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UNIVERSITAT PONTIFÍCIA COMILLAS

►► The jurist and adviser of the Government, Federico de Montalvo.

Interview ▸ Federico de Montalvo Adv

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FEDERICO DE MONTALVO Government Advise

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Federico de Montalvo is chairman of the Spanish Bioethics Committee, a member of the Unesco International Bioethics Committee, and a lecturer and researcher at the Pontifical Comillas University. He is graduated in law, de Montalvo has focused his activity on the legal side of science, especially medicine. This task has led him to draft various regulations in this area by the Government, including the latest presented by the Executive: the Health Research Bill.

–When does your relationship with the Principality begin?

–The Government of Andorra wrote to me a few years ago because of my profile, and asked me to take part in drawing up certain rules. It should be remembered that Andorra has been carrying out, for some years now, a process of regulating everything related to the field of health, because it had practically no regulations, which also happened in Spain. In the case of Spain, the Patients Rights Act was approved 20 years ago, and it seems that in Andorra they also wanted to start this path of regulating all health and research issues. So, the first task I was given was a review of the Patient Rights Act. Subsequently, I also drafted the Assisted Human Reproduction Act, participated in the drafting of a medical history decree, and revised two drafts, the Cell, Tissue and Blood Act, and a another of the Patients Act, in addition to working on other texts on time.

–How was the contact in the case of the Health Research Bill?

–In the specific case of the Health Research Bill, the Minister of Health, Joan Martínez Benazet, called me at the beginning of the legislature. I imagine that the government was satisfied with the work it had done on previous occasions, which is why it asked me if I could give them this draft legislation.

–What is your experience in this sector?

–I came to this world by chance, because while I was studying law I had cancer. This experience and direct relationship with the health field marked me a lot, so after a few years working as a lawyer, I was offered to join a clinical research ethics committee, which is precisely one of the elements included in the health research text. These are the committees that are responsible for ethically and scientifically evaluating research projects.

I started in 1993, first on the committees of Madrid centers, until I was appointed vice-president of the Spanish Bioethics Committee, a body I now chair. In addition, in 2014 I became a member of the Unesco International Bioethics Committee. At the same time, my line of research at the university refers to the right to health and bio-law, and I am also a professor of constitutional law. This subject explains the rules, and it also deals with the normative technique, so it can be said that I have a double aspect: I know well the system of rules and the field of bio investigation.

–What are the main features of the research text?

–First of all, there are two important ideas that I proposed to the minister and that he liked. One, that it was good to have a single law on health research. For example, Spain has two laws, one for drugs and health products, and another

> «Possibly one of the most advanced laws, in the sense that it incorporates very innovative and useful ideas»

for research and cell samples. I do not like this duality because there have been cases where there have been contradictions between the two laws, apart from the fact that, in practice, these are two issues that are closely linked and are governed by the same principles. That is why I recommended that Andorra make a single research law, which includes any research in the field of health.

And on the other hand, the second element that I suggested for the wording of this law is that, despite being detailed in its content, it was a law flexible enough to adapt to a very changing fact such as the fi-

viser to the Government on health legislation

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eld of biomedicine and its research. I think that drafting a very detailed law would have made the text obsolete after a year or two, because this field is moving very fast. In other words, it is a law that basically seeks to capture the limits of research, the frontier that cannot be crossed. It is not a law that regulates bio investigation in detail, because we are talking about a field that may have changed a lot in five years.

–In the presentation of the text it was mentioned that the previous laws have been taken into account. Did participating make it easier for you?
–Exactly. All the existing texts have been taken into account, and it has been the case that most of them have already been treated in one way or another.

–Compared to other European regulations, what situation would the Andorran woman be in?
–I think it is possibly one of the most advanced laws, in the sense that it incorporates very innovative and useful ideas. These are inputs that are found in all international bodies, and are values and principles already established, but in many cases, have not been incorporated into law. At the time, I believe that one of the virtues of the Andorran norm is that it is modern. Although I would like to make a point in this regard, as modernity is sometimes confused with allowing everything. It is a modern norm, which incorporates the latest ideas, but at the same time it is a cautious norm, which is intended to be at the service of human beings, not to their detriment. In other words, Andorra's health research law puts human beings at the center, and therefore does not allow research that could harm or justify it. There is a basic principle in the text that is safety, and when it comes to bioinvestigation, when you may find yourself working with genomic or genetic aspects of the individual, great care must be taken because the damage can be irreversible. So, safety and caution are very important here. This does not mean that you do not want to do things, but that you need to be careful about how you do things and that the harm you do is not unjustified.

–And the pandemic, has it been influenced?
–Yes, the pandemic has been taken into account because it has been an experience in the face of decision-making where the balance between individual interest and collective interest has been weighed heavily. In addition, it has also influenced the sense that the pandemic has given us a lot to learn about research.

–The text mentions the creation of a bioethics committee. Based on your experience, what profiles do you think should be part of it?
–The most important thing in a bioethics committee is that the team should be multidisciplinary. Different views need to be incorporated, because bioethics is not just about medicine or pharmacy. It is crucial that it is made up of people from different areas of knowledge and with different perspectives. In the end, in a research project, the scientific, methodological, economic, legal, ethical part, and the interest in the citizen must be valued. It is not a committee of scientists, it is a committee of experts that evaluates scientific projects.

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–You commented that it is an open text to be able to incorporate the novelties. How should it be expanded later?
–In fact, the law will have a development. The text sets out the essential principles that should underpin research, and somewhat what the framework is for the promotion of health research. From here, specific decrees can be drafted, such as a decree to regulate biobanks in more detail, a decree to regulate genetic studies, the requirements that certain establishments must have ... To incorporate these such detailed aspects in a framework law would have been a mistake, because then any changes should have been made by revising the whole law, and I repeat, we are talking about a very changing sector.

–Another element mentioned is that the law can contribute to the economic diversification of the Principality. What do you think it can do about it?
–Passing a good law offers legal security. I think that economics and legal security go hand in hand, so this text has been consulted with different sectors of research, and they have all agreed that it is a very appropriate law. Serious companies

> «Making a very detailed law would have made the text obsolete after a year or two, because the field is moving fast»

and research groups do not want to do anything that goes against the limits. Fortunately, in Europe, things cannot be done that are being done elsewhere and that are debatable. Therefore, making a law in the European framework that puts the person at the center, that protects the vulnerability and that is cautious, is not a problem.

–So, what does legal certainty offer? –It provides a safer economic framework. Furthermore, it is not a law that prevents everything, but a rule that regulates everything that is reasonable and of scientific interest. There are things that look great in PowerPoint, but they don't really work, so including things that may be very spectacular, but in the end don't contribute anything in research, doesn't make sense. For example, CRISP Cas9, which is genomic research, is unsafe today, but maybe in a little while it can contribute. It can be one of the great changes in medicine that may appear soon, as this is incorporated, because here there are possibilities to cure many diseases or to prevent.

–So, this legal security can bring serious companies together, as you say?
–Yes, I believe that Andorra can have an important field of competitiveness in the search for health given its situation: touching France and Spain, and close to two regions with a long tradition in research such as Catalonia and Aragon have traditionally been . I think it has potential, and often what research groups are looking for is not flexible principles that allow them to do things that can't be done, but they are looking for a light bureaucracy, that there are opportunities, that things can be done, that there is openness to interesting projects ... In other words, this law aims to carry out serious research in Andorra and with human beings at the center, it does not mean turning the Principality into a paradise where people can go and research everything which cannot be investigated in other parts of Europe. The big challenge will be for the Principality to be proactive enough to attract research groups.

–In fact, Andorra is approaching the European Union, so it cannot regulate lightly either.
–Exactly, but it is that, beyond the European Union, Andorra belongs to the Council of Europe, and this body has worked a lot with the Oviedo Convention, which precisely regulates medical research. So, the Principality, as part of this body, cannot do research that clashes with its principles. Andorra does belong to the European human rights framework. And in fact, the Council of Europe itself has revised the Health Research Bill, and the best news we have received is that they have really liked it. I think that also means that it is a very humane law. ≡