomy given up?
- When inevitable, only as much individual autonomy should be given up as is necessary, and only for as much time and to such a degree as is truly required. In this respect, perhaps we should focus on establishing 'minimum criteria'.
- It is important to note that an attack on autonomy is also an attack on the common good.

- Should the loss of autonomy be compensated for in some way, given that not everyone sacrifices their autonomy, or should it simply be considered a social obligation? Solidarity is a requirement, but this does not give us the right to censure people.
- How do we establish cut-off points which are based on criteria of justice?
- How should we prioritize resources on the basis of criteria of justice?
- We need an 'ethical perspective' to evaluate statistical data.

c) The proportionality of responses versus the precautionary principle

The proportionality of responses (recommendations or instructions) involves seeking to avoid responses which do not reflect or are disproportionate to the scope of the problem, avoiding in so far as is possible those actions that could restrict individual freedom or rights, or applying these only when absolutely necessary. In contrast, the precautionary principle favours adopting measures designed to protect the population, even in the absence of clear scientific evidence of the scale of the risk itself or of the effectiveness of the measures in question. While the first approach calls for a measured reaction, the second advocates a more proactive response. It is not always easy to reconcile these two concepts, even if it would intuitively seem desirable to propose responses that reflect a balance between the two. During the discussion, a number of issues were identified and various proposals were made with the aim of achieving this balance. These included:

- Resources are wasted and disproportionate actions taken, in part, because the authorities fail to coordinate their approach and are inefficient, with different bodies at every level organizing the same actions, issuing the same communiqués, or bringing experts together for the same purpose.
- In Spain the lack of coordination mechanisms has led to a waste of resources in these situations.
- To do this, it is necessary to create flexible protocols that include tools

- which make it possible to adapt actions to rapidly changing conditions.
- We need to identify and take into account the role of all stakeholders when addressing these questions.
- It is important not to misapply the precautionary principle, using 'chaos' as an excuse for decisions that are taken under pressure and without any basis in evidence (e.g., relieving pregnant teachers of their duties), or providing decision-makers or other stakeholders (political groups, professionals, companies) the opportunity to exploit crisis situations for their own benefit. In this respect, the failure to apply tools such as the CDC's *Pandemic Severity Index* (http://www.flu.gov/planning-preparedness/community/community_mitigation. pdf), which modulates the response in accordance with the seriousness of the impact, is worth noting.

4. Summary and conclusions

During the closing, plenary session of the workshop, participants identified a list of conclusions and recommendations, summarized in Table 3 (below), designed to ensure that the management of future pandemics and other situations posing a threat to public health would be informed by a genuinely ethical perspective.

Table 3. Key conclusions and recommendations. Flu pandemic case study, 2009.

Ethical dilemma or challenge	Conclusions and recommendations
Efficient planning, based on evidence and prior experience	 The purpose of planning is to administrate resources and time: both are frequently limited. Plans that have been poorly applied or thought out may harm the interests of some and advance the interests of others. Good intentions are not enough.
	Ideally, we should take the opportunity provided by pandemic-free periods for the purpose of planning, taking care to avoid the tendency of those who are in the risk-prevention business to overreact.
	■ When planning for disasters, it is better to focus on global, generic, strategic planning rather than on specific scenarios (such as, for example, a particular pandemic). This tends not to happen because specialization works against the need for flexibility and to adapt to the dynamic nature of crisis situations.
	■ We have a lot of experience and well-established plans. However, these plans can rarely be implemented without being adapted, and this means we need to reflect, be self-critical, and identify local, cultural or temporary factors or idiosyncrasies that might have an impact rather than simply applying actions automatically in order to avoid taking decisions. An example of this is the way that, although the CDC has established indexes of severity, the WHO ignored these during the pandemic.
	Health planning is a real challenge for society, and is conditioned by the interests of those participating in the planning process. As a result, in addition to declaring potential conflicts of interest, we must constantly strive to achieve consensus and to promote public consultation and participation.

Ethical dilemma or challenge	Conclusions and recommendations	
Transparent, non- paternalistic, collaborative planning	■ We need to identify, analyse and establish the limits on the concept of paternalism in public health, recognizing that, while this is necessary, its legitimacy is conditional upon the efficacy, credibility and evidence base of the actions taken.	
	There needs to be greater accountability (assessment), although this should not be viewed as part of a disciplinary process or as an attempt to determine guilt.	
	Assessment and accountability should be public processes.	
	■ Education plays a vital role in the planning process, and this includes educating the general public with regard to basic ethical concepts and principles regarding health emergencies, the concept of risk, the responsibilities of the general public in a crisis, and the issue of the loss of individual freedom and fairness.	
of the planning process, to mechanisms in advance. C successful planning, and tl explaining the plan must t	■ It is important to stress the need, as an integral part of the planning process, to specify communication mechanisms in advance. Credibility is essential to successful planning, and those responsible for explaining the plan must therefore reflect this (for example, in the case of flu this task should fall to medical experts).	
	■ In the light of these points, a key challenge is to ensure the participation of a wide range of stakeholders, so that the planning process incorporates their perspectives and in order to balance different interests, ensuring transparency and providing a source of moral authority.	

Ethical dilemma or challenge	Conclusions and recommendations
The common good versus individual autonomy and freedom	 Planning should include a definition of the 'common evil' (or that which is not the common good) to be avoided (e.g., special interests), not least because, during times of crisis, thinking is not at its clearest. The notion of what constitutes the 'common evil' changes over time, while planning is conservative by nature; as society develops, therefore, it is necessary to identify a consensus that reflects this change. The concept of individual autonomy or freedom must be weighed against the principle of reciprocity, in order to avoid harming others. While it may at times be necessary for actions to be compulsory, public health must also seek to exercise self-control in so far as is possible. During the pandemic, there was compulsion without any firm justification.
Responses that are fair and just: 'acceptable' paternalism	 In public health, paternalism must be reconciled with the need to protect fairness and social justice, given that not everyone can be included in the process of planning for pandemics. If it is handled carefully, then a degree of paternalism is acceptable. However, it should be noted that paternalism in public health relates not to the individual but to the population as a whole, with a particular focus on vulnerable populations or groups. It is important to consider the principle of reciprocity, which derives from the 'golden rule' (treat others as you would wish to be treated by them), and which means in practice that, for some interventions, the consequences must be the same for everyone.

Ethical dilemma or challenge Conclusions and recommendations The proportionality of Responses must be proportionate to the scope of the responses versus the problem, avoiding in so far as is possible those actions that could restrict individual freedom or rights, or precautionary principle applying these only when absolutely necessary. It is important to prevent inefficiency, waste and duplication, by involving all sectors in a collaborative planning process. It is also important to adopt measures designed to protect the population, even in the absence of clear scientific evidence of the scale of the risk itself or of the effectiveness of the measures in question. However, it is important not to misapply the precautionary principle, using chaos as an excuse for taking decisions under pressure and without any basis in evidence, and which may be motivated by private interests. It is not always easy to reconcile these two concepts, even if it would intuitively seem desirable to propose responses that reflect a balance between the two.

5. Bibliography and relevant literature

The four documents listed below were distributed to participants via the forum, to provide a basis for the workshop discussion. The article by Gérvas and Hernández summarizes the events of the flu pandemic in Spain, the response of the authorities, and the ethical dilemmas raised by this response. The two Hastings Center documents describe ethical principles to be taken into account in a pandemic, and present the perspectives of the different social agents involved in providing a response. The article by Torá and colleagues describes the impact in Catalonia of the recommendations of the authorities on temporary incapacitation (absence from work) in different sectors of the economy, particularly education and health.

Gérvas J, Hernández I. *Ética y salud pública. El caso de la gripe A (H1N1)*, 2009-2010 [Editorial]. Gestión Clínica y Sanitaria 2012; 13: 123-127.

Stern AM, Markel H. 'Influenza Pandemic'. In: Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns. 2008.

Berlinger N, Moses J. The Hastings Center, 2006. www.thehastingscenter.org

Torá I, Delclos GL, Martínez JM, Jardí J, Alberti C, Manzanera R, Yasui Y, Clèries R, Tobías A, Benavides FG. 'Occupational health impact of the 2009 H1N1 flu pandemic: surveillance of sickness absence'. *Occupational and Environmental Medicine* 2012; 69: 205–210.

The following three documents provide general frameworks that apply to ethics in public health, and which offer criteria, values, principles and guidelines.

Public Health Leadership Society. *Principles of the ethical practice of public health*. Available at: http://phls.org/CMSuploads/Principles-of-the-Ethical-Practice-of-PH-Version-2.2-68496.pdf [Consulted on 7 April, 2013].

Nuffield Council on Bioethics. *Public health: ethical issues*. London: Nuffield Council on Bioethics, 2007. Available at: http://www.nuffieldbioethics.org/public-health [Consulted on 7 April 2013].

Kass N. E. 'An ethics framework for public health'. *Am J Public Health* 2001: 91; 1776–82.

The following document includes a series of recommendations issued by the ethics subcommittee of the Advisory Committee of the Centers for Disease Control and Prevention (CDC) in the United States. It includes interesting ethical considerations relating both to the decision-making process with regard to pandemics, and aspects such as transparency and fairness, all of which are relevant to the discussion of case study 1 (the flu pandemic).

Kinlaw K, Levine R (editors). *Ethical guidelines in pandemic influenza*, 2007. Available at: http://www.cdc.gov/od/science/integrity/phethics/panflu_ethic guidelines.pdf [Consulted on 15 April, 2013].

The following document is typical of the World Health Organization, the result of the meeting of a committee of experts, divided into four working groups: (1) equitable access to therapeutic and prophylactic measures; (2) ethics of public health measures in response to pandemic influenza; (3) the role and obligations of healthcare workers during an outbreak of pandemic influenza; (4) issues that arise between governments when developing a multilateral response to a potential outbreak of pandemic influenza.

Ethics team of the Department of Ethics, Equity, Trade and Human Rights (ETH, WHO). *Ethical considerations in developing a public health response to a pandemic influenza*. Geneva: WHO, 2007 [who/CDS/EPR/GIP/2007.2. Available at: http://www.who.int/ethics/influenza_project/en/index.html [Consulted on 15 April, 2013].

Case study 2: Ethical conflicts in the adoption of precautionary measures in public health

David Larios

Vice-President of the Association of Experts in Health Law

1. Introduction

We normally use the term *ethics* to refer to an epistemological framework for moral decisions. Because we are moral beings by our very nature, when we construct organizations then these, likewise, cannot escape being moral agents.

In this context, the moral question *par excellence* is: *What should I do? What is right and what is wrong?* And nobody – whether individuals, or the organizations created and directed by them – can avoid asking themselves this question whenever they have to act or to take a decision, because every decision involves *values*.

When addressing the question of ethics with regard to decision-making in public health, we need to start by recognizing that moral decision-making in health authorities involves at least three spheres: the *political* sphere, involving decisions by politicians and government; the *management* sphere, responsible for implementing political decisions; and the *technical* sphere, corresponding to public health professionals.

We will focus on these three spheres, bearing in mind the following question: Do these moral actors share a single ethical framework, or are their decisions guided by different moral codes? Or, to put it another way, is it possible to find common ground between the ethics of politics, the ethics of management, and professional ethics, or are we doomed to continuous conflict because each of these agents serves different and at times incompatible values?

Let us look at a classic example of ethical conflict between two levels of decision-making in public health, the elements of which may help in the analysis of other, similar cases.

2. Case study outline

The Drinking Water Monitoring Programme initially detected the presence of a chemical pollutant in the well supplying a coastal resort whose economy was based primarily on tourism.

The analysis results showed a level of contamination that exceeded the limits established in the applicable legislation¹. After taking fresh samples and analysing these, the results were confirmed and recorded in the regional Water Quality Information System.

The public health officer responsible for testing this supply issued a report in which, despite recognizing that the limits established by law had been exceeded, he stated that consumption of water from the well did not pose an imminent, extraordinary threat to the health of the population. Despite this, the technical report concluded with a proposal to take the precautionary measure of closing the well and informing the population about the ongoing situation.

Upon receipt of the technical report, the health authority with competence for adoption of the precautionary measure evaluated the scale of the violation, its imminent impact on the health of the affected population, the economic impact on the locality of closing the well, and the social alarm that this would cause at the start of the tourist season. Following this, it met with the public health management team to inform it of its decision not to ratify the proposed precautionary measure in view of the fact that, having taken into consideration the other public interests at stake, it took the view that it was preferable that the well should continue to supply the population with drinking water while alternative solutions were sought.

When the officer responsible for monitoring the supply was informed by his management that, despite the report, the proposed measure would not be adopted, he asked himself what he should do.

3. Conflicting values and the impact on ethical principles

The process of taking decisions in complex settings, in which different and sometimes contradictory values are at play, is characterized by uncertainty. What bioethics can do is to provide a deliberative framework for such deci-

sion-making: it can act as a tool to help search for the optimal course of action, that which best safeguards (or causes least damage to) the conflicting values.

The decision-making process must start with a detailed description of the facts, and this then provides a basis for identifying the main ethical values and principles involved. In a situation such as the one described above, the workshop participants identified the following conflicting ethical values and principles:

- Protection of public health: Protecting the health of the population, an intrinsic value of the greatest importance, is not just an ethical imperative for health authorities but also a legal obligation. The Spanish Constitution recognizes the fundamental right to life and physical integrity (art. 15) and instructs public authorities to organize and safeguard public health by taking the necessary preventive measures and providing the requisite services (art. 43). The General Health Act and the General Public Health Act establish these principles as a series of duties that include public health monitoring, the prevention of disease, and specific actions designed to protect health from actual threats². The value of *health protection* is directly related to the ethical principle of *beneficence*.
- **Information:** Citizens have the right to be informed about factors that affect individual and populational health and, in particular, significant biological, chemical and environmental hazards, together with their potential impact on health. *Information* enables the population to exercise its *freedom of choice*.
- **Transparency:** Transparency is an essential aspect of health information. Both from an ethical and from a legal perspective, public health actions must be clear and comprehensible for the general population, so that citizens can exercise their *autonomy* when making decisions on the basis of the information provided.
- Precaution: The existence of clear evidence of a potentially serious impact on the health of the population, even where there is scientific uncertainty regarding the nature of the risk, places the competent authorities under an obligation to decide whether to suspend or

restrict the activity. Failure to do so would violate the principle of *non-maleficence*.

- Legality: the public authorities are obliged by this principle to comply with the applicable legislation, without exception. In the case described, the legislation places an obligation on the water authorities to make the public aware if the quality of drinking water is modified with the effect that, either temporarily or permanently, it is unfit for human consumption, and to take the corrective and preventive measures necessary to prevent any risk that may be posed to public health (art. 4.6 of Royal Decree 140/2003, of 7 February). Violation of this value is directly related to the principle of *non-maleficence*.
- Hierarchy: Hierarchy in public health organizations is expressed through the principle of competence. Political decision-makers and technical staff have different spheres of competence and their fields of action are clearly delimited, with the result that the tasks of undertaking analysis, providing information and suggesting solutions lies within the technical sphere, while final decision-making is the job of politicians with responsibility for the health authorities. Violating this principle of hierarchy or competence has both ethical and legal consequences. Action taken by those who lack the competence to do so is invalid, and all those involved in public health must therefore act within their powers. Hierarchical competence is related in this case to the *principle of justice* in the widest sense.

The workshop participants identified a potential conflict between these ethical values and principles and the following:

■ Proportionality: Public health actions should be commensurate to the scale of the health problems they seek to correct, justifying their necessity on the basis of principles of proportionality, efficiency and sustainability. Violation of this value in the case described, in which no extraordinary and imminent risks to the health of the population had been found, would cause unfounded social panic that would, in turn, have a significant negative impact on the local economy and would clearly contravene the ethical principle of non-maleficence.

- Social panic and the economic interests of the population: Strict compliance with the duties of information and transparency may harm other values that are worthy of protection, and politicians must weigh these competing claims when deciding whether or not to temporarily close the well and inform the population. In this case, the values referred to are directly related to the principle of *freedom of choice*.
- Fairness: public health actions that have an impact on the population should promote the reduction of social inequalities in health. Closing the well could generate inequalities between citizens who are able to buy bottled water and those who are too poor to do so, when the technical report states that consumption does not pose a serious and extraordinary threat to the health of any citizen. Harm to this value under the conditions described could imply violating the ethical principle of *justice*.
- Responsibility: implies the obligation (legal or moral) to repair any damage caused. In this case, responsibility could arise from the refusal of the health authorities to adopt the precautionary measure proposed by the technical officer, and also from the subsequent action of the officer, once he became aware that the precautionary measure proposed in the report would not be adopted. This value is directly related to the ethical principle of *justice*.
- **Professional autonomy:** the technical officer proposing the precautionary measure feels that his professional autonomy has been undermined by the political decision not to agree the closure of the well or to inform the population of the presence of a chemical pollutant in the water supplying the locality, and this leads him to question whether the hierarchical relationship linking him to the authorities, and binding him to respect political decisions, should prevail over his duties as a health professional, particularly as regards the ethical principles of *non-maleficence* and *autonomy*.
- Personal interests of the technical officer: At times, the professional
 or personal concerns of technical officers are treated as a value (corporate or individual) that is harmed by political decisions which, in

cases such as this, ignore a technical proposal to adopt precautionary measures. This value is related to the ethical principle of *autonomy*.

The following table summarizes the potential conflicts:

Conflicting Values		Ethical Principle Affected
Protection of Public Health	Proportionality	Beneficence
Information and Transparency	Social panic Protection of economic interests	Autonomy Non-maleficence Justice
Fairness	Protection of economic interests	Non-maleficence Justice
Precaution	Proportionality	Non-maleficence
Legality	Responsibility	Justice
Hierarchy	Professional autonomy Personal interests of technical officer	Non-maleficence Autonomy

4. Courses of action

After identifying the ethical values and principles involved in this case, the working group set out the following possible courses of action with regard to the problem faced by the public health officer after the refusal of political decision-makers to adopt the proposed precautionary measure.

 a. The technical officer remains strictly within his responsibilities and limits himself to submitting the report-proposal to the health authority.

- b. The technical officer does not limit himself to submitting the reportproposal, and instead considers using all the means of dialogue at his disposal to persuade the politician to reconsider his decision not to adopt the precautionary measure.
- c. The technical officer does not accept the politician's decision to refuse to adopt the proposed precautionary measure, and considers whether to send a copy of his report to his professional body, in the hope that this organization will mediate with or pressurize the health authority to persuade it to rectify its initial decision, close the well and inform the population.
- d. The technical officer is not satisfied with simply issuing his report-proposal, and suggests to his superiors that they issue an authorization to exceed the established parameter values, as established in arts. 22 and following of Royal Decree 140/2003, of 7 February^a.
- e. The technical officer is not satisfied with simply submitting his report-proposal, and suggests to his superiors that they evaluate the conflict, in order to learn from the situation and draw up protocols to address similar conflicts in the future.
- f. The technical officer does not accept the politician's decision to refuse to adopt the proposed precautionary measure, and considers whether to send a copy of his report to consumers' associations in the affected locality.
- g. The technical officer does not accept the politician's decision to refuse to adopt the proposed precautionary measure, and considers whether to make his report-proposal public by sending it to the media.
- h. The technical officer, in the face of the decision by the politician not to adopt the proposed precautionary measure, considers whether to report the case internally to the service inspectorate.
- i. The technical officer, in the face of the decision by the politician not to adopt the proposed precautionary measure, considers whether to report the case to the police.

After analysing the facts, identifying the conflicting values and the ethical principles involved, and listing the different courses of action the technical officer could take in response to the refusal of the health authority to adopt the precautionary measure proposed, the working group and the public health experts participating in the plenary session identified a number of issues to be taken into consideration, in the form of arguments for and against each of the possible courses of action, with the aim of achieving consensus in reaching the best decision, which would be the one that caused least harm to the conflicting values and that safeguarded all or most of the ethical principles involved.

5.1. The limits of the ethical and legal responsibilities of the public health officer

The first question that gave rise to heated debate in the working group revolved around the limits of the personal and professional responsibility of the public health officer with regard to the decision of the health authority not to adopt the precautionary measure proposed in his report.

Strictly speaking, the officer could be deemed to have complied with his professional obligations by issuing an objective report-proposal to help the health authority take an informed decision, with the health authority being responsible for adopting the proposed measure or not. The officer cannot, therefore, be held legally responsible for failing to take actions designed to modify the politician's decision. Any other approach might even be deemed arrogant, in so far as it would involve the officer attributing to himself competences and responsibilities that are not his.

From a broader perspective, and in accordance with the scope of the conflicting values (protecting public health, information, transparency, social panic, the protection of economic interests, proportionality and precaution) the passive attitude of an officer who limited himself to strict compliance with his professional obligations, meekly accepting the decision of the health

^{5.} Discussion

a. See annex, page 54

authority not to close the well (course of action a), was seen as too dispassionate, lacking moral commitment, and contrary to the ethical principles of beneficence, non-maleficence and autonomy.

For this reason, members of the working group ruled out this extreme course of action, consisting of the officer's meek acceptance of the decision not to close the well and not to inform the population (a), and decided to consider intermediate courses of action.

5.2. Weighing values: dialogue as a tool for deliberation

Participants in the meeting agreed on the existence of a conflict between the values defended by the officer in his report-proposal (protection of public health, information, transparency and legality) and those defended by the health authority (protection of economic interests, avoiding social panic, importance of maintaining the supply in the absence of an imminent, extraordinary hazard).

At this point, it is worth recalling the thesis formulated by Professor Gracia³ when he argues, with regard to decision-making in health organizations, that it is not possible to speak of a single set of morals, because there is no single moral agent, or of a uniform moral duty, and that despite the fact that politicians and health professionals share (or should share) a single, primary objective (guaranteeing the highest possible level of health to the population with the resources available), the roles performed by each give them different moral perspectives on the same situation. Politicians with responsibility for health and health professionals share the same logical framework, but their respective professional roles mean that they defend and promote different values.

Politicians and decision-makers primarily promote instrumental values (reference values, that we attribute to things that have value in so far as they serve to achieve an end goal) while health professionals and technical officers traditionally promote intrinsic values (those which we attribute to something that is an end in itself).

Starting from the fact that the political role tends to promote material values, while health professionals traditionally promote instrumental values, it is not uncommon for conflicts such as the one described here to arise.

According to Peiró, the causes of these conflicts can be attributed to the simultaneous participation of professionals in two systems – the health profession and the organization – and to the fact that the organizational principles of the profession and of the bureaucracy are different⁴.

However, we cannot ignore the fact that values do not exist in abstract; rather, they find expression in people and in things, the basis both of tangible and intangible values. It is for this reason that the purpose of ethics is not to prioritize one over the other, but rather to defend both or to infringe them as little as possible.

This is why traditional medical ethics is wrong to concern itself solely with intangible values (protecting health, autonomy, etc.) and ignore instrumental values (economic resources), because health decisions taken at the technical level often have unavoidable financial implications.

Over recent years, health professionals have gradually become aware of the financial implications of their actions, in the context of the concepts of *efficiency* and *opportunity cost*; however, in Spain this remains a small minority of the profession and we are some way behind other western European countries.

Nor is it possible to defend the current tendency to argue that, in the event of conflict, the criterion of efficiency should always prevail. Categorical approaches of this sort simply create dilemmas, and dilemmas invariably lead to wrong decisions.

For this reason, the working group took a positive view of those courses of action that involved promoting dialogue between the technical and political spheres (course of action b), even where this meant involving external agents such as professional bodies in the dialogue, so that they could act as conflict mediators (course of action c) or, in the absence of an acceptable body, the involvement of intermediate structures between the technical and political spheres, such as a multidisciplinary ethics committee, an agency, or some

other independent technical body. (It was noted that, in the past, scientific societies acted as mediators between health professionals and the political authorities.)

5.3. Conflicting values or uncertainty regarding risk? The possible inadequacy of the parameters established by the applicable legislation

During the course of the discussions, the public health experts in the working group raised the issue of the lack of correlation between parameter values for water pollutants established in the applicable legislation and the actual effective risk associated with the consumption of drinking water, and argued that this gap often gives rise to conflicts such as the one under discussion here. In this case, the technical officer, in strict compliance with the applicable legislation, proposes the precautionary measure of closing the well and informing the population, despite recognizing in his own report that there is no extraordinary and imminent threat to public health. In contrast, the politician, taking into consideration other well-founded values (preventing social panic, preventing economic loss as a result of the supply being interrupted, safeguarding the principle of equitable access to the consumption of bottled water) decides to ignore the proposal, despite being aware that the level of contamination in the well exceeds the parameters established in the legislation.

Before addressing the specific issues, the members of the working group stressed that the health authorities should consult with professional bodies such as the Spanish Society for Environmental Health (SESA) before establishing parameter values that do not correspond to a real risk, preventing a situation where water quality criteria contain provisions that in practice are inadequate and generate problems when applied, as in the case study.

On the basis of the legal situation, the technical officer has correctly applied the regulations on water quality and, despite recognizing the lack of any imminent, extraordinary threat to the population, submits a report and proposes the adoption of a precautionary measure, without taking into account that this would harm other interests and values requiring protection, values to which the health authority accords precedence and on the basis of which it refuses to adopt the proposed measures, even to the point of disregarding the principle of legality.

In this respect, and having exhausted the channels for dialogue, including the intervention and mediation of a third party (the professional body), the technical officer has both an ethical and a professional obligation to make the health authority aware of the possibility, contained in arts. 22 and following of Royal Decree 140/2003, of 7 February, of issuing a temporary authorization to exceed the established parameter values, so long as the drinking water supply cannot be maintained in any other reasonable way, empowering the health authority to establish a new parameter value, so long as the exception does not constitute a public health risk.

This is an intermediate course of action (d) that, so long as the requirements established by the legislation are satisfied, would provide a suitable way to resolve the conflict facing us, as it would offer the possibility of safeguarding all of the conflicting values, without harming any of the ethical principles involved.

5.4. Evaluation report: learning from one's mistakes

In addition to these actions, the working group argued that, regardless of the final outcome of the incident, the ethical and professional obligations of the technical officer include submitting to his managers an evaluation of the conflict, with the aim of learning from the experience and drawing up protocols to help tackle future similar conflicts (course of action e).

This is an appropriate course of action that, while it does not provide for resolution of the specific case, should be embarked upon in addition to whichever course of action (a, b, c or d) is pursued.

5.5. The ethical duty to alert the population to risks vs. the legal duty of secrecy

Faced with the refusal of the health authority to reconsider its decision, or its refusal to issue a temporary authorization to exceed the established parameter values (or in the event of the material or legal impossibility of doing so), the technical officer considers the possibility of releasing the report-proposal by sending it to consumers' associations (course of action f) or even to the media (course of action g).

These courses of action were unanimously rejected by the working group as too extreme and in contravention of the duty of secrecy imposed upon public employees by the applicable legislation (art. 52.13 of the Basic Statute on Public Employees, Act 7/2007, of 12 April) which states that statutory officers and staff are obliged to "maintain the secrecy of classified material or other material, the dissemination of which is legally prohibited, and must maintain due discretion regarding those issues of which they become aware for reasons of their position, without being allowed to use the information for their own benefit or that of third parties, or to the prejudice of the public interest," and that they must be aware that it is, in the final instance, the responsibility of the politician and not of the technical officer to consider the protection of the public interest.

In addition to administrative penalties, any technical officer who released the report-proposal would be committing an offence under art. 417 of the Penal Code, which provides for the imposition of fines and the disqualification from office of any civil servant "who reveals secrets or information to which he has access as a result of his position and which should not be released," and the offence may incur higher penalties where "serious damage to the public interest or third parties" occurs.

With respect to the limits on this duty of secrecy, which could constitute extenuating circumstances or grounds for exemption based on a state of necessity (perpetrating a crime to prevent a greater evil), the working group concluded that this did not appear to apply here, given that the technical report itself recognized that there was no imminent, extraordinary threat to

the health of the population. (Had the existence of such a threat been demonstrated, this could have constituted a limitation on the general rule of the duty to secrecy.)

5.6. Reporting to the service inspectorate or to the legal authorities

Finally, the working group rejected the extreme courses of action which consisted of the technical officer reporting to the service inspectorate (h) or the legal authorities (i) the health authority's decision to refuse to adopt the proposed precautionary measure, as these courses of action were deemed disproportionate given the absence of an imminent, serious threat to the health of the population, as recognized in the officer's own report, because an action of this sort would place the officer in a difficult professional position *vis-à-vis* his superiors.

In particular, and with respect to the legal aspect, the action would be inadmissible in so far as there would be no grounds for the accusation of criminal misconduct by the politician, given the absence of evidence of criminal harm or of the authorities or its officers having committed a legal offence.

6. Recommendations and proposals

Following the discussion process, the working group proposed the following recommendations, to be applied sequentially:

- The technical officer cannot simply do nothing in the face of the health authority's decision, and must instead exhaust the opportunities for internal dialogue with the aim of persuading the politician to reconsider his decision. This promotes respect for the principles of protecting health, information, beneficence and professional autonomy.
- 2. Faced with the failure of channels of internal dialogue, the technical

officer may seek to involve a professional body as mediators in order to persuade the health authority to reconsider its decision. The technical officer should not submit his report to the professional body, in order to avoid accusations of violating his duty of secrecy, and should instead restrict himself to explaining the context to the professional body so that it can formally contact the political decision-maker. This course of action promotes respect for the same principles as the preceding one.

- 3. As an alternative to the two preceding courses of action, the technical officer could propose to the health authority that it issue an extraordinary temporary authorization to exceed the established parameters, so long as the level of contamination detected does not represent a public health hazard as a result of consuming the water. This course of action respects all the conflicting values, safeguarding the responsibilities both of the technical officer and of the political decision-maker, making it possible to maintain the water supply within a framework of legality while corrective measures are adopted, preventing social panic and the economic losses that would arise from the adoption of the proposed precautionary measure.
- 4. As a complement to the preceding actions, the technical officer should in any event propose or undertake evaluation of the conflict, in order to learn from the situation and draw up protocols to address similar conflicts in the future.

In addition to the preceding recommendations, the experts identified the following proposals:

- Establishment of multidisciplinary committees, agencies or other existing organizations (professional bodies) with moral authority, who could act as mediators and channels of communication in conflicts similar to the one described.
- 2. Active participation of scientific bodies and professionals in resolving doubts and concerns prior to establishing parameter values in the legislation, in order to avoid contradictions between the legal limit

and the real risk, with the aim of helping to prevent situations such as the one considered here from arising.

7. Bibliography and relevant literature

Bibliography

- Lozano, J.M; Gracia, D; Peiró, M; Ethics in health institutions: the logic of care and the logic of management, Barcelona: Fundació Víctor Grífols i Lucas, 2012.
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Legislation

- Act 33/2011, of 4 October, General Public Health Act.
- Royal Decree 140/2003, 7 February, establishing the health criteria for water quality for human consumption.

8. Notes

- 1. Royal Decree 140/2003, 7 February, establishing the health criteria for water quality for human consumption.
- 2. Arts. 3 to 11 of Act 14/1986, General Health Act and arts. 12 to 31 of Act 33/2011, of 4 October, General Public Health Act.
- 3. Gracia, D., "Professional ethics and institutional ethics: between collaboration and conflict," in Ethics in health institutions: between the logic of care and the logic of management. Barcelona: Fundació Víctor Grífols i Lucas, 2012, pp. 17, 19 and 20.

4. Peiró, Manuel. "Professional ethics and institutional ethics: between collaboration and conflict", Barcelona, Pub. Fundació Víctor Grífols i Lucas, 2012, pp. 24 and 25.

9. Appendix

Article 22. Exceptions to the established parameter values

The decision-maker may ask the health authority to authorize temporary exceptions with respect to established parameter values when breach of the parameter value of a specific parameter of part B of annex I for a given supply has occurred for more than 30 days in total during the last 12 months and when the supply of drinking water cannot be maintained in any other reasonable way. The health authority shall establish a new parameter value, so long as there is no possibility that the exception constitutes a threat to the health of the supplied population.

Article 23. Authorization of exception

- 1. The decision-maker shall submit an application to the health authority, consisting, as a minimum, of:
 - a. Copy of document from the decision-maker to the municipality, where applicable, informing of application for authorization of exception.
 - b. The application, which will follow the model form contained in part A of annex VI.
 - c. Original and copy of a report containing the following sections:
 - Results for parameter for the last six months.
 - Report on the grounds for the application, supported, if applicable, with a technical opinion.
 - Report explaining why it is not possible to maintain the water supply in any other reasonable way.
 - Information supplied and method of communication to the population affected by the exceptional situation.
 - Specific sampling programme, increasing the frequency of sampling for this supply for the requested period.

- Plan of corrective measures, provisions for evaluation of the plan, work schedule and cost estimate.
- 2. The health authority shall have a period of two months to notify authorization of the application, following inclusion of the documentation in the registers of the body with competence for processing it.
- 3. Following authorization of the exception, the health authority will have 15 working days to notify the General Department for Public Health of the Ministry for Health and Consumer Affairs of the authorization. This notification should be effected using the form contained in part B of annex VI and, where the supply distributes more than 1,000 m³ per day as an annual average, the notification must be accompanied by a copy of the documentary report submitted, together with a list of the relevant food industries affected.
- 4. The Ministry of Health and Consumer Affairs will notify the European Commission, in accordance with current European Union legislation, of the authorization of supplies distributing more than 1,000 m³ per day as an annual average.
- 5. Exceptions must be limited to the shortest time possible, and may not exceed three years, at the end of which the applicant shall present to the health authority a situation study and the total cost of the measures adopted.
- 6. Once the exception has been authorized, the decision-maker shall inform the other decision-makers affected by the supply of the new exception situation and, in coordination with the health authority, will offer health recommendations to the general population and specifically to those population groups for whom the exception could represent a health risk.
 - The period within which such communication must take place will be no longer than two days following the day of notification of the authorization.

Article 24. First extension of the exception

- 1. Where the period of three years has not been sufficient to resolve the grounds for the request for an exception, the decision-maker may request that the health authority extend the exception.
 - In this case, two months before completion of the first authorized period, the following documents must be submitted:
 - a. Copy of document from the decision-maker to the municipality, where applicable, informing of application for the extension.
 - b. The application, which will follow the model form contained in part A of annex VI.

- c. Original and copy of a new, updated report.
- At the end of the first authorized period, the decision-maker shall send to the health authority the original and a copy of the situation study, detailing progress since authorization.
- 2. The health authority will have a period of two months to notify authorization of the application, following inclusion of the documentation in the registers of the body with competence for processing it. This extension shall not exceed three years. After authorization of the extension, the procedure set out in sections 3, 4, 5 and 6 of article 23 will apply.

Article 25. Second extension of exception

- 1. In exceptional circumstances, when the grounds for the application have not been corrected after two authorized periods, the decision-maker may request a second extension that, subject to favourable reports from the municipality, where applicable, and the health authority, the Department of Health and Consumer Affairs will process the application to the European Commission for a period no greater than three years.
- 2. In this case, two months before completion of the second authorized period, the decision-maker must submit the following documents to the health authority:
 - a) Copy of document from the decision-maker to the municipality, where applicable, informing of application for the second extension.
 - b) The application, which will follow the model form contained in part A of annex VI.
 - c) Original and copy of a new, updated report.
 - At the end of the second authorized period, the decision-maker shall send to the health authority the original and a copy of the new situation study.
- 3. The health authority will submit the application, documentary report and situation study to the General Department for Public Health of the Department of Health and Consumer Affairs, accompanied by a technical report from the health authority supporting the application for the second extension of the authorized exception.
- 4. The Department of Health and Consumer Affairs, in coordination with the health authority, the decision-maker and the municipality, where applicable, will draw up a report on the need for a second extension and this will be submitted to the European Commission together with the other documentation.
- 5. The Department of Health and Consumer Affairs will inform the health authority, the decision-maker and the municipality of the decision of the European Commission within a period of no greater than one week.

Consumers and other decision-makers affected by the supply will be informed of this second extension of the exception in accordance with the provisions of section 6 of article 23.

Article 26. Short-term exception

- 1. When it is predicted that the problem can be resolved within a maximum period of 30 days with corrective measures, and when breach of the parameter value is considered by the health authority to be insignificant, the decision-maker will ask the health authority to authorize a short-term exception, so long as the value proposed may not constitute a threat to human health.
- 2. The application for a short-term exception authorization will consist, at a minimum, of:
 - a) The application, which will follow the model form contained in part A of annex VI.
 - b) Plan of corrective measures with the schedule of work.
 - c) Proposed statement to be distributed to the population affected by the situation.
- 3. The health authority will have a period of 10 days to notify authorization of the application, following inclusion of the documentation in the registers of the body with competence for handling it.
- 4. Once the exception has been authorized and the decision-maker notified, the decision-maker shall, within 24 hours, inform the consumers and other agents affected by the new situation and, in coordination with the health authority, shall offer health recommendations to the population or to population groups for whom the exception could represent a health risk.

Case study 3:
Functional foods
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1. Case description

1.1. The search for better health through food

During recent years, the consumption of so-called 'functional foods' has become increasingly widespread, making it one of the most significant changes in social nutrition habits. This should be interpreted as part of a wider phenomenon, one which can be traced back to the start of the 20th century and is still spreading today. This is the search for 'optimal health', 'a perfect body', 'eternal youth' and so on that has become a decisive element of modern lifestyles and is the basis for a fully-fledged 'health ideology', according to which health is the ultimate objective of any reasonable life plan, something that is desirable in and of itself, as much a duty as a right'.

A concern with notions of health has become an omnipresent part of our daily experience in a society characterized by the dominance of image, communication and consumption. In our time, 'healthiness' has become a priority, and is used as a criterion to evaluate relationships and situations that previously were valued for themselves or on the basis of other criteria: for example, personal relationships, including intimate ones, can be classified as healthy or 'toxic', leisure can be 'healthily active' or 'pathologically passive', buildings can make you sick, and so on. And of course diet, apart from satisfying the basic human need to feed oneself, is not judged in this cultural context solely according to the traditional value of 'the pleasure of eating', but rather, and primarily, for its capacity to improve health, promote a longer life, enhance physical well-being, contribute to a more beautiful body, etc.

The reasons for the development and proliferation of the 'ideology of health' have been clearly identified by historians. Speaking in general terms, it is no exaggeration to describe the 20th century as being characterized by the triumph of medical science and the medical profession (the golden age of medicine)², together with the involvement of the State in the health of the population, developing welfare economies, with huge social, legal, political and economic implications³. Following a first stage, which focused on improving and increasing the productive forces of states (consolidating and

reproducing the labour force), the period from the 1950s until the early 1970s saw the development of a 'community medicine' that, in western Europe, gave rise to huge public health systems, in which health was configured as a universal right⁴. With regard to the crisis of these public health systems (a crisis in which we are still immersed), the key points for the purpose of this report are: a) there is a constant transfer of resources and provision from the public to the private sector; b) the concern with meeting the traditional objectives of public health are gradually displaced by an economic policy in which medicine focuses on efficiency (understood as a correct ratio between costs and benefits) so that, for example, prevention is primarily valued for its capacity to prevent higher treatment costs⁵; c) the social understanding of the right to health develops in two directions: first, the growing awareness of a personal responsibility for one's own health (promoted both by public agencies, concerned to reduce costs, and by private agents, wishing to maximize profits); and second, the belief, equally widespread, that when it comes to health the individual is king and is, therefore, the person who should decide. This last point is fundamental. Paradoxically, as the culmination of a lengthy period of the steadily rising prestige of medicine (based on its triumph over infectious/contagious disease), this prestige ceases to depend on the medical profession (increasingly seen as a simple provider of services) and citizens affirm their right to judge how best to obtain 'perfect health'. This may involve conventional or 'alternative' medicine; it may be linked to the consumption of non-medicinal pills (available without a medical prescription); or, of particular relevance to this discussion, by designing for themselves food that is not just healthy in the sense of not being harmful but which acts to directly produce 'health'.

To end this brief outline of the problem, it is worth noting a point stressed by Bernabeu and Trescastro that the current phenomenon of functional foods is strongly reminiscent of what occurred with vitamins during the 1920s. For a period, following the discovery of the link between vitamin deficiencies and some diseases, the idea that vitamins could cure everything gained currency. These are fashions that go far beyond the scope of the scientific facts about the relationship between certain components of food and some diseases. At that time, and continuing to the present day, the prestige

gained by vitamins led to their excessive consumption, whether as pills or in enriched foods (such as the ubiquitous breakfast cereals). These products were not always harmless in health terms, and were very frequently pointless and thus harmed consumers' finances (given the higher cost paid for the vitamin supplements)⁶.

These authors also point out that the notion of foods as a therapeutic agent is nothing new: "During the first half of the 20th century, nutritionists focused on essential nutrients, what we would call 'adequate nutrition'. During the second half of the 20th century, in addition to stressing the importance of adequate nutrition in preventing specific health problems, interest gradually began to focus on the bioactive compounds in food, and the role of food in promoting health (what we know as 'optimal nutrition') in recognition of the fact that diet goes beyond its mere nutritional contribution."⁷.

1.2 The concept of functional food

A number of objections have been raised to the concept of 'functional food', and specialists often point out the difficulty of agreeing upon a definition⁸. For example, Roberfroid, one of the leading experts in this area, has argued that "[the concept of] a functional food is not and cannot be clearly defined, because a huge range of food products are classified as such, or will be in the future. There is not and probably never will be a simple, universal definition of functional food, which is above all a concept." Despite this, neither Roberfroid himself nor other authors with an interest in this area have held back from proposing a definition. For example, in the consensus document on "Scientific concepts of functional foods in Europe", immediately after stating that there is "no universally accepted definition of functional food", the following definition is proposed:

"A food can be regarded as 'functional' if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease. Functional foods must remain foods and they must demonstrate

their effects in amounts that can normally be expected to be consumed in the diet: they are not pills or capsules, but part of a normal food pattern.

A functional food can be a natural food, a food to which a component has been added, or a food from which a component has been removed by technological or biotechnological means. It can also be a food where the nature of one or more components has been modified, or a food in which the bioavailability of one or more components has been modified, or any combination of these possibilities. A functional food might be functional for all members of a population or for particular groups of the population, which might be defined, for example, by age or by genetic constitution." 10.

On similar lines, during the discussion organized by the Víctor Grífols i Lucas Foundation on which this report is based, Miguel Ángel Royo proposed the following definition: "A functional food is one that, when consumed as part of a normal diet, produces positive effects on health and the prevention of illness, beyond its role as a source of material and energy for the organism. A food may be naturally functional, or may be functional due to the addition or reduction of biologically active components, or by altering their bioavailability." And, as a final example, here is the definition proposed by public health specialists: "A functional food is one that contains a component – either nutritional or otherwise – which exercises a selective activity in relation to one or various functions of the organism, with an added physiological effect in addition to its nutritional value, and whose positive action provides a basis for claims as to its functional (physiological) or healthy character." 11.

From the above, it is clear that there are definitions of functional food which are backed by a broad consensus; the problem is that the definition of *functional food* is in itself functional, and this always gives rise to a degree of indeterminacy with respect to the fact that specific structural or other characteristics are necessarily linked to this function, while in fact it may be the case that no particular characteristic is necessary. As a result, almost any food could potentially be a functional food; for it to be considered as such, it is sufficient that one of its effects on the organism, beyond the merely nutritional, be seen as functional¹². Some foods are specifically manufactured to be functional (the so-called 'new foods'), while others ('traditional' foods) have

subsequently been considered to be (and marketed as) functional. If the 'functional' label was initially reserved for new foods, today we have no choice but to accept the wider concept¹³.

From the above, it seems clear that it is best to focus on the concept of *functional declaration*. As a result, functional foods would refer to those "whose characteristics support a functional declaration, whether with respect to nutritional properties, health-giving properties, or the reduction of the risk of illness".

At the same time, in order to clarify the concept of nutritional declarations, we can refer to European legislation, in particular *Regulation (EC) no.* 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, which, in article 2, establishes the following:

- 4) "Nutrition claim" means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:
 - a) the energy (calorific value) it
 - i) provides,
 - ii) provides at a reduced or increased rate, or
 - iii) does not provide; and/or
 - b) the nutrients or other substances it
 - i) contains,
 - ii) contains in reduced or increased proportions, or
 - iii) does not contain;
- 5) "Health claim" means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.
- 6) "Reduction of disease risk claim" means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

The reader will find examples of these declarations on much ordinary food packaging: for example, "contains Omega-3", "fat-free", "0% sugar", "helps

your defences", "a delicious way to look after your heart", "light", "containing 100% vegetable oils that look after your heart", "cholesterol-free", "naturally helps lower cholesterol", "source of fibre", "improves your performance", "rich in phytosterols", "calcium", "aids concentration" etc.

1.3 The bioethical perspective on functional foods

From a bioethical perspective, there are a number of ways of looking at the issue of functional foods. Here, we are interested in focusing on the area of public health and, more particularly, the phenomenon we want to consider is the one of *social* consumption (generalized consumption by population groups) of functional foods within the food market (what we will refer to as the *public health context*). This means we will be ignoring two other possible areas of analysis: that of the *individual* consumption of functional foods within the framework of a consumer relationship mediated by an expert (dietician, nutritionist and/or doctor), and the *individual* consumption of functional foods which is unmediated by any nutritional or medical advice.

We can therefore define our case study as follows:

What ethical problems arise from the general practice, in Spain and, with variations, in developed countries as a whole, of promoting the sale of food with nutritional declarations of health: that is, by prioritizing the functional character of foods (whether traditional or new) over their nutritional profile or relative role within the context of a healthy diet?

2. Main dilemmas and ethical principles involved, potential conflicts of interest, and foreseeable or actual consequences

Within bioethics, a consensus has developed in recent years regarding the validity of a series of principles, understood as general moral standards, that establish *prima facie* obligations and that are not hierarchically structured,

with the result that our identification of the specific obligations of any actual situation depends on how we prioritize these principles in the light of the actual circumstances¹⁴. These principles are *autonomy*, *non-maleficence* and *beneficence*. Next, we identified what we felt were the key questions with respect to each principle in terms of bioethics and functional foods. It is important to note that all of the questions necessarily involve more than one principle (otherwise, there would be no dilemma), even though they are identified as being more closely linked to one principle than the others. Finally, it should be noted that the consensus that underpins bioethics grants a certain pre-eminence to the principle of autonomy, with the effect that *freedom* (in this case, the freedom to sell or consume foods) establishes the framework, so to speak, within which we decide whether it is possible to justice certain 'restrictions on freedom', but always as exceptions.

2.1 Questions regarding the principles of beneficence and non-maleficence

Questions regarding the principles of beneficence and non-maleficence can, in turn, be divided into questions relating primarily to the balance of harm and benefits, and questions relating primarily to the responsibility of agents (public authorities, scientists, food industry etc.).

- **2.1.1.** What is the risk/benefit balance of permitting the use of health claims as a food marketing strategy? Should we expect benefits in the context of public health as a result of the free distribution of functional foods? Is science able to demonstrate such benefits in the context of public health? Or can it be argued that the free distribution of functional foods actually brings with it significant health risks? Could the marketing of nutritional and health declarations contribute to the decline of healthy diets and even of suitable drug treatments?
- **2.1.2.** Does the extensive legal regulation of nutritional declarations, in addition to exercising a control function, indirectly act to legitimate the sale of food on the basis of such declarations? Is the food industry able to demonstrate the benefit (or, at least, the absence of harm) for

the general population as a result of the free distribution of functional foods? Is there an overlap between the interests of the industry, science and public regulators that is in conflict with the general interest?

2.2. Issues regarding the principle of autonomy and, in particular, regarding the conditions that must exist in order for consumption to be free and informed

Do nutritional declarations satisfy the conditions of clear, comprehensive information that is comprehensible for the average consumer? To what degree is it reasonable to expect the consumer to be an expert in nutrition, able to manage the information in health declarations and food labelling that at times resemble patient information leaflets for medicines? Does the reluctance to adopt initiatives such as nutritional traffic light systems, or informing about the negative qualities of foods, such as trans fats, indicate that what we are dealing with is just a new form of propaganda rather than greater information about foods? Are we dealing with more information or more manipulation? Is scientific knowledge becoming a marketing tool? Are there some particularly vulnerable groups, such as children or people with learning difficulties, who should receive special protection from the industry's aggressive marketing techniques?

2.3. Questions relating to the principle of justice

2.3.1. Is there a link between quality of diet and levels of income? Should we look at 'living conditions' rather than 'lifestyles'? Is it reasonable to predict that functional foods will accelerate the process of abandoning the Mediterranean diet for low income consumers, whose objective living conditions make it difficult for them to pursue healthy lifestyles? Is adequate attention being paid to the needs of particularly vulnerable groups (for example, diabetics or coeliacs)? Are we gener-

ating the conditions for fair access to the benefits of functional foods (in those cases where such benefits may exist, particularly for people with specific illnesses or conditions who require such foods, under expert supervision), regardless of levels of income, social development etc.?

3. Reflections to address or resolve each of the problems mentioned above, identifying the most acceptable and reasonable decision from the perspective of ethics and public health

3.1 Questions regarding the principles of beneficence and non-maleficence

3.1.1. Balance of harm to benefit

Firstly, it should be clearly stated that health declarations should only be permitted for those foods for which a beneficial effect on health has been demonstrated. In this respect, it should be noted that one of the factors currently limiting the development of new functional foods is the lack of adequate health biomarkers. That is, we do not have effective, validated parameters to establish whether a given functional food produces an improvement in the health of an initially healthy person and/or improves his or her expectancy of health in the future.

At the moment, we only have scientific tests of the efficacy of some functional foods for specific population groups: for example, in individuals with high cholesterol levels, functional foods enriched with vegetable sterols to normalize cholesterol levels have been shown to be effective in reducing these levels. And we should be careful not to confuse the theoretical conclusions reached in a scientific study, which are by their nature open to discussions.

sion and revision, with the practical decision to authorize sale of a functional food or to recommend its general consumption¹⁵. In this regard, it is important to bear in mind that there is still no scientific evidence as to whether the introduction of functional foods produces an improvement in the general health of the population.

We need tools that enable us to evaluate their impact both upon consumption patterns and upon long-term health. The vast range of functional foods available can lead to changes in patterns of consumption, causing excess consumption of some compounds and contributing to dietary imbalances, a weakening of good eating habits and even changes to pharmacological patterns. Returning to the previous example, foods containing plant sterols do not only produce reductions in cholesterol, but also in levels of carotenoids (antioxidants with multiple beneficial effects), and should therefore be consumed within the context of a diet rich in vegetables¹⁶. While the regulations involve studying the impact of ingesting a specific functional food (for example, to regulate cholesterol levels), in this context we also need tools that enable us to evaluate the influence on the health of the population of all the commercially available functional foods.

In the context of public health, the expected benefits of functional foods depend (in the mathematical rather than the organic sense) on several variables, including the education of consumers in nutrition and diet, overall diet, and more or less active lifestyles. Each of these variables involves both objective and subjective factors. The first, the objective factors, do not affect the whole population equally, but are instead strongly biased according to social class: for individuals belonging to low income groups, the opportunities for accessing adequate nutritional education, the ability to make rational choices about their diet, or the capacity to modify their lifestyle are all equally low ('living conditions' mean that 'lifestyle' is not the consequence of a choice)¹⁷. Again, we have to stress that there are no grounds for claiming, from a scientific perspective, that the free distribution of functional foods (based on nutritional declarations on the packaging) will produce beneficial effects for the health of the population in general. In fact, the opposite is the case, as over half of the food products advertised on Spanish TV and for

which health claims are made have a low nutritional profile¹⁸. It therefore seems reasonable to assume that the consumption of such foods as an alternative to a suitable diet, as a remedy for the impossibility of leading a more active lifestyle, or as a counterweight to the consumption of other particularly unhealthy foods, far from providing benefits, would actually intensify the problems that we are seeking to avoid.

3.1.2 Responsibility of agents

The first section of this report stressed the tendency of recent years to make health, and illness, a question of individual responsibility. We recalled how, for a large part of the 20th century, governments assumed huge responsibilities for the health of the population, to the point where health was recognized as a right, that is, as a state of affairs that the individually was legally entitled to demand from the authorities. With the decline of the welfare state, beginning in the final third of the last century, this responsibility for the health of the population gradually shifted, with the result that, both in theory and in practice, it has become the private responsibility of the individual (who is responsible for "lifestyle", for the decision to take out health insurance, for dietary choices, etc.). To summarize, the tendency now is to see health as a duty.

This tendency is joined by another one, much more widespread and deeprooted, as a result of which specialization at work (whether intellectual or manual, public or private) has vastly multiplied the complexity of mediation, to the point that nobody is *fully* responsible for any damage (because everyone is responsible only for a limited part of the 'chain') and, increasingly, nobody is *sufficiently* responsible to be reprimanded or to accept guilt, either morally or legally. As a result, the only people who are clearly linked to such damage are those who suffer it and, paradoxically, end up being held solely responsible.

Bioethical analysis, therefore, is of no consequence if it does not restore the *principle of responsibility*. It is not possible to explain the regulation of the market for functional foods on the basis of the traditional dichotomy

between regulators and the regulated: the regulated influence the regulators, sometimes legitimately and sometimes not, and the regulators in turn influence the framework of what is possible. Large and small food companies, scientists and, in particular, scientific bodies, state regulators, consumers' organizations and NGOs all have moral responsibility. The *principles of transparency* (to reveal potential conflicts of interests which might otherwise generate collusion between these interests against the wider society), *publicity* and *veracity* with regard to decision-making procedures are unavoidable corollaries of the principle of responsibility.

3.2. Issues regarding the principle of autonomy and, in particular, regarding the conditions that must exist in order for consumption to be free and informed

From the perspective of the ethics of public health, respect for individual autonomy must be reconciled with pursuit of the goals of general wellbeing. This reconciliation (or weighting of principles) requires, among other conditions, that consumers have access to accurate, clear and comprehensive information. However, as López Nomdedeu explains, "at present, consumers receive a lot of their knowledge about food and nutrition through advertising and the mass media," and this is why the responsibility of everyone involved in the food market, and in particular of the food industry, goes beyond simply avoiding fraud; they also have a responsibility for nutritional education²⁰.

If information is accurate, then normal consumption of the final product should produce the beneficial effect declared. Declarations must have a scientific basis, taking into account all the available scientific data and weighing up the evidence. Ensuring the accuracy of information has been the main concern of legislative initiatives on functional foods, primarily through European Union law. However, this was done at the cost of permitting the use of this information as a marketing tool, thereby legitimating it. Propaganda is not information. A good example of information, in contrast with

the propaganda of nutritional declarations, is offered by the GDA information system (guideline daily amounts) on packaging.

If information is to be clear, then misleading uses of information must be forbidden (for example, the use of information that attributes medicinal properties to foods). Once again, we must stress that propaganda is not information. Clarity involves taking into consideration the normal characteristics of the average consumer (based on the population group for whom the food is designed). Here, it is worth noting that some information initiatives designed to delivery clarity and simplicity (such as nutritional 'traffic light' labelling) have been contested by sectors of the food industry for precisely this reason (that is, because they provide information rather than propaganda).

Finally, comprehensive information entails an obligation to report the overall nutritional properties of the food (beyond its functional properties). The idea of providing a nutritional profile for foods, enabling adequate understanding of these foods in terms of the nutritional quality, should prevail over the issue of 'functionality': it does not seem reasonable to permit nutritional and health claims for foods that do not exceed an average standard of nutritional quality. Just as information (including propaganda) about functional properties is permitted, information must also be provided with respect to 'dysfunctionalities': for example, the presence of trans fats²¹.

3.3. Questions relating to the principle of justice

It seems plausible to assume that functional foods, generally more expensive than the alternatives that are not marketed as being functional, are however more likely to be consumed by the less well-off, because of their greater difficulty in pursuing healthy lifestyles²². Functional foods can be seen as a replacement for a balanced diet or a more active lifestyle. An ethically acceptable approach to functional foods should insist both on promoting the research and development of functions that are beneficial to health, and of ensuring that the general population is able to access these benefits on a fair basis. Achieving this would involve addressing the disadvantages faced by some groups as a result of income inequalities, disability and illness.

At the same time, the enormous imbalance of power between the food industry and public health organizations (whether governmental or non-governmental) is a fact that must be taken into account.

4. Summary and conclusions

- 1. The bioethical implications of functional foods can only be fully understood in the context of the triumph of the ideology of health, the crisis of bureaucratic social security systems, the development of huge markets for the sale of health products, and the rise of individuals, that renders health a duty rather than a right.
- 2. The debate around the concept of functional foods has generated various proposed definitions, which overlap to a lesser or greater degree. From the perspective of bioethics and within a public health context, it is important to stress the concept of the nutritional statement, which can serve both as a marketing tool and as a form of information for the consumer.
- 3. The case of functional foods within a public health context requires a radical change of focus: The requirement is not merely to ensure that nutritional declarations are accurate (although this is very important) but also to abandon the practice of basing marketing on health promises that necessarily involve such claims.
- 4. The health functionalities of these foods should be the subject of information, not propaganda. Comprehensive, unbiased information must start with the nutritional profile of foods, including probable dysfunctions (predictable harmful effects on health as a result of normal consumption). One specific proposal is that such declarations should cease to be used as advertising claims and be treated instead as relevant information (following the GDA model, for example).
- 5. Science should remain independent. Functional foods are a promising research field that deserves to receive both private and public support.

However, scientists have a responsibility to ensure that their research is not used to support groundless promises made by the food industry. This responsibility requires scientists to play an active role in informing the public, participating in regulatory bodies and exercising independent judgement in their dealing with the food industry.

- 6. There is no good reason for abandoning the common sense approach that suggests that promoting a varied, moderate diet, combined with an active lifestyle, is the best way of delivering positive public health outcomes. In so far as the proliferation of functional foods may help undermine this balance, we need to treat such foods with great caution.
- 7. We need to support low-income and vulnerable consumers, such as children, the elderly and people with cognitive deficits, in the face of pressure from the food market. Experts and professional bodies must make an effort to inform people about the fact that functional foods are neither as necessary nor as beneficial as the industry claims. We also need to support consumers with special needs, for whom some of the functionalities offered by these foods are indeed indispensable for medical reasons.

5. Bibliography

There is a vast amount of regulation regarding food and, in particular, food safety, including consumer information and advertising. However, the following legal documents are of particular relevance to this issue:

- Regulation (EC) no. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
- Regulation (EU) no. 1169/2011 of the European Parliament and of the Council of 25 October 2011, on the provision of food information to consumers.

In Spanish legislation, these issues are covered by:

- Act 33/2011, of 4 October, General Public Health Act.
- Act 17/2011, of 5 July, on Food Safety and Nutrition (in particular chapter VIII).

There are a number of websites relating to this issue, of which the following are particularly useful:

- European Food Safety Authority
 http://www.efsa.europa.eu/en/topics/topic/nutrition.htm
- Spanish Agency for Food Safety and Nutrition http://www.aesan.msc.es/AESAN/web/cadena_alimentaria/subseccion/ declaraciones_nutricionales_saludables.shtml

There is also an extensive bibliography, in addition to the items cited in the text. The following offer interesting perspectives on the issues:

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- gy-dense and nutrient-poor foods: an experimental study", *Public Health Nutr*, 2011, 14(6), pp. 1071–1079.
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- Cuevas-Casado I, Romero-Fernández MM, Royo-Bordonada MA. "Uso del marketing nutricional en productos anunciados por televisión en España". *Nutr Hosp*, 2012 (27), pp. 1569–75.

6. Notes

- 1. Porter, Dorothy. "The Healthy Body". In: Cooter, R and Picstone, J. (eds.). *Medicine in the Twentieth Century*, Singapore, Harwood Academic Publishers, 2000, pp. 201–216.
- 2. Brandt, Allan M. and Gardner, M. "The Golden Age of Medicine?" In: Cooter, R and Picstone, J. (eds.). *op. cit.*, pp. 21–37.
- 3. Pickstone, John. "Production, Community and Consumption: The Political Economy of Twentieth-Century Medicine". In: Cooter, R and Picstone, J. (eds.). *op. cit.*, pp. 1–19.
- 4. Ibid.
- 5. Pickstone, John. "Production, Community and Consumption: The Political Economy of Twentieth-Century Medicine". *op. cit.*, p. 17.
- Bernabeu, Josep and Trescastro, Eva. "Alimentos funcionales: ¿Necesidad o lujo?" Text presented at the "Seminario sobre Bioética y Nutrición 2011: los alimentos funcionales". University of Alicante, 10 November 2011.
- 7. Bernabeu, Josep and Trescastro, Eva. "Alimentos funcionales: ¿Necesidad o lujo?" *op. cit*.

- 8. See Bañares, S. "Los alimentos funcionales y las alegaciones alimentarias en la Unión Europea: una somera aproximación jurídica", *Alim Nutri Salud*, 13 (3), 2006, p. 81.
- 9. Roberfroid, M. B. "Les aliments fonctionnels: Concepts et stratégie", *J Pharm Belg*, 56 (2), 2001, pp. 43–44.
- 10. Diplock AT, Aggett PJ, Ashwell M, Bornet F, Fern EB and Roberfroid M. B. "Scientific concepts of functional foods in Europe: consensus document", *British Journal of Nutrition*, 81, 1999, Suppl. 1, S1–S27.
- 11. Silveira Rodríguez, M. B. et al. "Alimentos funcionales y nutrición óptima. ¿Cerca o lejos?", *Revista Española de Salud Pública*, 2003, 77, p. 318.
- 12. This confusion as to the definition of 'functional food' is based on different conceptions as to what is being defined. From a conventional perspective, the process of definition involves linking a set of intentional properties or connotations (the concept) to an expression ('functional food') so that the definiendum (that which is defined) is interchangeable with the definiens (the concept). Definitions are conventional but not arbitrary, and seek to reflect general use of the expression, specifying its meaning on the basis of this use or establishing a new meaning in accordance with certain propositions. Where, then, is the source of the particular difficulty in defining 'functional food'? Apparently, it is not a problem of intentional vagueness (the indeterminacy of the properties of the concept), but rather of extensional indeterminacy: that is, indeterminacy as to which precise set of foods fall within the delimitation 'functional food'. What is clear is that scientists are not applying a conventional notion of definition: in the empirical sciences the delimitation of the object of study does not depend on a definition, because these objects appear as differentiated, natural classes, whose properties must be revealed by investigators (and the definition is a description of reality, rather than the attribution of meaning to a linguistic expression). In this case, because functional foods do not constitute a natural reality that is distinct from other foods

- and can be defined on the basis of its natural properties, it is not possible to have a simple, universal definition, because 'functional food' is above all a concept. This is, then, an essentialist notion of definitions (as opposed to a conventionalist one).
- 13. This, for example, is the position of the *American Dietetic Association*, which includes 'conventional foods' within the category of 'functional foods'. See "Position of the American Dietetic Association: Functional Foods'", *Journal of the American Dietetic Association*, 109 (4), 2009, pp. 735–746.
- Regarding the scope and limits of this method of weighting in bioethics, see Alemany, M. "El paternalismo médico". In: Gascón, M., González, M. C., and Cantero, J. (eds.). *Derecho sanitario y bioética. Cuestiones actuales*. Valencia, Tirant Lo Blanch, 2011, pp. 745–788.
- 15. A number of studies demonstrate the need for ongoing review of tests on the effects of functional foods. See, for example: González Díaz, C., Meléndez Illanes, L. Álvarez-Dardet, Carlos. "Alimentos como medicamentos: La delgada línea divisoria entre la industria farmacéutica y la industria alimentaria", *Rev Esp Salud Pública*, 2012 (86), pp. 313–317.
- 16. See note 15.
- 17. Research conducted in 2008 by the CEACCU (Spanish Confederation of Housewives, Consumers and Service Users Organizations) on consumers and the new food labelling, offered the following conclusion, among others: "Interviewees with a higher level of education were more critical and more sceptical regarding the numerous benefits claimed in advertising." See López Nomdedeu, C. "El consumidor y su actitud ante los alimentos funcionales en el contexto de una dieta saludable". In: Juárez Iglesias, M. and Perote Alejandre, A. (eds.). Alimentos saludables y de diseño específico. Alimentos funcionales. Madrid, Instituto Tomás Pascual, 2010, p. 204.
- 18. Cuevas-Casado, I. Romero-Fernández, MM. Royo-Bordonada, MA.

- "Uso del marketing nutricional en productos anunciados por televisión en España", *Nutr Hosp*, 27, 2012, pp. 1569–75.
- 19. López Nomdedeu, C. "El consumidor y su actitud ante los alimentos funcionales en el contexto de una dieta saludable". *op. cit.*, p. 201.
- 20. Anyone who is sceptical as to the power of the food industry to modify social eating habits (for the worst) would do well to read the following book: Ritzer, G. *The McDonaldization of society* (6th ed.) New York, Sage, 2010. Along the same lines, although in a lighter vein, are the ideas presented in: Alemany. "Super size me y Fast food nation: la denuncia de algunas realidades indecentes en torno a la alimentación humana". *Quaderns de Cine*. N. 4 (2009), pp. 7–12.
- 21. It is important to note the development of European law in this direction. Regulation (EC) no. 1169/2011 of the Parliament and of the Council, of 25 October 2011, on the provision of food information to consumers states that "food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties" (Art. 7.3) while nutritional and health declarations for some foods which were previously voluntary are now obligatory, and the manner in which they must be presented is set out in detail. This is the case regarding foods containing phytosterols, phytosterol esters, phytostanols and/or phytostanol esters, for which the labelling must include "a statement that the food is intended exclusively for people who want to lower their blood cholesterol level", "a statement that patients on cholesterol lowering medication should only consume the product under medical supervision", and "the advice that the food is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels", etc. (see Annex III, with respect to art. 10.1). It is clear, then, that with regard to these products nutritional declarations are treated as information and not as advertising.
- 22. What we are seeing is a nutritional epidemiological superimposition, where malnutrition is superimposed upon obesity. As has been clearly

established, the 'epidemic' of obesity primarily affects low income groups in rich countries, because these groups consume higher proportions of low quality foods that are marketed as 'fast food', 'ready meals', etc. 'Living conditions' dictate 'lifestyles'. See Aguirre. P. *Ricos flacos y gordos pobres. La alimentación en crisis*. Buenos Aires, Capital Intelectual, 2004.

Summary, evaluation and outlook

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Coordinators

The second meeting on ethics and public health, held on Lazareto island in Mahón, on 11 and 12 September 2012, was dedicated to the analysis and discussion of three different situations, selected from the many issues faced by public health practitioners in particular, and by society and general.^a

These three situations, naturally enough, were selected on the basis of their ethical component, but also because they represented current issues that would benefit from analysis and discussion. A final reason for the choice was that these three case studies were particularly amenable to discussion using the approach set out in the introduction to this document.

Our aim was not simply to analyse and discuss but also to produce material that would provide a basis for training public health practitioners. Following on from the commitments made at the first meeting, we decided to focus our contribution to the application of ethics in the sphere of public health by presenting examples that would establish the benefit of introducing ethical considerations in this field. In addition, these case studies provide a source of insights and experience that will serve to help improve public health interventions in situations similar to those under discussion, and will also be applicable to other similar situations. For this reason, they focus on aspects that can be applied to professional practice. However, the aim is not solely to improve the quality of public health activities, in the sense of affording more and better protection to the population's health (the terms in which we usually think about such issues) but also, and above all, to take into account the existence of diverse interests and values that may ultimately lead to conflict and give rise to ethical dilemmas. Interests and values to which we often do not pay as much heed as we should.

This is not mere rhetoric, for it is our awareness of these interests and values that underpins our ability to act with justice and, at the very least, to explain the reasons for applying any given public health measure. All of this should, ideally, lead to greater understanding by the general public of public health

interventions and, as a result, promote the active participation of people in shared health-related issues. Such involvement is essential if we are to overcome the traditional dilemma faced by public health – as a collective institution – with respect to bioethics: the conflict between individual rights and the common good.

Clearly, public health operates at the level of the general population, and for this reason focuses on protecting common interests, even where this is at the expense of the interests of individuals or groups. Such differences of interest may lead to conflict and require a whole range of complex ethical dilemmas to be addressed, but this process is made easier if we recognize that human nature includes not just physical but also spiritual and communal aspects; these characteristics correspond to the definition of health adopted by the WHO in 1948 as *somatic*, *mental* and *social*.

The recourse of public health to ethics can be understood, then, as the choice of an approach based on deliberation and dialogue, one which in a sense complements the commitment of bioethics to protecting people's rights by defending the right of the community to health protection: in other words, the collective dimension that we all share.

Returning, then, to the reasons for selecting the three case studies explored in this monograph, we can say that they all potentially raise issues and arguments that are of more general application and can be applied to similar situations. In this respect, it is important to be aware of the potentially negative effects that may arise from protection measures themselves, and to remember that any such effects must, at the very least, be outweighed by the expected positive outcomes. In this regard, the experience of Serious Acute Respiratory Syndrome (SARS) is useful both in the first case study presented and in the third. The fall in GDP suffered by some economies in Southeast Asia as a consequence of the implementation of drastic measures to prevent the spread of SARS had a negative impact on some of the factors that, collectively, influence population health.¹

a. It is important to note that public health interventions do not occur solely within the context of the health system. Responsibility for many collective health protection activities, from guaranteeing the health of homes and buildings to road safety, lies outside of the health sector.

1. Conclusions from the case studies

One

Analysis of the health response to the flu pandemic is instructive not just with respect to such a specific threat, but also in any case where the degree of scientific understanding of the predicted epidemic varies, as does the level of threat it poses. This relevance is increased by the heated public debate about the measures that were implemented. For example, the position of Spain's Foundation for Health Sciences, that "any excess in the prevention of an epidemic is justified" contrasts with the attitude of SESPAS³ or the blog "Gripe y calma" [Flu and calm] (http://gripeycalma.wordpress.com/) or the article by Tarantola⁴, associate editor of the Journal of the American Public Health Association before the pandemic occurred, that whether or not the pandemic materialized there would be victims (direct, if it occurred, and indirect if it did not, because of the opportunity cost of taking 'unnecessary' measures).

Among the conclusions and recommendations of the meeting, we should note the importance of the advance planning of responses to potential epidemics, while responses must always reflect the actual development of the health problem, and for this reason it is advisable to use appropriate indicators of the seriousness of the event in order to modulate the intensity of prevention and control actions. In so far as is possible, we need to ensure that responses are proportionate to the threat, in order to keep the inevitable adverse effects to a minimum.

Two

By contrast, the case study that looked at the advertising of functional foods is interesting because it shows how, at least in some cases, exaggerated expectations of the potentially beneficial impact of these products can be generated with regard to the health of the population, and in others how such advertising may even promote food behaviours that constitute a threat to health. This danger may, at least partially, be a consequence of the insistence of the public health services of the importance of a healthy diet and eating habits and,

more specifically, of following recommendations about the consumption of individual foods or food complements that are perceived more as miracle cures than as nutrients with specific effects.

The meeting argued for the need to draw a clear distinction between information and propaganda, and stressed that information should include the nutritional profile of the food to which it relates. The potential of functional foods deserves to be adequately researched, given their capacity to make a significant contribution to controlling certain health problems in some cases. However, they do not (at least at present) represent a basis for the promotion of healthy eating, something which instead continues to depend on the importance of moderation, balance and variety.

Three

Finally, the public health services, at least in Spain, are part of wider government structures. Indeed, until 40 years ago, these were a part of the Ministry for Public Order, with responsibility subsequent passingly to local government. This set them apart from the rest of the health services. Although they are now increasingly integrated with the health system, thanks both to the Public Health Act at the national level and to regional legislation, they still operate as a health authority, and this creates an anomalous situation with regard to professional hierarchies and responsibilities.

Health protection decisions almost always entail both gains and losses: that is, they may produce benefits to the community as a whole (which is what is desired) but also losses, above all for individuals or companies, but which may also affect the community if the measures taken are ineffective, inefficient or disproportionate.

The feeling was that, given potential discrepancies between how different health professionals and authorities evaluate the health risks involved with community health protection activities, there is a need to consider the possibility of strengthening the intermediary role of multidisciplinary committees, agencies or other types of institution, including scientific and professional bodies.

2. Participant evaluation

Participants gave a positive evaluation to the workshop as a whole, rating it even more favourably than they did the first meeting on ethics and public health. According to the 20 surveys completed (out of a total of 23 participants) the meeting almost fully satisfied the expectations of participants, with an average rating for this heading of 4.5 on a scale of 0 to 5. The usefulness of the session for participants' own professional activities was rated 4.25, while the usefulness of the conclusions received a score of 4.65. The highest rating of all went to the organization for the discussion and the interchange of experiences, with a score of 4.80. The communication abilities of coordinators and speakers were ranked only slightly lower, at 4.65. And participants rated the likelihood of their recommending participation at similar meetings to colleagues at 4.55.

3. Plans for the future

The previous monograph in this series⁵ has been well received, and it is to be hoped that this success will be repeated here, with the resultant publication being used as teaching material for students of public health, both at postgraduate and undergraduate level (Davos MC *et al. Gaceta Sanitaria*. Mahón meeting on the teaching of public health as a part of university medical education programmes), or within continuous professional development and in-service training activities for public health professionals. It therefore seems advisable to continue to compile case studies and situations that illustrate the benefits of applying an ethical perspective. Examples include:

- 1) Risk factors of a genetic nature, distorted expectations, and the inappropriate use of genetic testing. Analysis of prenatal screening.
- 2) Negative and positive effects of the crisis on health services and health.
- 3) The health obsession. The limits of health promotion.

- 4) Between disempowering paternalism and blaming the victim.
- 5) Public health practitioners: between professionalism and authority.

Finally, the working group could cooperate with the management board of SESPAS to apply ethical considerations to the development of moral and ethical standards in professional practice in public health, and in the representation of their members by the societies that constitute SESPAS.

4. Notes

- 1. WHO: The World Health Report 2007: Chapter 3. Accessible at: http://www.who.int/whr/2007/07_chap3_en.pdf
- 2. http://www.fcs.es/docs/publicaciones/NP_epidemias.pdf "Desde la Memoria: Historia, Medicina y Ciencia en Tiempos de...", organized by Fundación de Ciencias de la Salud.
- 3. See their website at www.sespas.es
- 4. Tarantola D. H1N1 Flu and the tartar Steppe. Am J Public Health, 2009:99 (Supl 2):209.
- Ethics and public health. Barcelona: Fundació Víctor Grífols i Lucas, 2012.

List of participants

Coordinators

- Andreu Segura, Director of the Office for the Interdepartmental Public Health Plan, Department of Health of the Government of Catalonia
- Andrea Buron, doctor with Parc de Salut Mar, Epidemiology and Evaluation Service
- José Miguel Carrasco, Sociologist, specializing in Public Health

Speakers

- Macario Alemany, Lecturer in Legal Philosophy at the University of Alicante
- Jordi Delclós, Lecturer at the Pompeu Fabra University and director of the Occupational and Environmental Health Division at the University of Texas School of Public Health
- David Larios, Vice-President of the Association of Experts in Health Law (Asociación de Juristas de la Salud)

Invited specialists

- Gracia Álvarez, President of the Clinical Ethics Committee of the Regional Health Service of León
- Rosa Ballester, Professor of the History of Science at the Department of Public Health, History of Science and Gynaecology at Miguel Hernández University
- Marc Antoni Broggi, Surgeon and President of the Bioethics Committee of Catalonia
- Josep M.^a Busquets, Member of the Bioethics Committee of Catalonia

- Victoria Camps, President of the Víctor Grífols i Lucas Foundation
- Javier García León, Technical Advisor to the Agency for the Evaluation of Health Technologies of Andalucía, Department of Health and Social Welfare of the Regional Government of Andalucía
- Juan Gérvas, Doctor and Honorary Professor of Public Health at the Autonomous University of Madrid
- Rafael Guayta, Director of Projects and Research for the Official College of Pharmacists of Barcelona
- Ildefonso Hernández Aguado, Professor of Preventive Medicine and Public Health at Miguel Hernández University
- Isabel Marín Rodríguez, Head of the Health Service of the Local Department for Health and Social Welfare of Granada
- Màrius Morlans, Doctor and President of the Ethics Committee of the Vall d'Hebron University Hospital, Barcelona
- Joan Maria Pons Ràfols, Scientific Advisor to the Agency for Information, Evaluation and Quality in Health, Government of Catalonia
- Àngel Puyol, Director of the Department of Philosophy at the Autonomous University of Barcelona
- Bernabé Robles, head of the Neurology Service, and President of the Clinical Ethics Committee, *Parc Sanitari Sant Joan de Déu*
- Begoña Román, Professor of Ethics at the University of Barcelona
- Miguel Ángel Royo, Head of the Studies Department of the National School of Health Sciences
- Francisca Serra, Professor of Nutrition and Food Studies at the University of the Balearic Islands

Publications

Bioethics monographs:

- 29. Case studies in ethics and public health
- 28. Ethics in health institutions: the logic of care and the logic of management
- 27. Ethics and public health
- 26. The three ages of medicine and the doctor-patient relationship
- 25. Ethics: the essence of scientific and medical communication
- 24. Maleficence in prevention programmes
- 23. Ethics and clinical research
- 22. Consent by representation
- 21. Ethics in care services for people with severe mental disability
- 20. Ethical challenges of e-health
- 19. The person as the subject of medicine
- 18. Waiting lists: can we improve them?
- 17. Individual Good and Common Good in Bioethics
- 16. Autonomy and Dependency in Old Age
- 15. Informed consent and cultural diversity
- 14. Addressing the problem of patient competency
- 13. Health information and the active participation of users

- 12. The management of nursing care
- 11. Los fines de la medicina (Spanish translation of The goals of medicine)
- 10. Corporate responsibility in sustainable development
- 9. Ethics and sedation at the close of life
- 8. The rational use of medication. Ethical aspects
- 7. The management of medical errors
- 6. The ethics of medical communication
- 5. Practical problems of informed consent
- 4. Predictive medicine and discrimination
- 3. The pharmaceutical industry and medical progress
- 2. Ethical and scientific standards in research
- 1. Freedom and Health

Reports:

- 5. Ethics and Synthetic biology: four streams, three reports
- 4. Las prestaciones privadas en las organizaciones sanitarias públicas (Private services in public health organizations)
- 3. Therapeutic Cloning: scientific, legal and ethical perspectives
- 2. An ethical framework for cooperation between companies and research centres
- 1. The Social Perception of Biotechnology

Ethical questions:

- 3. Surrogate pregnancy: an analysis of the current situation
- 2. Sexuality and the emotions: can they be taught?
- 1. What should we do with persistent sexual offenders?

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