

Biomedical research in Spain: the patient's point of view*

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Spanish Minister of Health and Consumer Affairs (2007–2009)

Resum. Hi ha un desfasament clar entre el lloc que l'Estat espanyol ocupa a Europa des del punt de vista econòmic i el lloc que ocupa en recerca, en general, i en biomedicina, en particular. La biomedicina serà, sense cap mena de dubte, la ciència principal que protagonitzarà els canvis i avenços del segle XXI. Per això és essencial que el resultat del coneixement arribi a la pràctica clínica i es converteixi en teràpies efectives. Per aconseguir que aquest desfasament desaparegui, el govern espanyol ha elaborat una sèrie d'iniciatives que promouen el desenvolupament i la recerca biomèdica, i que inclouen accions conjuntes entre les institucions, les universitats, les empreses i la resta de la societat. Aquestes iniciatives, agrupades sota el pla *Ingenio 2010*, promouen les polítiques del Ministeri de Sanitat i Consum. Juntament amb l'Institut de Salut Carles III i els Centres d'Investigació Biomèdica en Xarxa (CIBER), han permès un ràpid creixement de l'R+D a Espanya. El Consell de Ministres també ha aprovat una sèrie d'accions estratègiques amb l'objectiu que els beneficis de la recerca biomèdica arribin als pacients al més aviat possible. Aquestes accions transversals se centren en els camps del càncer, la medicina regenerativa, la nanobiotecnologia, les molècules innovadores i la Biblioteca Virtual del Sistema Nacional de Salut.

Paraules clau: recerca en biomedicina · càncer · medicina regenerativa

Abstract. There is a clear gap between Spain's economic ranking and its position among other European countries, both in general research and in biomedicine. Biomedicine in particular is and will be, without a doubt, the premier science in the 21st century, initiating the most changes and leading to the most significant discoveries. It is therefore essential that the knowledge gained reaches clinical practice and is converted into efficient therapies. In order to reduce this gap, the Spanish government has set forth a series of initiatives that support biomedical research and development, and which encompass institutes, universities, and private companies. These initiatives, grouped under the *Ingenio 2010* plan, promote the policies of the Ministry of Health and Consumer production. Together with the Carlos III Health Institute and the Network of Biomedical Research Centers (CIBER), it will allow the rapid growth of R&D in Spain. The Minister's Council has also approved a series of strategic actions whose goal is to ensure that the benefits of biomedical research reach patients as quickly as possible. These actions are focused on cancer therapy, regenerative medicine, nanobiotecnology, molecular innovation, and the Virtual Library of the National Health System.

Keywords: research in biomedicine · cancer · regenerative medicine

The gap between Spain's position in the economic ranking of nations—it is said that we are 8th—and its position in research in general and in biomedicine in particular is no secret in the country. In order to reduce this gap, huge investments will be required, but also imagination and a broad set of coordinated actions by our researchers, encompassing those at institutes, universities, and private companies, and the rest of society. It is also no secret that biotechnology in Spain has highly qualified

personnel. The work of these scientists, and biotechnology as a whole, is thriving due to the increasing funding for research, development, and innovation provided by the Government and by private firms.

The same is happening in other European countries, where government and private funding are converging, but in Spain the contributions of the private sector remain comparatively small in terms of population and GDP. However, the effects of political willpower are evident, as was the case in 2005, when the President of the Government presented the *Ingenio 2010* plan to support research and development in Spain. This plan is focused in part on biomedical research, through a promotion of the policies of the Ministry of Health and Consumer Protection.

Research, development, and innovation have been targeted by our Government because of our conviction that the knowl-

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edge acquired will translate into added wealth as well as technological, social, and welfare benefits. We know that investment in the health industry has strong economic advantages. Indeed, according to experts, in Spain it could reach a ratio of 4:10, that is, every 10€ spent, benefits assessed at 4€ are generated for society.

There are also other, indirect benefits in that a national health system with quality medical services, like we have here in Spain, provides foreigners a feeling of security and thus attracts tourists. Clearly, when we consider the health system and medical services we refer to the health of the Spanish population, but we also have to think of the most competitive industry in Spain, which is tourism, and thus to keep in mind that in offering a high-quality health system we are ensuring the continued strong performance of this industry.

Figures that reflect industry growth are the number of companies created in the biotechnology sector, which in 2003 was 149 whereas in 2006 it rose to 216. According to studies carried out in 2004, the value in terms of income and direct and indirect employment of biotechnology in Spain was 400 million Euro and 36,000 people employed. Assuming that growth continues at the current rate (around 25% for research investments and 20% for direct employment) the prediction for the year 2010 is 1.6% of GDP and 100,000 people employed. Biomedicine in particular is and will be, without doubt, the premier science, the one that initiates the most important changes and leads to the most significant discoveries in this century. We must take advantage of this historical opportunity by making sure that we are in the right place to do so, and by undertaking those measures needed to bring about the necessary changes.

Spanish society is highly open to and prepared for technological changes and looks forward to the results of biomedical research. But it is of no use to society if these results remain in the laboratories or are confined to specialized journals; instead, for patients and their relatives it is essential that knowledge gained is converted into efficient therapy. In Spain, knowledge production in biotechnology accounts for 4% of the content of global publications, which makes our country very competitive in the international community. However, the application of this knowledge is clearly inefficient, as only 0.16% of European patents are awarded to Spain. The Government is aware of these figures and is engaged in attempts to boost biomedical research that is application- and therefore patient-oriented. Nonetheless, in order to convert our country into a biomedical research capitol and to ensure that the results of investigation reach clinical practice, we will need profound reforms and new strategic actions.

One of the first reforms that the government must undertake is to equip our country with appropriate legislation to allow scientific research in the biomedical field. This is to be done in a proper administrative context and keeping in mind respect for individual rights and ethical treatment. Accordingly, the Spanish Parliament recently approved laws on assisted human reproduction and biomedical investigation. These laws form the normative basis that will allow biomedical research in Spain to converge with that of our neighboring countries.

Currently, we are working on regulations that form the laws governing biomedical research. Amongst these regulations are Royal decrees addressing: (1) requirements for importation and exportation of gametes, cells, and human embryo tissue; (2) regulation of the employment of civil servants by private companies subsequent to the granting of patents or the achievement of research results generated in government centers; (3) the development and functioning of the Guarantee Commission for the Donation and Utilization of Cells and Human Tissue, and (4) the constitution and functioning of Ethics Committees in biomedical research. In addition to juridical rules regulating research, we need a structure to develop research centers and innovative projects, both of which will be financed with public funding.

During the past several years, the role of the Instituto de Salud Carlos III in furthering biomedical research in Spain has been crucial, but now a further step needs to be taken to transform that institute into a structure that will allow us to introduce a new philosophy, management by targets, and thus a philosophy that allows higher flexibility in management processes. Consequently, the Institute will become a state agency and its responsibilities will be leading the research activities of the National Health System and promoting the transfer of results in clinical research in order to facilitate the development of their practical applications. Additionally, we need to finance research and create policies that stimulate private companies, thereby uniting government and industry in the common task of generating wealth and well-being.

In this sense, the Ministry of Health and Consumer Protection has invested strongly in the development of basic and clinical research and in projects and new buildings related directly to biomedicine. Increases in public funding, from 99 million Euros in 2003 to 215 million Euros in 2006, of centers such as CIBER (Network of Biomedical Research Centers) and the Regenerative Medicine Center of Barcelona, under the auspices of the Instituto de Salud Carlos III, have allowed R&D to grow in a spectacular fashion. Of interest to this audience is the fact that of the nine divisions of CIBER, three are led by Catalan researchers, and over 1000 Catalan researchers participate in CIBER. This indicates the extraordinary importance of researchers in Catalunya to the leadership of biomedical research projects throughout the country. During this past year, the growth of those projects has increased by 15% and in the 2008 budget an increase of 25% in R&D in biomedical research was predicted, which will correspond to a total investment of 417 million Euros.

These are figures that specifically refer to the budget of the Ministry of Health and Consumer Protection, but the total investment of the Government of Spain in biomedical and related research is much higher. For example, the Ministry of Education and Science, during the year 2006, established many programs aimed at improving the quality of life. The funding for these programs was 142 million Euros. Summing the amounts invested in health and biotechnology by these two ministries and by the Ministry of Industry, we reach a total investment of over 2 billion Euros.

As noted above, research results must benefit society and

its individual citizens. This is particularly the case for biomedical research. Patients, their relatives, and their loved ones are not satisfied with knowing that many resources are devoted to research activities and thus to many researchers; they want results and expect that all this knowledge and resources will eventually be transformed into effective therapies that heal the ill. This was my aim as a researcher and it remains my aim as Minister of Health in the Spanish Government, to advocate patient-oriented research. For this reason, the Ministers' Council recently approved a series of strategic actions whose goal is to ensure that the benefits of biomedical research reach the patient as fast as possible. These actions, for which 75 million Euros have been allocated, will mobilize resources in the following fields: advanced therapies in regenerative medicine, child and adolescent psychiatry, human genetics, and rare diseases and orphan drugs.

Of particular interest is regenerative medicine, which as we know will be the most revolutionary medical field in the 21st century. The Spanish Government, from the very start of its current term of office, has given high priority to research in regenerative medicine and the transfer of its discoveries to the National Health System. Of the 21 million Euros invested, 10.5 million are through direct funding by the government and the rest through joint funding. The pathologies included in the clinical research program reflect the needs of patients: islet cell transplant for the treatment of diabetes; cell therapy in complications due to diabetes, such as diabetic foot and diabetic cardiomyopathy; cell therapy for amyotrophic lateral sclerosis, multiple sclerosis; graft-versus-host disease, Crohn's disease, muscular dystrophy, and spinal cord injury; the regeneration of skin, bone, and cartilage; and hepatic regeneration. With this list we start down a path that will inevitably lead to new targets, as research groups develop proposals with experimental and clinical implications that also meet the ethical and regulatory standards of the European Union.

The group of five actions specified in the research, development, and innovation plan is aimed at scientific production, the training of researchers and medical staff, increasing the number of biomedical-related patents in Spain, increasing the number of Spanish licenses and contracts, the creation of new companies (spin-offs), obtaining private funds to finance biomedical research, and of course, to improve the quality of medical care. These five actions are focused on: (1) cancer, with the goal of accelerating the transmission of scientific knowledge to cancer sufferers, with a total investment of 90 million Euros; (2) regenerative medicine, with the aim of giving continuity to

actions already initiated in this field and to incorporate similar initiatives in the future, with a total investment of 22 million Euros; (3) nanobiotechnology, bioengineering, and health technology, the interaction of which is one of the most promising fields in research, with the intention of unifying the methods and concepts of engineering, biology, medicine, physics, materials science, biotechnology, etc., including experimental and theoretical approaches and their applications, for which 20 million Euros is destined; (4) molecular innovation, another encouraging field in this century for fighting certain diseases, with a total of 30 million Euro invested, and (5) the Virtual Library of the National Health System, the main target of which is to provide all professionals in the National Health System access to bibliographic and documentary resources in health sciences.

All of these actions that form, but do not completely constitute, the immediate future of biomedical research in Spain, are only the first steps in achieving parity with our neighboring countries. Moreover, they also send a message of determined commitment, evidenced by the specific steps undertaken by the Government, to society, researchers and professionals in the National Health System, and especially to patients, who, after all, are the main motivation for our work.

Finally, I would like to mention and honor Pascual Maragall, for the strength with which he has faced the diagnosis of Alzheimer's disease. I do so both personally and as head of the Ministry of Health and Consumer Protection. The fight against Alzheimer's disease is one of the main priorities of the Spanish Government, as expressed in its laws aimed at improving the situation of patients and their care-takers; but it is also a battle that includes other fronts, such as early diagnosis, productive investigations, and the search for new and more effective treatments. In 2006, the CIBER division of neurodegenerative diseases was established, comprising 48 research groups and a funding commitment of nearly 6 million Euros. I would also like to emphasize the research units of the Alzheimer Project of the Reina Sofia Foundation, within the Institut Carlos III, with its ties to the Ministry of Health and Consumer Protection. During the past few years, 33 research projects focused on Alzheimer's disease have been financed. These figures are meant to reassure the sufferers of this disease and their relatives that the determined will of the Government in this matter goes much further than just words.

Society, its citizens and its patients have placed their hopes in our work. Our obligation is not to disappoint them, to not disappoint you.

About the author

Bernat Soria is the former Spanish Minister of Health and Consumer Affairs (2007–2009) and one of the world's leading experts in stem cell research. He obtained his Ph.D. in medicine at the University of Valencia, and completed his

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with the university's founding in 1997, and also established the University's Institute of Bioengineering. His team at the Institute was the first in the world to obtain insulin-producing cells from embryonic stem cells in mice. He was the first

president of the European Stem Cell Network. He was Professor of Physiology at the Pablo de Olavide University and director of CABIMER—the Andalusian Center for Molecular Biology and Regenerative Medicine in Seville, and the first

state-funded institute dedicated to stem cell research. He has received numerous awards, including the Award from the Royal Academy of Medicine, the Gold Medal of Andalusia, and the prestigious Galien Award for Biomedical Research.