THE PHARMACEUTICAL INDUSTRY AND MEDICAL PROGRESS

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PROLOGUE

The following pages contain the issues surrounding the debate "The Pharmaceutical Industry and Medical Progress" held in May 2000 by the Fundació Víctor Grífols i Lucas. The talks given by Fernando García Alonso and Xavier Peris, acted as the starting point for the ensuing discussion in which pharmacologists, doctors, philosophers and journalists participated.

Basically two issues underpinned the debate. The first, derived from the very title of the conference, consisted in challenging the relevancy of the idea of "medical progress". What does medical progress actually mean? The data used to measure the progress should not be accepted unquestionably. As for the rest, they are data and numbers, when medicine is becoming more concerned with the idea of quality. Fernando García Alonso encouraged this discussion from the outset putting forth his own skepticism regarding effective medical progress in the last 40 years. If medical progress has to do with health, we know it doesn't depend exclusively on medical factors; environmental, social, and more recently, genetic factors are just as important. What should we now refer to when we talk about progress?

The second issue that arose focused on the question of the extent to which the pharmaceutical industry satisfies its commercial interests in contrast to issues of justice or even effective improvement in the people's health. Xavier Peris spoke using the example of a businessman who held his work in high regard although seeing its shortcomings from a social justice perspective. The debate addressed the role of politics and its responsibility in dealing with phenomena such as the control held by an industry which is one of the biggest economic powers today. The existence of uncontained diseases and inequality in healthcare between the rich and poor, both nationally and internationally, questions the true accessibility of welfare, as well as the responsibility on the part of politicians who should in the first instance guarantee the right to healthcare for everyone. Is the money spent on healthcare fair and rational? Is research carried out in what is most important or of greatest concern? And if things aren't as they should be, what should be done about it? Given (on observation) that the pharmaceutical industry is one of the most legislated ones, what other interventions could be considered?

Other issues arose from the previous two, such as the definition of medication when well-being and health increase and enter into the category of medication substances which don't strictly have a curing role. However this question gives rise to others: Is curing the only aim of medicine? Should not the care of people be addressed instead, a concept which covers a broader spectrum of possibilities?

The question about responsibility was drawn to a different arena, beyond that of politics, to medical practice and patient education instead. The problems found aren't always related to the production of pharmaceutical products. The prescription or the demand for these can also be irresponsible. The creation of an appropriate medical culture is something that should be promoted alongside recognising the right to healthcare.

Finally, from the observation of a deficient medical culture arose the debate about the information that society receives, and the role the media plays in this. We refer to information which misinforms or informs partially and is biased. If on the other hand the pharmaceutical industry has fallen victim to bad press, the reasons for it should be analysed, as should the impact of it as a way of presenting the problems to public opinion, which highlights above all, bad practices and scandals.

The conflicts which result in the field of bioethics have the effect of raising more doubts and questions than generating answers. This shows that at times the discussion is valid in itself and is an invaluable preamble to being able to move closer towards doing things somewhat better.

VICTORIA CAMPS
CHAIRPERSON

THE INFLUENCE OF MEDICAL PROGRESS AND THE PHARMACEUTICAL INDUSTRY ON OUR HEALTH

Fernando García Alonso

Popular belief says that the improvement in health of a population is linked with medical progress and in particular, breakthroughs made by the pharmaceutical industry. There is truth in this. The impact on health that the discovery of antibiotics and vaccines have had is undeniable. Or the surgical possibilities that became available through the appearance of general anaesthetics. Or even the impact that insulin, antipsychotics and beta-blockers have had.

But these surprising and wonderful discoveries have had a lesser impact on health than other "discoveries" which have gone unnoticed: the improvement in nutrition and hygiene, and a higher standard of living. The increase in life expectancy in the West, which has gone up from 45 to 75 years in less than a century, has been attributed more to social progress than to medical progress.

Keeping in mind that social and medical progress have grown in a parallel way, it's not easy to identify the weight that each of these has had in the different areas of health. This has lead to an interesting controversy and extreme stances, which have generated a certain amount of confusion. When we analyse the events of the last 25 years, the present situation is better understood.

Recent backgroung information

A book titled *Medical Nemesis*[1] was published in 1975 which became remarkably popular amongst the left. Written by Philosopher and theologian, Ivan Illich and supported by statistics, it claimed that medical progress had not had any impact on public health. He said that infections like tuberculosis and poliomyelitis were disappearing due to better hygiene as opposed to the availability of vaccines and antibiotics, and that modern medicine caused more harm than good.

In 1979 a book titled *The Role of Medicine*[2], written by British epidemiologist, Thomas McKeown, appeared. With more convincing arguments than Illich but along the same lines, he states that if vaccines and antibiotics were of use and helped control the spread of some infections, these were of lesser impact on global health than nutritional and hygienic measures. He also claimed that intrinsic hereditary factors and environmental factors

were the cause of disease. Therefore, he argued, given that the most significant genetic diseases had disappeared through natural selection, the main cause for disease in the West was attributed to environmental factors, many of which could be controlled. Finally, he suggested a review be made of current models of healthcare and proposed that a greater emphasis be placed on public health and preventive medicine.

In 1988 the same author published *The origins of human disease*[3], where he extensively develops the arguments put forth in his previous book. In addition, he stated that scientific progress had not always been applied to solve health problems. He used as an example the fact that 100 years went by before they used the knowledge about optics to correct vision. In the same way, the emphasis placed on the origin of diseases over the mechanism of their appearance had significantly retarded the acknowledgement of the effects tobacco and lack of exercise had on the development of heart disease.

Over the last 25 years there has been a lot published in favour and against these theses. For example, *Science and the quiet art.*[4] was published in 1995. Its author, David Weatherall, a specialist in human genetics, played down McKeown's arguments and instead emphasised the important role genetics plays in the control of disease. He held the position that genetic and environmental factors together with ageing has brought us to the present day spectrum of pathology. In order to combat this, the genetic factors which exert an influence here should be researched more extensively apart from just controlling environmental factors.

Weatherall's eclectic position could serve as a springboard to analyse the extent of the influence medical progress and the discoveries made by the pharmaceutical industry has presently had on our lives, and especially what we can be expected in the next 25 years.

Where are we now?

About 20% of what we spend on healthcare goes to medications. Therefore the trend in the numbers in the pharmaceutical industry can show where we are. According to data from the Centre for Medicines Research International[5], spending on research in 1998 was close to 4 billion dollars, double that of 1990. This was thanks to total sales in 1998 which amounted to over 300 billion

dollars, double that of 1990. In other words, there has been an upward trend in research expenditure and sales, but not in the number of new medications.

In figure 1, we can see the number of new medications introduced into the market in the last 40 years. The progressive slow down from the pharmaceutical boom in the sixties is obvious, and now despite all the promises made by the biotechnology industry in the early eighties, the numbers of new molecules continue to go down. The progress in medications has not been held back, however they are failing to produce the sort of discoveries that changed the health prospective of patients about 50 years ago.

The first edition of the 1999 *Lancet* [6] described those groups of medications from which therapeutic improvements could be expected: leukotriene receptor antagonists, endothelin receptor antagonist, IIb/IIIa inhibitors, cyclo-oxygenase type 2. Despite their obvious interest, none of these are having the sort of impact that the previously mentioned antibiotics, general anaesthetics, antipsychotics and beta-blockers are having.

If we cannot expect an important impact on health from the development of medications, we should perhaps look at modifying environmental factors. Reviewing the consumption patterns of alcohol and tobacco in the west reveals that although not on the increase, their restriction remains challenging. For example in Spain in 1980, 64.7 litres of wine, 53.4 litres of beer and 32 litres of distilled drink was consumed per person. In 1995, 36.2 litres of wine, 66.6 litres of beer and 2.5 litres of distilled drink was consumed per person. In litres of alcohol we have come down from 13.6 litres per person in 1990 to 10.2 litres in 1995.

In regards to tobacco, 55% of males over the age of 16 and 23% of females smoked in 1987. In 1997 44.8% of males and 27.2% of females smoked. Therefore we cannot say that there has been any significant progress in controlling environmental factors.

"Other biomedical progresses" could be the chapter where most of our hope has been placed in genetics. Nonetheless, even the most optimistic can't say for certain that progress made in this field has had up to now any significant impact on health. In the last edition of McKusick[8], bible for geneticists, more than 5000 monogenetic diseases are described. However, these diseases do not occur frequently therefore making their treatment

through genetic therapy of minimal consequence to public health at large. Unfortunately, the most common diseases are all multi-factor ones, for which there is no solution with genetic therapy.

Biomedical progress and its impact on health in the next 25 years

When it comes to evaluating improvements in health, the way this is measured is rather decisive. Fortunately today there is good standardisation[9] which allows us to compare between countries. However, when it comes to evaluating long term impact, the most logical way would be to use the traditional way of measuring health: incidence, prevalence and mortality of a disease.

If we review the data on coronary disease in the United Kingdom in figure 2 using demographical projections, we observe an increase in prevalence with the current extent of medical knowledge (standard).

When the scenario is adjusted accordingly to the opinions put forth by panels of experts based on the expected progress in biomedicine in the following years, we can observe a slight decrease in prevalence when projected 20 years from now (prediction). In figure 3, both in the standard and especially in the predicted projection, there is a significant decrease in mortality rates due to coronary disease.

If we look at data from the same source[11] regarding lung cancer, we can see in figure 4 an important increase in its incidence both in the standard and predicted projections. We must note that the increase is mainly found in women seeing as there is a predicted stabilization in men. Figure 5 shows an increase in mortality in the standard projection, with only a slight decrease in the predicted, which indicates that patients will live a little longer. Similar data has been obtained regarding lung cancer in Germany.

The data shown for coronary disease and lung cancer explicitly indicates that the impact of medical progress on health is indeed small, especially when we use such objective health measurements as incidence, prevalence and mortality for a given disease. Naturally this information doesn't exclude other health improvements when less rigid measurements are used like functional

capacity, psychological well-being, social health, pain, general ones and those specific to quality of life[12].

The panel of experts, which had made the aforementioned predictions, were also questioned about the percentage they would attribute to "environmental factor control", "pharmaceutical advances" and "other medical advances" in lowering the mortality rate for various diseases in a 25-year period. As you can see in table 1, experts from the United Kingdom, France, Germany and the United States gave their opinions regarding preventable deaths in coronary disease, cardiovascular disease, breast cancer and lung cancer.

For cardiovascular and cerebrovascular disease, great confidence was shown in the modification of environmental factors, lesser confidence in pharmaceutical advances, and little confidence in other biomedical advances, which include genetic therapy.

For breast cancer there is a greater confidence in medications for results in contrast to environmental modifications. Again, other biomedical advances generate lesser confidence.

For lung cancer, with the discrepancy of Germany, confidence was shown in the influence of environmental modifications, with much less confidence in pharmaceutical advances and other biomedical advances.

Discovery *versus* development

According to the data presented, the impression is given that progress in biomedicine contributes little to health and that big changes are not expected in the next 25 years.

To understand this paradox, we have to accept that in the sixties we experienced a flattening of the curve which depicted the improvement in health. The increase in the standard of living (in the West) back in the sixties and discoveries like penicillin, the polio vaccine and chlorpromazine seem unlikely to happen again. The progress in health in the eighties and nineties was due to the development of new treatments and ways of focusing disease, more by the apposition of knowledge than by the sudden discovery of new concepts.

There doesn't seem to be new discoveries in environmental factors which determine the course of a disease, or new genetic factors that conclusively explain a certain pathology, on the horizon. Logically, an increase in genetic and environmental knowledge will allow a progressively greater control of disease.

Victor McKusick, in his recent visit to Spain, expressed this with some clarity: "With knowledge of genetic factors we can act on environmental factors"[13]. He spoke in greater detail about a new model for preventive medicine with genetic considerations: "Technology will allow us, in the not too distant future, to carry out a global analysis on the genome. This will allow us to detect predispositions to certain diseases, which include the most common ones and which could affect 40% of the population, like cardiovascular disease, diabetes, asthma or psychiatric disorders. Understanding the susceptibility and its relationship with genetic, environmental and social risk factors, preventive measures could be outlined to help modify risk…"[14].

The concept of health

To study its relationship with biomedical progress, more academic type of health concepts have been used: incidence, prevalence, mortality. Other perfectly standarized concepts exist which are used in scientific work: the Katz Index, the health profile of Nottingham, the WOMAC questionnaire, etc. [15] Simply, for most doctors or patients, "health is the absence of disease", which could lead us to think that "a healthy person is one who as not been sufficiently or adequately examined"[16]. The World Health Organisation defines health as "a state of total physical, psychological and social well being", which agreeing with Henry Miller, is only achieved in states of acute mania or when you're having an orgasm. As you can see, the concept of health is not a simple one, but rather a subjective one at times and with strong cultural components.

Accepting the fact that health doesn't mean the same thing for everyone, it would seem reasonable to prevent any negative impact that medical progress could have there. If medical advances are foreseen in the next 25 years, as already observed, any potentially negative effect that environmental factors, pharmaceuticals and other biomedical advances could each have, should be revealed.

In the case of other medical advances (including genetics), conflicts appear systematically and are basically of an ethical nature[17]. Some of the major ones include the use of genetic therapy in germinal cells, the use of human embryos in cellular therapy, xenotransplants and human cloning. For many people, these advances carry certain risks. For example, the concern with genetic therapy in germinal cells lies in the alteration in the genetic make up of the person receiving the therapy, and that of the person's descendant's. Another example is in the performance of xenotransplants where there's concern with the potential transmission of retrovirus from animals, which could have long-term effects.

In regards to pharmaceutical advances, fears lie largely in the economic arena. The ever-increasing research costs into new medications have direct repercussions on the pharmaceutical bill. These costs are detrimental to other health care costs (medical attention, diagnostics, hospitals), and so give rise to doubts surrounding the efficiency of pharmaceutical costs when it comes to finding the greatest relevant impact in health care.

In the case of environmental factors, problems arise from the never-ending list of recommendations regarding risk prevention which come from epidemiological studies. Even though many of these are supported by conclusive data, others lack the necessary weight so as to give them as general recommendations. This could mean, in the case of coronary disease, that an unending list of prohibitions and recommendations could actually bring about a negative effect on health. A list of some of the risks here could illustrate the seriousness of the problem: male, smoker, high levels of cholesterol, high levels of LDL, low levels of HDL, high blood pressure, obesity, diabetes, excessive alcohol intake, sedentary lifestyle, no naps, not eating fish (especially mackerel), living in Scotland, English as the first language, scrupulous when it comes to keeping appointments, not taking cod liver oil, snoring, having a low income living in a developed country and being bald[18].

Whoever tried to adhere to all these recommendations or became anxious over being effected by one or more of these risk factors could inadvertently experience a deterioration in their health. Also an important risk factor, as is a family history of coronary disease, cannot for now be modified. Therefore it's obvious that we're seeing only one part of the problem and that there are

genetic factors, which we know little of, that probably have the greatest bearing in determining the appearance of coronary disease.

Doctors have a fundamental role in transmitting all this information. A good doctor-patient relationship should allow for good communication, without any omissions, but with an appropriate focus. An informed patient is not one with the most information, but the one who has been able to understand it. This way, he could gain an adequate understanding of his own health.

Conclusions

It would seem reasonable to accept that biomedical progress has had a positive impact on health, a minor impact which progresses slowly and is not accessible worldwide in the same way. Although the concept of health is objective, when it comes to carrying out research, in practice there are subjective aspects, it changes with time and there are strong cultural components.

Society's perception, especially of those scientists involved in genome research regarding the potential of biomedical progress, is overly optimistic. The expectation placed in the "discovery" of a cure for cancer or cardiovascular diseases in the medium term (25 years) seems somewhat unrealistic. It's more likely that over the years with genetic and environmental knowledge, greater control will be gained over the disease. Meanwhile, drugs developed by the pharmaceutical industry will palliate discomfort by giving symptomatic relief or will moderately increase survival rates.

	Coronary disease				Cerebrovascular disease			
Factor	**United Kingdom**	**France**	**Germany**	**USA**	**United Kingdom**	**France**	**Germany**	**USA**
Environmental factors	**76**	**35**	**50**	**50**	**58**	**25**	**47**	**50**
Pharmaceutical advances	**19**	**32**	**21**	**40**	**31**	**38**	**15**	**40**
Other biomedical advances	**5**	**33**	**29**	**10**	**11**	**37**	**38**	**10**

	Breast cancer			Lung cancer				
Factor	**United Kingdom**	**France**	**Germany**	**United Kingdom**	**France**	**Germany**	**USA Afters del 2000**	**USA After del 2010**
Environmental factors	**57**	**19**	**30**	**90**	**68**	**20**	**A lot**	**Little**
Pharmaceutical advances	**28**	**65**	**41**	**3**	**26**	**19**	**Little**	**Increased**
Other biomedical advances	**15**	**16**	**29**	**7**	**6**	**61**	**Impact**	**Impact**

Table 1

Percentage of contribution each of the three factors have towards mortality prevention in 4 diseases in the United Kingdom, France, Germany and the USA, in a prediction period of 25 years.

Source: MEDTAP International

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19. Pharmaceutical industry is developing therapeutic interventions based on genic therapy; this could cause an overlap between the concepts of "pharmaceutical advances" and "other biomedical advances" we have used.

Joan-Ramon Laporte

When I read the paper, I felt it was going back to the main ideas of Ivan Illich and especially those of Thomas McKeown on public health, the content of which I generally agree with. However, on further consideration I think it's lacking in some perspectives.

The paper criticises the strictly medical focus progress gets, as you've made out at the beginning, and have pointed out as the main issue in your address. You endeavour to distinguish medical progress and incidence in health, which is great. But I would perhaps add some other perspectives other than purely medical ones. Especially for the interest it could generate in the future.

First consideration: you want to distinguish medical progress from health. I agree. But I also think the pharmaceutical industry should be distinguished from medications. I believe that if we talk about the pharmaceutical industry, we talk about what it produces (medications and vaccines), but we also refer to its general behaviour, and general social influences which are manifested through the political power it has in the media in creating expectations, etc. Therefore, medications and industry are two rather different things.

It's rather limiting to talk about medical progress and medications. Could we discuss the possibility of adding to your paper, for example, recent North American meta-analytical research on the undesirable effects of medications on health, which positions medications as the fourth greatest cause of deaths in the United States, behind infarct, all types of cancer and cerebral vascular accidents, and in front of diabetes, chronic obstructive pulmonary disease, traffic accidents, violence, etc. I would perhaps add this as an element of thought for the medical perspective. However I do think it would need other perspectives.

Without a doubt, one would be the economic perspective, especially when we think of the future; the economic perspective in terms of cost-benefit. In other words, we can progress, but at what price? What price is society willing to pay? And, which society is willing to pay each price? It's not the same to talk about the United States or Denmark than Malawi or Botswana. Who is able to pay all of this?

The second would be the social perspective. This is a social perspective considering that all health systems, and not just the use of medications, have

serious organisational problems found in the existence of inequality and unfairness. Inequality nowadays is observed in such a confronting manner, in short on a global scale, the difference between developed countries and less developed countries is getting greater. We're talking about the difference between barely one fifth of the world's population and the rest. This is a model which I doubt about regarding its social, general and political sustainability on a global scale, and which makes the future unpredictable. How long will all this last? How long will immigrants continue to arrive in small boats and not by other means? And this is only one aspect regarding differences.

Then there's the political perspective. I'm thinking particularly in the political perspective from two viewpoints: the one dealing with politics and trade, which is the politics of globalisation, the World Trade Organisation, the TRIPS agreement, and the impact this has along with what they call intellectual property (in other word, the respect for and extension of the validity of patents) on Third World countries. It's hypocritical to say, as said only a few days ago, that the prices of AIDS medications destined to Third World countries are going to be reduced. I have here a table in which I recently put together with professor Stolley for an article which dealt with similar issues, where we compare the income per capita of some countries (refreshing the memory, Tanzania $120 – annual income - ; Haiti $250; Egypt, better now at almost $800; Barbados $6500; Colombia between $3,000 and $4,000) and the cost of some medical technologies. A seven day course of ceftriaxone costs $130, that's more than the annual income per capita in Tanzania, and ceftriaxone is an essential drug as it's the only alternative for now in treating a number of diseases. A single dose of streptokinase in the case of infarct is $400, or even a course for multiresistant tuberculosis, which is the major theoretically preventable cause of death in the Third World, costs $5,400, an amount that can't be paid with the annual income of many countries. Then we have the three-way treatment for AIDS, it costs $16,000, a price well over the annual income per capita of many countries.

I believe all this is political, as is the problem of mergers: it's not a question of stopping them, but they are creating a certain phenomena whereby some corporations, lessening in number in recent times, progressively gain greater political control and influence. The political power is undeniable, established and exerted in various ways. In any case, the United States and European Union representatives, more so those of the United States and more explicitly,

are and do consider themselves as representatives of the interests of these multinational companies when it comes to proposing guidelines for behaviour at WTO talks.

I also believe the ethical and bioethical perspective should be added here in several ways. We should ask ourselves how the ethical and bioethical criteria used today (and not just referring to clinical research, specifically clinical trials or other types of investigation, but also to medical practice) could be received in countries with such different cultural bases then ours, and to what extent could all that's been developed in the ethical and bioethical fields be an imposition of certain cultural values, which don't have to be accepted as we have, on other cultures, even though it's all done in good faith, no doubt. There is an ethical and bioethical perspective that arises in many issues directly related to the development of medications, like for example, the tremendous discussion that took place in 1999 over possible modification in the Helsinki Declaration as a basic ethical guideline for clinical trials. These modifications refer mainly to the problems associated with informed consent, whether it's licit or not to carry out clinical trials using placebos for diseases or symptoms with known treatments, as well as the problems in obtaining an informed consent, which they do intend to modify. I believe this has to do with the phenomena we call globalisation, which is more than technological innovation in an information society, seeing as it consists of a society that accumulates power, where differences grow wider. All this raises a number of very important questions regarding perspective and the prospect of medical progress.

There's another issue: in many aspects I believe we should distinguish vaccines and medications. I know of epidemiological studies which are quite convincing when it comes to demonstrating or suggesting that vaccines have had positive results on the traditional health indicators you mention in your address. And amongst various medications, having revised bibliographies systematically, I only know of a few that have had a real impact: H2 antihistamines in the treatments of ulcers. These have not only lowered the need for surgical intervention, but also mortality due to peptic ulcer complications. This has been seen in Europe where the mortality rate due to peptic ulcer was observed to decrease after a few latent years and in consequence of the gradual introduction of these medications to the market in each country, namely from West to East.

I would like to make a small remark regarding the article in *Lancet* and the new medications you mentioned. I'm a member of the committee that selects articles for *Lancet* and I would like to point out that they are not published as medical advances – this must be clear - but rather as new developments for the information of our readers, but which is not said prior whether or not it these will make great progress in health.

Fernando García Alonso

Very briefly: my talk was set within self-imposed, defined boundaries. The first restriction is that of setting, if not the Spanish one, that of the West closest to us, because if one has to write ten or fifteen pages on the subject, one has to be selective. Even though I have been selective, I have left things out. Basically, I'm not going to respond point by point to what you have said. Some things are clear to me, others aren't so much. However, I would like to clarify that I purposely left out all issues to do with the Third World. Many of the concepts I mentioned aren't applicable to the Third World, and if they were considered, they would sound almost ridiculous. I have limited myself to the West.

You are right about what you say concerning the *Lancet.* However you would at least acknowledge that groups have been selected from which a lot can be expected, and not otherwise. The proof will be with the passing of time if any of it turns into a new and useful therapeutic development (independently to the commercial interests of some company) which is why I chose the 1999 selection and not the 2000, which also exist.

Vicenç Navarro

I would like to make some comments on three levels. The first refers to the article. I disagree with some of its the intellectual structuring, where you seem to emphasize the biological and the environmental as decisive factors in the health of the population. I was pleased however to hear in your talk references to other causes, indeed more important ones, such as social causes. In reality, the most important changes experienced in the twentieth century regarding the health of populations have been due to social transformations.

You said this but it wasn't mentioned in your article. In this aspect, I have also found the references missing from the article which highlight what I'm saying. Hence, I'd like to make a protest against what you said regarding the

popularity gained by the book *The Medical Nemesis* amongst the left. Perhaps it was meant as a provocation, because it was precisely the left who criticised it the most strongly. I know that nobody is a prophet in their own country, but I recommend you read my works regarding Illich which are very critical and well known in the United States, but not in Spain.

Fernando García Alonso

Let me clarify something Vicente, and I say this to everyone; there are two or three jokes in the article. Those who know me can appreciate the humour, those who don't, won't. The quote attributed to Arthur Miller is not true. I made it up that it was Arthur Miller. The thing about the left was to laugh a bit. They are touches of humour that are understood by those who know me. But you are right; it's not an academic article. It's an article of ideas.

Vicenç Navarro

I didn't perceive it as a joke. I would advise you to be more obvious in your use of humour, because just as it's written, the touch of humour is hard to detect.

Seriously now, I suggest you include a series of references and works like those of Richard Wilkinson and others, which analyse the root causes of diseases in a social context. I hope that the works of various authors, amongst who I include myself, are published in our country and which analyse the relationship between, for example, social inequality, lack of social cohesion and disease. I'm not referring here to social exclusion.

The already famous Wilkinson study showed that in Great Britain the upper class live two years longer than the lower upper class; the lower upper class lived two years longer than the skilled working class; the skilled working class lived two years longer than the unskilled working class and the unskilled working class lived two years longer than those on unemployment benefits. There's an eight-year difference in life expectancy between the upper class and the unemployed, which by the way is less than the difference in Barcelona between these two classes which is ten years. This is not only because there are more poor. In reality, the lower upper class lives less than the upper class. The dichotomy of biological causes/environmental causes is too limited to say what the casualty on health and disease is.

I was pleased to hear your introduction where you qualified the title. I have my doubt as to whether the pharmaceutical industry contributes to medical progress. I also liked Joan-Ramon's clarification that we must make a distinction between the pharmaceutical industry on the one hand the medications on the other. The pharmaceutical industry is creating a medical culture that stands in the way of resolving the healthcare problems of our society. This is not mentioned anywhere in your article and I believe its central to the issue. Due to its enormous influence on the medical culture, the pharmaceutical industry is emphasizing biological aspects, and because of the power it has and the priorities its able to establish, all social aspects and those related to public health take second place. Catalonia is a clear example of this. There are magnificent hospitals in Catalonia. In addition, centres for genomic investigation are going to be set up, and so forth. Meanwhile, we are seeing public health become the poor cousin. We had a public health organisation called the Institute of Public Health of Catalonia, which is going under at a time when the institute for genomic research is going to be set up. Catalonia is almost paradigmatic in its strong biological concept of health, and yet the data shows something quite different. The fact is the problems require a different type of intervention. Workplace accidents are the highest in Europe; food poisoning is the highest in Europe; drug addiction is one of the highest in Europe, and so forth. These are all social problems, not biological. I think this aspect is important. Another aspect, and I refer now to the situation in Catalonia and Spain, is that due to the enormous amount of power held by the pharmaceutical industry, 20% of public healthcare money goes to pharmaceuticals. We are all well aware of the pharmaceutical industry's opposition to the introduction of generic products, which I believe goes somewhat against this idea of progress. Only 3% of pharmaceutical products are generic. I feel it's an outrage. I'll relate an anecdote. When I was in the White House helping Mrs. Clinton with the Healthcare reform, I was able to obtain information about the use of generic products through the United States Federal Government. I saw that this Government doesn't pay for a commercial product when a generic one is on the market. This promotes the production of generics for sure. Medicaid and Medicare, but especially Medicare has a high percentage of expenditure on generic pharmaceuticals. However, in our country it's only 3% due to the enormous influence of the pharmaceutical industry.

I also experienced the enormous power held by the pharmaceutical industry when I was advising one of the presidential candidates for this country, Mr Borrell. When Mr. Borrell resigned, the Socialist Party office received a phone call within four hours from the pharmaceutical industry spokesman, asking if it was true that Dr. Navarro was also resigning. Apparently they were apprehensive about me and my possibility of directing or influencing healthcare policies in this country. They believed, and with reason, that it could effect their interests. You understand when I say that one thing is the pharmaceutical product, the other the pharmaceutical industry. Their optimising of profits is in conflict with the interests of the population. This can be observed more clearly in underdeveloped countries where the situations are quite extreme. A fourth of the population in South Africa is going to die of AIDS. This information was released just last week, and the pharmaceutical industry is opposing the idea of introducing and discounting the cost of these products that don't cure as such but 'looks after' it. Meanwhile, the North American government, as you pointed out, acts as the pharmaceutical industry's spokesperson so that South Africa can't reduce the price of its products. This is of such a dimension that I don't know how to qualify it.

The pharmaceutical industry, contrary to popular belief, doesn't cure, but rather "looks after" with its products. Here I refer more to pharmaceuticals than the industry itself. Medicine is not curing a lot these days, but does "look after". This is rather important in itself, but you didn't include it in your graphs. When the people have a headache, an aspirin works well. This is what medicine does – it gives aspirins. I'm speaking symbolically. It does not resolve the cause of the headache, but it makes life more bearable. Again it's what medicine does. Therefore we can't evaluate the pharmaceutical industry, or rather its products, by looking at morbidity or mortality, we should do so looking at quality of life. This is where the value could lie with pharmaceuticals, and not the industry. In this respect, my criticisms are aimed not at the value of the products, but at the behaviour of the industry.

I'd like to make another comment. My criticism is not so much against the pharmaceutical industry, as they do what any company has to do; optimise their profits as their major objective, but towards the public authorities. The fact that only 3% of products used in this country are generic ones isn't the industry's fault. They are only trying to optimise their profits. It's logical that

they do so, because this is what's expected from any company, that it optimise its benefits. The public authorities, who are incredibly sensitive to the influence of this industry, are more at fault. The criticism is aimed at the political figures who allow this industry to have the hold that it does. It's shameful that politicians allow the interests of this industry to go before general interests. These political factors, ignorant most of the time regarding the economic analysis of this industry and of medical costs, are decisive. With this I conclude, grateful for being invited to share my comments on the article.

Fernando García Alonso

I'd like to highlight only one point so to not waste time. My closing remark in my conclusion was: "Meanwhile, drugs developed by the pharmaceutical industry will provide, and in fact are palliating discomfort by giving symptomatic relief or will moderately increase survival rates." Basically, in my eight or ten line conclusion, I emphasize that we should discuss palliative medications more. Also, as you will have seen throughout the article, I clearly differentiate between traditional ways of measuring health and measurements for quality of life, which I understand are those the industry feel more comfortable with. Thank you.

Guillem López

I'll pick up from Fernando's last point, from who I've noted down a new quote: "Quoting the Social Security Research Fund director, the most accurate definition to the WHO's definition of health is an orgasm" Beyond the cleverness of the statement, there's no doubt some truth in it. Please allow me to expand on my idea, seeing as this will be my only intervention due to agenda problems.

What we observe from an economic point of view, is that if we set a particular value for health and then relate it to health spending (McKeown said this in 1976), we're going to get a production function for health whereby there will be a decrease in its marginal development. Which is to say that in the first phases of health spending there's a great impact on the improvement in the state of health, but from ongoing more developed phases, the impacts are much less, more complicated and, seeing that growth in health is directly related to healthcare spending, much weaker.

There are two relevant elements in healthcare spending. The first is how it rates in the general productive function of the economy. This includes employment, a weighted capital, (we'll obviously be referring to human capital, not just capital assets) and the other parameters that define the level of technological progress. What would be interesting to know is whether medical progress in relation to the pharmaceutical industry and in other areas in general, are based on these *inputs* in an isolated way, or on technological parameters. Innovative success would be that it came through the latter, as this would mean greater results amongst other productive functions to continue to grow in other ways such as the areas of declining productivity, which would follow a qualitative leap having this an almost full impact on social well being.

From this view point and my understanding, we could redirect the discussion regarding the importance of pharmaceutical innovation in relation to human progress to evaluate the point to which recent advances made by the pharmaceutical industry have acted as substituting elements in traditional healthcare inputs, or simply as complements. This requires at least some evaluation as to how innovations affect professional practice. Which is to say that it's a question of finding out whether what we're doing is continually increasing healthcare costs through health service, instead of promoting qualitative growth in levels of health. This on the one hand.

The second issue has to do with our reference to the 'orgasm'. Health parameters in strong economies have, as is known, two components: to cure and to care. The values of curing and caring come near to a broad concept in which things are valued in terms of use and change. In the area of health, the professionals are used to working with concepts of use: effectivity, the impact of what you spend and what you get. However, there are also values in terms of change, of usefulness, the possibility of accessing certain assets, of hard and fast utilitarianism, for who the aspect of caring takes on all its value. The change value is the comparison I'm making, it corresponds with the caring concept and which could be in someway overvalued in our current situation. Something that wasn't relevant in the past now seems to be, therefore, and I shall finish my disquisition here, it has become of interest to know how, who and to what point this change is willing to be financed. The willingness to spend here doesn't only rely on the exclusive parameter of objective health, in other words curing or "the use value", but also on values of change, which then

raises the question of to what point should public funds be used to finance medical advances which have little bearing on the "use value" in healthcare. This for me is the perspective with which we can regard some of the advances being offered by the pharmaceutical industry in medical progress.

In general terms using economic reasoning, as Joan-Ramon said, cost effectiveness and cost benefits make a lot more sense in terms of effectiveness in curing than in caring. This means that society has to think about the extent they want the public sector to ration health services with the single mind of cost effectiveness, putting aside other aspects of qualitative "care", because integrating change is a complicated matter in terms of "curing". This data could be trustworthier. The elements that make up "care" are not just limited to health these days, but to individual well-being. In this respect, there is more uncertainty observed in society regarding the role the public sector should have. Prioritisation has as its aim the relief of shortages, but, relieve shortages in terms of what?

Fernando de Andrés

I would like to stress a difference that must be established. It's rather clear to me that the pharmaceutical industry is not going to solve our problems, nor even those of the world, as it sometimes endeavours to. One of the reasons for these misconceptions is that the pharmaceutical industry conditions our perception of problems through its ever-increasing power in the media. So many times it seems like the only problems that exist are those that only the pharmaceutical industry can deal with. They only stress those problems they can deal with, whether they can resolve them or not. Sometimes they create them themselves and then find solutions. The media coverage of medications, which is often associated with information about health, and in many instances it is, is controlled, for lack of a better word. However it's influenced by the pharmaceutical industry, who seem to have it well set up with everything taken care of; it's obvious the pharmaceutical industry has the solution to some problems. I don't know whose fault it is. Maybe they simply just work well at their job and the rest don't at theirs. However, these are the facts.

It's clear that the pharmaceutical industry is an industry and can only solve problems that are paid for, otherwise there would be no incentive. That's one

of the problems. It's the wrong incentive. We have trails, pharmaceutical trails to treat some non cost-effective diseases, and the pharmaceutical industry habitually does not follow the trail.

The incentives are wrong. I remember last year's colloquium that addressed the problem of AIDS mentioned here also. I believe the pharmaceutical industry is more interested in the sort of medications we have today, in other words, those that prolong the life of the patient but don't cure, because he has to take them long-term. It would probably provide a lesser incentive to develop a vaccine that required a single dose. Obviously nobody would make a profit with small pox vaccines because small pox doesn't exist anymore. However, if we had a substance that prolonged the life of smallpox patients and required long term use, the commercial incentive becomes obvious. I'm not accusing anybody of anything, that would be the last thing. The reasoning here is somewhat clinical, but it's evident that what the pharmaceutical industry has as incentives should not be the same for those in health planning, which is to say medications to promote health.

My initial argument was that we shouldn't confuse the pharmaceutical industry with pharmacology-the motives are different. I don't think this has been made clear enough. I'd like to defend pharmacology as such. It's said that pharmacology has solved few things. I believe it's resolved little when we look at rigid variables. I believe that in such flexible variables as pain, it's been partly resolved, which is quite good. It doesn't alter the morbidity or the mortality, etc., but it's obvious it's been resolved. In other word, it depends on what problem we look at. Perhaps it doesn't resolve many of our problems, but some it has.

I would like to offer a contrasting prognosis on the future contribution of pharmacology. When we get old, we think that everything is getting worse and everything has been exhausted. I do agree that traditional pharmacology could have perhaps been exhausted. Obviously, everything that is evident has been investigated using traditional pharmacological criteria, and there's not much more to do there. But, when something new comes up, perhaps it finds a solution. Traditional pharmacological criteria has meant a giant step in something as new as this disease invented by whoever did: AIDS. Look at how the old criteria continues to work when we find ourselves amongst new problems.

One thing is that traditional pharmacology be exhausted, and the other that future pharmacology is not. Naturally we can't continue to think about adrenaline receptors, which is what some generations have done. We have spent a lifetime studying adrenaline receptors. Today we know about other chemical mediators; cytokines, the agents that control genetic expression. All this will lead us to new areas of discovery. We're not sure where we are in the scheme of things. Maybe the prospects are enormous. It could force us to change the ways in which we measure results gained from applying supposedly new cures. We'll simply have to change them. If the clinical trial is no good to us, we'll have to change it. Traditional pharmacology, because it is traditional, is starting to be exhausted, in that, the way of resolving problems has been applied to all the problems we've had. What's clear though is that we don't know what impact new discoveries will have. We are still evaluating the impact of some cures from several decades back. I'm sure we'll see the impact of the cures we are recommending today in the future. I'm speaking in terms of pharmacology which I wanted to distinguish from the pharmaceutical industry. The problem is that things are becoming confused, probably because pharmacology is financed and selected by the industry itself.

Fernando García Alonso

More so than pharmacology, we should talk about pharmacologists, who are in a class of their own. I'd simply add this.

Victoria Camps

Before finishing this first round of questions, I would like to put forth one last one. If us philosophers have a purpose, I believe it's to clarify concepts. So therefore, what is medical progress? Criticising medical progress, from what we've seen with the different contributions, we end up criticising the pharmaceutical industry. Medical progress, what is it exactly? Or what should it be? If you say that it's not focused the way it should be, what is health protection? What does progress mean?

Fernando García Alonso

I don't think there's a canonical definition of medical progress. It doesn't exist anywhere. Basically however, I believe that in a well informed group or community of biomedical and related health professionals (allow me to use

those terms), everyone can distinguish what medical progress and health improvement is. Medical progress has a more academic component, more research orientated and publishing in journals.

Victoria Camps

In a corporative nature?

Fernando García Alonso

Not in a corporative nature. To be clear on this, I believe there are things that are considered biomedical progress, as is our knowledge of a receptor or sub receptor of a particular population, whose incidence on health is nil. This is the difference I wanted to establish regarding medical progress, that it can increase our knowledge and the prestige of certain institutions, but doesn't actually extrapolate to the state of health in a broad sense which includes palliating and caring.

Victoria Camps

Which is to say, the internal progress of science.

Fernando García Alonso

Exactly. It's the sort of progress that looks in on itself, a bit like what was said about the pharmacologists.

THE PHARMACEUTICAL INDUSTRY AND MEDICAL PROGRESS

Xavier Peris

From the beginning man has succumbed, and with greater frequency than would be desired, to the temptation of unlocking the mystery of his existence using key dichotomies. "Good" and "Evil" are concepts that, as superficial abstracts of reality, have managed to polarise ideas and criteria, not only of the general community, but also of a significant part of those who have made up the aforementioned group down through history. From Zoroastro to our politician today, focus and analysis have been sacrificed on the alters of power as has the supposed clarity of the message.

If we claim that man is different from other species because of his ability to progress at a rate infinitely superior to that of his planet companions, we'd get the support that any obvions statement always gets. However, if we try to verify and define the concept of progress, and more so, if we try to examine and evaluate it from an ethical point of view, we would observe a dramatic decrease in that support.

Progress has sometimes been portrayed as some sort of biblical plague, comparable to the concept of sin, hence it's been confronted by many religions and social systems; the case of the Catholic church against Galileo; the Amish in America or the medievalism of many Islamic fundamentalists.

On the flip side of this, progress has been used to justify a number of monstrosities such as the experiments carried out on children during the Nazi years, or to cause enormously consequential problems, such as the violation of the environment we are all aware of.

Progress is a poly-faceted concept that shouldn't get a simplistic analysis. Progress, like history itself, is also a concept with millions of synapses and whose analysis would be severely compromised should it be limited excessively to time and space.

Pharmaceutical research, especially in the last few years, has been subject to strong criticism by those who deem it futile and inane based on arguments that happily mix thalidomide, the consequences of transgenic research and the enormous benefits of an industry that forgets the diseases that affect the Third World. On the other hand, there are some who tend to have a blind faith in the achievements of pharmaceutical research, who see as the final aim of these ventures the disappearance of pain and disease and, currently drunk on the post-genomic craze, appear to consider the possibility of man's immortality.

Art and religion have existed for 80,000 years; science on the other hand, with Galileo as it's father, only 300 years. The last 150 of science have turned out to be far more explosive than 5,000 years of pre-scientific culture. Bertrand Russell summarises these years as the transformation of science from a contemplative existence to a manipulative one *(The Scientific Perspective,* p. 214, Ariel, 1975), based on well-known pragmatic and instrumental philosophies. Pharmaceutical research is therefore according to Russell's definition of the word, essentially manipulative. Some have not yet understood this change. No one can predict the consequences.

The use of a hand's breadth to measure longitude turns out to be incredibly accurate when you want to measure the size of a room, however it is totally useless in measuring the wingspan of the common fly. Some writers highlight the lack of important discoveries in the last 4 to 5 years to talk about the decline or lack of perspectives that pharmaceutical research has. The period required for research and development for a single product could encompass 10-12 year, hence to analyse with any accuracy what contribution pharmaceutical research has on biomedicine, we should allow for the time required for the analysis, allowing us to enjoy a temporary perspective which would raise the extent of our objectivity.

There's fundamental data that from the beginning puts the magnitude of the field we're analysing into perspective from the beginning. The consumption of pharmaceutical products by industrialised countries represents just over 1% of their GDP (USA: 1.1%; Japan 1,5% and EU 1.3%; *OECD-Health Data,* 1998). That is, we only spend 1% of our revenue on pharmaceutical products. Each North American citizen consumes $0.64 in pharmaceuticals, $0.53 in tobacco, $0.91 in alcohol, $2.80 in clothes and $7.94 in food daily (US Department of Commerce, Bureau of Economic Analysis, 1998). The figures speak for themselves. It would be tempting to relate this data to the increase in life expectancy in these countries, which has almost doubled in the last hundred years, so that in Europe, life expectancy for women is now 80.5 years and 74.1 years for men (www.europa.eu.int/en/comm/eurostat). However, it's obvious that advances in healthcare and hygiene in general, including the extension of medical attention and particularly of surgery, are also largely responsible for this spectacular evolution. Even so, it would be unfair not to acknowledge that many of the advances in surgery are thanks to new anaesthetics, new

antibiotics and, of course, immunosupressants which have allowed organ transplant to become a daily and happy reality.

Nonetheless, a more detailed analysis reveals a number of such notable changes that they can only be explained by the way they coincide with the arrival of new pharmaceuticals. Hence, in the period 1960-1981 the mortality rate for hypertension in the USA fell 53%; in the period 1965-1999 la mortality rate for ulcers fell 72%; the mortality rate for renal infection fell 77% and for tuberculosis 87% (*PhRMA Statistical Handbook*, 1986; *PhRMA Statistical Handbook*, 1999). Half of the 50% reduction in deaths due to heart attack in the USA between 1980 and 1990 is attributed to the introduction of new medications (*Hunick*, *JAMA*, 277: 7, 1997). In just 3 years, the mortality rate for AIDS has been reduced 70% thanks to the combined therapy (*HIV Outpatients Study Investigators*, *New Eng. Med J.* 338: 13, 1998). And of course, the experts know about the undeniable impact of beta-blockers, H2 receptor antagonists, certain vaccines and antibiotics, etc.

The positive impact of new pharmaceutical can be evaluated in ways other than in terms of years of life. Studies done in pharma-economy go into greater depth each time regarding the comparative cost between a pharmaceutical treatment and non-treatment, or another alternative. The governing bodies are asking for these studies more and more as part of their evaluation process concerning the proposal of a new medication. The results are, in the majority of cases, spectacular. Hence, the introduction of a new treatment for migraine in this last decade has allowed a reduction in the social cost from a migraine-inducing $435 a month to now $44 a month (Legg, J. *Occup. Envir. Med.* 39:5, 1997). The recent accessibility to new treatments for depression has allowed an annual saving of $822 per depressed worker in the USA (Rizzo, *Health Econ.* 5:249, 1996). In patients with congestive cardiac failure, the use of angiotensin converting enzyme inhibitors saves $9,000 in just hospital costs (The SOLVD Investigators, *New Eng. J. Med.* 325:293, 1991). The figures could multiply.

Apart from prolonging a patient's life or saving money for society, a medication could significantly increase the life of a patient. We're dealing with a subjective and intangible concept that's hard to quantify. Amongst the number of proposed systems for calculating the added value and quality of life that a medication might bring, the Willingness to Pay method is gaining popularity over the more traditional Human Capital method, substituting it

with some advantage. Hence we observe in various studies (see Rovira Forns, *Therapy and Quality of Life*, Camps y Pérez-Oliva eds. , p. 25-29, Fundación Esteve, 1993) that patients with rheumatoid arthritis would be prepared to pay 22% out of their own pockets to be cured, and that 59% of patients on nitrates would accept paying an additional 2,900 ptas out of their own pockets a month simply for substituting oral therapy with transdermal. Even those often-condemned symptomatic treatments (anxiety, pain, fever) possess a direct and measurable effect on quality of life. (see Costa, Therapy and Quality of Life, Camps and Pérez-Oliva eds., p 31-35, Fundación Esteve, 1993).

The proliferation of these sorts of studies could give a rather accurate idea regarding the percentage of GDP the society would be willing to spend on its health. The political bodies should be in theory showing some sensitivity towards the desires of the people who are promoting these studies and respecting their consequent outcome. All the above also raises questions about political ethics: to what point can administrators limit or cut in on the decisions of the administered to.

When the costs of medications are criticised worldwide, there's not one other example of a good or service, with the exception of the cost of basic foods, for sure, that incurs high cost/benefit ratios.

Some, including social representatives, accept the glorious past, but defend that the number of advances the future will bring will be quantitively and qualitatively less, and that the number of new compositions released on the market will drop and will offer less advantages. In other words, pharmaceutical research's golden age has passed, and the resources could now be redirected into other areas instead of using them to oil the expensive workings of some pharmaceutical companies, which are progressively less efficient and more focused on the so called pathologies of an opulent society (impotency, alopecia, *jet-lag*, etc.).

It's true that the number of pharmaceuticals released on the market annually has fallen by half in the last decade. This partly reflects the more demanding criteria of the regulating agencies, which have, amongst other objectives, turned down those compositions with little added value. Nevertheless, it is just as true that the number of new compositions commercialised per year since 1989 has been virtually stable. On the other hand, it would be perfectly reasonable to expect effective treatments for such

pertinent conditions as are neurodegenerative diseases (e.g. Alzheimer), chronic inflammatory diseases (e.g. rheumatoid arthritis), the various types of cancer, including prophylactic treatments, the so-called atopic diseases (e.g. asthma), whose morbidity and mortality are growing at an alarming rate, cerebral infarct, and in general the many other diseases that don't have any effective treatment today.

As Prof. Antonio G. Garcia (*La Vanguardia,* 15.3.00, p. 40) recalled recently, more than 95% of the pharmaceutical arsenal available today has been researched and developed in the pharmaceutical industry. Just because the pharmaceutical industry is by far the most efficient system in obtaining new products, doesn't mean it lacks disadvantages. The problem of these so called orphaned diseases that have little economic return, either because there are only few sufferers or because of the limited economic capacity of the affected population, are today a difficult situation to solve. The massive and successful dedication to AIDS is rather insulting when you compare it to the decisive lack of treatments for diseases which, like leprosy, exclusively affect people with virtually no power of acquisition.

The current system leaves no room for philanthropy as the survival of each company is on the line. In this respect, the objectives selected are key factors for success. In the eighties, Glaxo and Wellcome were two companies of equal power. So in the period 1984-89, Glaxo spent $1,560 million in R+D, managing to place 27 compounds in developmental phases, meanwhile Wellcome spent a similar amount, $1,235 million and placed 25 compounds in developmental phases. The end of the story is well known: Glaxo absorbed Wellcome in 1995. The reasons being the return rates on the compounds being developed. Glaxo had concentrated on areas of great economic potential (asthma, migraines, anxiety, cephalosporins) and had 6 compounds with expected turn overs of $250 million a year, while Wellcome only had 1 compound in this league, and 7 in the $50 million segment. The industry learnt its lesson. There are by far not the necessary measures to mitigate this lack of dedication to these orphaned diseases, especially in Europe.

When the pharmaceutical industry talks about its contribution to the progress of society and the concept of a medication as a common good, it almost always contra-argues with itself giving the example of the *me-too* product. Why spend millions of dollars researching a compound which is the

same as an existing one? What benefit does society gain from it? Shouldn't these resources be destined to finding truly innovative compounds? The issue has many aspects, but it no doubt involves concepts of free enterprise and the promotion of competition that so characterises our western society.

How popular would micro information be today if IBM had had exclusive ownership? What sort of role have clone PCs played in reducing the costs of and making the use of information technology wide spread? In the car industry, each new model of car supposedly contains a small advance, sometimes insignificant, respecting its predecessors that allow it to access a certain segment of the market. It would seem unimaginable that we should drive around in 15 or 20-year-old cars waiting for the ultimate revolutionary car to appear that doesn't pollute and is guided by satellite. En the pharmaceutical industry there's a revolution every 30 years more or less, but society appreciates not having to take two pills when they can take one, and doctors being able to prescribe anti-inflammatory drugs without having to think about their interaction with coumarin anti-coagulants. We've all got air-conditioning in the car without having had to wait for water-powered cars.

Ranitidine was for many a copy of cimetidine, but its small advantages made it leader in the market. The same thing between enalapril and captopril, its minor cough suppressant effect catapulted it in sales.

We all agree that the future will provide us with more specific compounds that are aimed at much more reduced sections of the population, thanks to pharma-genetics and pharma-genomics. The existence of *me-too* products is an attempt to cover, using an empiricist approach, what a rational and systematic approach would without a doubt resolve within 20 years: different options for different patients; they're not diseases but patients, as many an experienced doctor has always intuitively affirmed. Just like the evolution of the species, science and technology need to move ahead millimetre by millimetre so that by every evening they will have moved ahead several metres. Without the small changes in the vertebrates and in the strength of dorsal muscles, the *Australopithecus* would never have stood upright.

As mentioned, we need to admit that the current system allows for improvement, and that it suffers from many defects, but at the same time as any other system, it has proved unproductive. What outstanding therapeutic

advances have come from Eastern Europe at a time of economic reform? Which have been the ones that have come entirely from public research centres in the West? The discovery of a new pharmaceutical is no easy task and demands appropriate financing, co-ordination and motivation in a chain made up of highly different links. For now, the only examples of success come from countries where free competition and private financing have always been the system. Even the relative protectionism in the form of atypical patent laws existing in countries like Italy and Spain have compromised the productivity of R+D of these countries. Compare the success of Swedish or Swiss companies (with small national markets) with Spanish or Italian ones and you'll see that this atypicalism and protectionism has not done any good. While we were here playing at inventing methodology patents, they were forming enormous corporations that are now hard to compete with.

We have been witnesses to an interesting phenomena in the last few years. While Europe – the home of Hamlet – was looking at itself doubting as to whether it was necessary/licit/ethical to devote so many resources to a pharmaceutical R+D race that *benefits few* – the companies – *and pay for between all of us*, American companies increased their spending on R+D in the USA by 17% in 1999, and only 2% outside the USA (*Horizontes Salud*, 37:24, 1999). European companies invest in biotechnology in the USA. Research money goes to North America. USA has won the genomic battle, and will probably win the more important proteomics battle, unless Europe doesn't compete with some drive. There's the paradox that in Europe, and specifically in Spain, where the pharmaceutical companies are pressured by the health department to reduce prices, and on the other hand, the academic administration pressures them to invest more in public research to reduce the distance that separates us from the US. These two extremes are incompatible.

There are enough signs to indicate that on a worldwide scale pharmaceutical research will undergo a mutation in the next few years. This is not only because of the availability, thanks to genomics and proteomics, of new therapeutic targets that will allow more reasonable and efficient approaches to a number of pathologies.

It's possible to speculate looking on the pharmaceuticals with sales of over $1,000 million, otherwise called *blockbusters*. Pharma-genetics create the possibility of obtaining especially designed products for each patient (e.g. their

specific metabolic profile). This brings us then to a future scenario whereby the development of each product will be more economic due to less variation in results, which makes carrying out clinical trials on tens of thousands of patients unnecessary. So hence, a scenario where the small and medium sized companies can act with more efficiency than the big corporations being breed (Wilson, *Scrip. Mag.*, p. 35, May 1998).

Another way that pharmaceuticals can be cheapened lies in the arrival of new technologies that allow the reduction in compound screening costs and foresee the failure of a given pharmaceutical before it gets to the costly stages of toxicological and clinical development. A relatively unknown fact is that 41% of projects fail because of the deficient biopharmaceutical profile of its products (Lipper, Moder Drug Discov, p. 55, January 1999). The efforts in developing new technologies that can make early predictions of this failure have their root here, like the in vitro metabolism of human hepatic fractionation, intestinal absorption in human cellular lines, and the pharmacokinetics evaluated in its initial stages via liquid chromatography techniques applied to mass spectrometry.

Even though it has never been a solitary venture, the future will provide us with a scenario made up of difference social agents in the R+D pharmaceutical process:

– The Academic aspect. The pharmaceutical industry acknowledges its increasing inability to face the process of discovery of new pharmaceutical on its own. The need to obtain new therapeutic targets as a result of basic research work carried out by public research centres is obvious. Therefore, companies have designed various collaborative and co-financial strategies with public institutions. In his book *Modern Strategy for Preclinical Pharmaceutical* R+D (J. Wiley, Chichester, RU, 1997), David Cavalla and Co. make a detailed analysis of the ways and results of some of the many examples of collaboration that there have been in the last few years. Cases like the *Cruciform Project* in London, or CNIO in Madrid are recent examples of how mixed financing formulas gain supporters.

– The collaboration between various specialised companies in different stages of process (e.g. biotechnology companies, *Discovery Industry, Contract Research Organisations*).

– Sufferer's or consumer's associations, that act as true lobbies with the capacity to finance projects, but also with enormous influence in regards to where public resources are to be destined, and sometimes even private ones.

– Patients themselves who will cease to be passive actors in this health scenario will determine the success or failure of a product through their spending and direct communication capacities with the pharmaceutical companies (through internet or court).

– Those professionals specialised in pharma-economy, who are already playing an increasing role in the decision that effect national healthcare systems and who in the future will have a direct influence on the regulating agencies and, needless to say, on the consumers association.

– Epidemiologist who specialise in areas such as quality of life will highlight aspects in a products that have up to now been largely undervalued.

– So, the future will provide new types of therapeutic interventions that will set themselves on the limit of, if not cross, our current codes of ethics. Without a doubt, many other social sectors will join the debate.

To conclude, it's predictable and undoubtedly desirable that pharmaceutical R+D will tend to become a true social project in the near future, where we'll find many agents and sectors currently not found. Pharmaceutical R+D will continue to use up enormous amounts of resources that will not always be profitable, but at the same time it's also the main road towards a better future. The vocational premises of innovation and quality that distinguish this industrial sector, are seated in the best guarantee that the ideas of our scientists materialise into safe and efficient medications that will meet the needs of society in an area as important as that of health.

I would like to add a couple more things to illustrate what I've presented in the previous pages. I believe the most positive aspect of your presence and of ours as speakers is the opportunity to debate about something important for society, probably with preconceived ideas that we all have, and probably from quite consolidated positions. For example, the position that believes that the pharmaceutical industry should be criticised.

Those seated with me at this table know that I don't attempt to defend radical position at any stage, and that there is more than one way of looking at

things. I do believe that we have a great opportunity to leave with a different idea to the one we came in with, which I think is a good thing, in fact the really good thing about this debate; being able to understand other positions. In any case, and I say this with humility, your criticisms of the pharmaceutical industry which I have the obligation to defend (not just my individual position, nor even just that of my company, but of the industry in general), will probably help us greatly in coming up with a better pharmaceutical model for the future.

I shall use only one slide, just to start in a totally different manner to Dr. Garcia Alonso. I'd like to give a warning regarding the slide, because what I'm about to present containing data taken from *Script*, a world wide renowned magazine within the pharmaceutical industry that provides data for the industry, that contradicts the first slide presented by Dr. Garcia Alonso. Which is to say, that the number of new compounds does in fact increase in direct relation to pharmaceutical investment in research and development.

Having said this, I would not like to expand on my presentation with criticisms of Fernando García Alonso's presentation, but in any case I would like to say that I believe in the slides when, for example, they communicate what's going to happen in the next 25 years, perhaps simply because of a period of regression – there's a lot to question, especially when we talk about research and development and biomedical progress.

I for one want to congratulate the organisation, not only for having invited me here today, but for the objective and concept behind the sessions and of course for the title. Contrary to that said by Fernando García Alonso, I congratulate you for the title, because I think it's magnificent and because if offers a magnificent opportunity for the pharmaceutical industry to come, not so much in defence of itself, but to show its position in an open manner and expose its contribution to medical progress, which I obviously believe is considerable.

I think that firstly one has to understand the pharmaceutical industry from a determined parameter. Professor Guillem López has already, and I will also in simple terms in the same way modern business schools do, and from a broad vision of management as defined today, said that the pharmaceutical industry is the combination of capital, direction and work with a double objective: an economic and social one.

In accordance to this idea, one has to understand the pharmaceutical industry as something vocational, as those of us involved with it are there for purely vocational reasons, because it's a fascinating world where there's the opportunity to look at problems and find solutions, which is not always easy. Above all because the pharmaceutical industry is one of high risk. All of you are in some greater or lesser extent linked or involved with the processes of R+D, and I think you can all appreciate that the high risk means that we start many projects well aware from the beginning that many won't go anywhere (neither regarding the economic balance nor the social balance of the company); which is to say, we are not going to get the economic benefits or the scientific crown of glory, that I don't doubt those in the industry look for in each project.

I believe this high-risk makes us particularly significant companies in the market, and perhaps also in the stock market. Don't forget that the pharmaceutical industry is at the moment the third stock market value in all markets, and that after communications (essentially mobile phones, which we truly depend on, like medications) and technology (innovative, information and new technologies), it's third in all world wide stock markets, in a high percentage of them. This should make people think, from an individual point of view, about what is expected and how much we all expect from the pharmaceutical industry.

This is a contradictory position regarding what I also think is very real: the easy target the pharmaceutical industry is, and in particular medications, are of criticism. I'm not sure to what extent we can separate in such clear terms what is pharmaceutical industry and what is medications, having heard it on more than one occasion this morning. I think both are quite inseparable; perhaps from a more philosophical point of view this could possibly be done, but from a social perspective of broad use, I don't think you can really separate the pharmaceutical industry from medications.

I understand that a lot is asked from the industry, and that the concept people hold of it is that it contributes little and normally reuses or uses its available resources unwisely to bring about a common good. I've always said that this is all easy to say when we are all, including those of us sitting here at the table, enjoying good health. The ability to criticise the pharmaceutical sector and medications, and I go back to the individual perspective and to the

most basic position of a human being, is always done where health is optimum. And evidently, I'll remind you that, and again from the individual point of view, when we feel danger, when we feel threatened by disease, the first thing we perhaps do is find this drug-doctor relationship to help us continue to feel strong and continue to live life.

The pharmaceutical industry is asked for returns from its profits in a social perspective. Sometimes I hear, and this morning I have, that there are situations that help the Third World, where given the poverty, the misery and sometimes misery in terms of health, the pharmaceutical industry should be more considerate. Obviously, one of the first things I should affirm is that the industry needs a significant amount of capital and human resources – which involve a cost – to be able to contribute to progress towards the future; and to ask for this duality of progress and charity, charity in the sense of good works, is at times terribly difficult. It's a complicated issue trying to achieve this somehow. I believe that demanding that the pharmaceutical industry produce cheap medications, or reducing costs for those destined to underprivileged societies, is something that can be asked for, but I'm not sure if it can be done; in economic terms, according to western economic systems, it can be done. I'm assuming that the debate regarding the pharmaceutical industry as a generator of medical progress, where I'd like to participate in an open-minded position, is taking place either this morning or afternoon.

In respect to this role that is sometimes asked from the pharmaceutical industry, I believe that the political bodies should have a special sensitivity towards it. I believe that, in this binomial formed by what the politician understands and what the businessman understands from the perspective of returns of means and of economic resources which is available to them to produce new social and economic goods, there would be a greater balance rather than resting in the assumption that this role belongs just to the industry.

In regards to generics, which were also included in the second part of the debate by Fernando García Alonso, the debate will allow us, with the participation of everyone I hope, to clarify many more things. I'd like to point out, now that the subject has been raised and I feel I can expound on it well, that there are totally original medications and there are repetitive ones; we're talking about products that have been on the market for many years, whose patent has now expired and should be seen as part of the formula in an attempt

to reduce healthcare costs. But I believe, that in a progressive society we shouldn't lose our bearings and start using medications that due to them being generic, are old and cheap. This is not the only way to the future. Obviously, like in all things, and I've mentioned that I try to hold as least a radical position as possible and instead look for balance, this type of drug should be found, however we shouldn't deny that it's the other type of drug that'll provide the pharmaceutical industry with the capacity to advance in the creation of new products and be able to finance new research projects. So therefore, I would think that generic products aren't the only solution or the answer to generating medical progress and continue to give the pharmaceutical industry a vision for the future.

Another aspect I feel we should consider and which illustrates my talk somewhat is what it means to consume medications. It's been stated by two of the participants in today's session that the percentage of medication consumption in respect to healthcare spending is 25% according to one person and 20% according to the other. I sincerely believe that sometimes figures, and I've tried to be a little critical towards statistics, slides and graphs which could help us see the future, and certain data can cloud reality somewhat. It's true that our country has a low general healthcare expense bill compared to our neighbours. Of the global healthcare bill, 20% or 25% (the 5% difference is irrelevant), makes up expenditure on medications: this is pharmaceutical expenditure. From an absolute values point of view, this figure is very close to that of our western neighbours. Therefore it could perhaps mean that we really don't have such an excessive pharmaceutical bill, but rather low healthcare costs; a country that has limitations from a structural, hospital and medical assistance perspective, and doesn't offer, because it doesn't use, certain levels of healthcare, distorts the data regarding medication expenditure. I believe this point, which probably generates more debate than was my intention at the moment, can give us a better idea as to what is medication.

Obviously, the price of medications goes up, and this is another point I want to make in my talk. The weight of the demands that the industry places on itself and is placed on by society is undoubtedly heavy; society as a whole increasingly pushes for good medications, not only highly efficient medications but also highly safe too. The very government, naturally because of its own criteria as well as that of societies, sets higher standards each time, which then rules out any possibility of producing cheaper medications in the

future. Therefore, I once again appeal to a sense of reality: medications, in some way or form, need financing to be able to serve the public, as it undeniably incurs a cost. Regarding the cost, (and this is an absolutely personal opinion which I defend vehemently) unfortunately, the options for bringing the capital back into the pharmaceutical sector are but one: through the pricing of medications.

This could be an unsettling issue that I hope we have the opportunity to debate: the cost of medications and who should finance it. I believe that simply, there are changes in social models, and that things have to be redefined in terms of public tax principals which is to say, the more you consume, the more you pay. We would perhaps be moving away from the social welfare state model, obviously desirable, but increasingly difficult to sustain, where the distribution of goods is absolutely desirable, but at times unquestioning. Sometimes from an unreasonable perspective, one can endeavour to see things differently to what they are, but the truth will overcome us, unless we change the entire structural model. Understanding that we are where we are from an economical perspective, the capacity of the pharmaceutical industry to develop different strategies for the financing of medications is difficult.

Having said this and in defence of the Spanish model, I think that co-paying models for the future which include not only medications but any type of medical use, should appear normal and necessary to society. Other types of approaches probably weigh heavily from a conceptual point of view, from the ideal, from the idyllic, but finally from a realistic point of view, if society wants to continue to progress with similar parameters, then it won't have too many doubts about this.

Last of all, I'd like to make a bid for something that is absolutely true. I don't think we can trivialise medical progress, as it's incredibly complex. I was trying to say this at the beginning of my talk. It would be quite difficult to come up with a single definition that I don't believe exists, not in a clear form. In any case, this progress, which is rather slow, trusts in the pharmaceutical industry whose evolution towards the future from a research and development perspective is also slow. Slow as well as committed from a standards perspective. Often standards precede the very capacity for development, or for research and development of the pharmaceutical industry, which means that not only does it generate a certain cost, but also rather complex levels of

uncertainty. The one and only way to resolve what could be the future is through devoting more resources, especially time and human capital, to the scientific aspects.

From the pharmaceutical industry perspective, what I believe I can transmit to you is that this idea of companies going after profits (which has generated criticisms, like the ones here at this conference), leads to pharmaceutical mergers that give rise to the acquisition of greater power, whether economical or political, not sure, is not entirely true. In any case I'd say that most of these mergers are based on scientific aspects, well beyond commercial or industrial aspects of the pharmaceutical industry. When we talk about scientific aspects, we refer to the capacity of being able to continue being competitive, in a business sense, in an area of need that society expects the pharmaceutical sector to respond to. Obviously, these united efforts can ensure a future exists, from the perspective of hope held by the pharmaceutical industry and of the very recipient regarding progress. In other words, a perception of medication which is what in some form or other what society is going to consume.

I'm sure that in this vocational effort made by the pharmaceutical sector, behind every research project, behind every desire to progress in a scientific and biomedical sense, there is the aim, and I would say a tremendously dedicated and excited one, and the ideal of constantly improving what could be the quality of life of human beings. It's been stated, again this morning, that some drugs, specifically H2 antagonists, have indeed been revolutionary and have cut social costs, and obviously prevented a number of deaths hence reducing the mortality rate. However I can assure you that behind this group of drugs (H2 antagonists), there have been proton bomb inhibitors. With all certainty, the pharmaceutical companies have put all their effort into producing better drugs, better meaning sometimes even cheaper, and getting products that will improve the quality of life in various ways: taking them less frequently, easier or less expensive ways to take them, and probably shorter treatment periods. Evidently on many occasions, and this is a clear example, it's not been possible.

In any case, to conclude the expansion of my presentation, I'd like to reiterate that the pharmaceutical industry has vocational and high risk aspects from a double perspective, business and social objectives, that in it's bid for

research it looks for a way that leads to development and generating a positive impact on the quality of life. And I also believe that its business role, described in terms of social and economic objectives, can have a good effect. Apart from the fact that the pharmaceutical sector is highly criticised, no one can deny that their ability to bring about final results lie in this position and vision. I believe that having justified the contents of my document, that I wanted to expand on in relation to some issues raised during this morning's session and the beginning of the debate, it would be appropriate to continue with it and allow that everyone's contribution, in the least help us fulfil the objective that has bought us here today which is to leave with greater knowledge or at least, with positions that will allow us to understand contrary ones and enrich our own opinions.

Fernando García Alonso

First of all, I'd like to clarify something, as I believe it would be good if Javier and I agreed on the figures. I think it's important. I'd like to give you some information about Javier that many of you are not aware of, because he was given a fairly brief introduction as general director of the company, which is an executive position. He also holds positions in professional associations, specifically those of publicity agencies, and he is (this is important) for use of correct terms, the owner of the production line. In other words, we are before a general director who is also the owner of the company, which does give it a rather special perspective. When it comes to discussing these issues, we find ourselves in front of someone who has a double interest. It's not the same being a paid general director of a company than being the general director of a company you own. I believe that enriches the debate quite a bit, although logically, it does put a bias on things one way or another. Perhaps this biographical profile I've allowed myself to outline was necessary.

Just to clear the small dissonance between your presentation and mine, it would perhaps be good to address it. I read on page 5 of your talk, after it says "Impotence, alopecia and *jet-lag*", it follows with "it's true that the number of products introduced into the market have fallen by half in this last decade". This is what you literally say. I'm trying to reconcile your data and mine. I go back to the source of the information as I didn't actually put it together myself. Perhaps the table from *Script* refers to the number of pharmaceutical specialities and mine to the number chemical entities, because what is obvious

and outside the bounds of discussion is that the number of new chemical entities, which is a very specific parameter, has fallen between the sixties-seventies and eighties-nineties. True that you do clarify this further on when you state "but it's not less true that since '89 the number of new compounds commercialised has remained virtually stable". Basically, in the table I have presented, a stabilisation occurs even when you apply it to new chemical entities. It's just that the line is situated in the seventies and has a downward trend. I say this looking for a point of mutual agreement because it's not possible that our sources be so different. It would be strange that the data could be so wrong both in Script and in the source I have which is the Centre for Medical Research International, a very well known service provider in the UK and the most famous one in it's field.

Perhaps we could come to an agreement if we say that the number of new chemical entities, understood as the number of therapeutic targets, is stabilised because of the explosion in the seventies, and so probably the number of specialised medications are indeed maintained. I'm trying to look for some middle ground, as I would really regret that you say black and I white.

Xavier Peris

I'm not sure how much knowing more about me has contributed to all this. Obviously I'm not at all going to deny what Dr. García Alonso has said to you. My role is general director of a Catalan and Spanish pharmaceutical company which at the same time is a family business. I'm not Bill Gates. I say this because I'm not the founder of the company and have been in it for a very short time. I'm 43 years old and I'm part of the third generation. For those of you who know something about Catalan culture, it's said in this country, a country of businessmen, that the grandfather starts it, the father maintains it and the son destroys it. The truth is that I work with much devotion and hopefulness, and a high degree of risk, thinking that if I destroy the company I'll have fulfilled what's said. In addition to this, as Dr. García Alonso says, I'm a board member for the Pharma-industry. I'm the representative for the national group of small and middle-sized businesses, and at the moment I also preside the National Association of Pharmaceutical Specialties Publicity (ANEFP) where, from a management point of view, specialised pharmaceutical and para-pharmaceutical publicity is organised for the 8% that makes up the over-the-counter market sector in Spain.

I don't know if this information will allow you to be less critical about the pharmaceutical industry, but in any case, I don't think it's all that relevant whether someone is speaking in representation of the capital, the management or the work. I think we have a particular concept of the pharmaceutical industry. I think those of us who work in the business world in companies, have very similar criteria. I insist that the people who work for a pharmaceutical company, those that apply their criteria to matters of management and the capital at risk have one same objective, and do very similar things. Also the look for the same thing: the survival of the company, their company especially and of the business, but also of the business model in general, because it's our livelihood, I would say many of us in the industry and in different sectors that receive a salary which comes from the taxes paid by the industry. In some way as I understand, the vision I have doesn't necessarily support the idea of capital or the defence of capital, but for the defence of the pharmaceutical industry. I believe this is the truth.

Regarding the issue of the data, whether it's the number of new chemical entities that increase or it's the number of products commercialised in a given country, I simply think that Fernando García Alonso and I can agree here and decidedly we will. So indeed, with my one slide, the only thing I wanted to say was to be careful using data, graphs and statistics as they open up the possibility of not one but two interpretations, of being misused by someone who at that moment wants to obtain specific data to use in a different context. I was endeavouring to say this and obviously I clearly do say that I agree with the information you've brought forth; it's quite different reading it as the introduction of new compounds on the market or as the development of new compounds in a research and development sense.

DISCUSSION

Carlos Vallvé

I have to say in the first place that this morning's session has left me completely overwhelmed. To explain why I feel overwhelmed first I should make a statement regarding the conflict of interests. Evidently, thirty of my professional years that are spread over a period of forty years, have been dedicated to the pharmaceutical industry always in research and development. I have to say that during those years my job has been very interesting and I have never felt under too much pressure. When there has been some pressure that I've felt to be too excessive, I can assure you that I've had sufficient resources to be able to maintain my chastity, which is one way to put it.

This situation is probably quite common to many of you, but the conditions are that, from my point of view, I've been paid well, and they continue to pay me well. Obviously everything I'm going to say is impregnated with all this, which is both undeniable and unquestionable.

During these years of dedication to the pharmaceutical industry, I've always sought to develop a medical role. I studied medicine and joined the pharmaceutical industry to perform the role I had studied for. They taught me to cure patients and alleviate them. What I really wanted to do in the pharmaceutical industry was to contribute to the development of medications that would help to cure patients or alleviate their suffering, simply this. I never thought that my professional activity would have an impact on public health, if I'd known and I had a chance to start my professional career again, I'm afraid I'd rethink about it. What I cared about was the patient.

Naturally, at the end of the day, after many years, given that you don't have contact with the patient (you ignore contact with the patient): they give you some figures, a value of p, a statistical information, and so forth, but you want to find a patient that'll you tell you something. About 10 years ago I found him. I'm going to show you an slide which is in German for various reasons. Firstly, because many people here can boast of many things. I can boast about the fact that I know German, and I do. Secondly, because in German, this particular writer has a musicality to his writing which is difficult, extraordinarily difficult to reproduce in Spanish. Thirdly, and this is the most important reason, because the translation of this paragraph by Miguel Sáez, a magnificent translator, is wanting. I have allowed myself to translate it and I'm going to read it to you very carefully. I have been very mindful of the translation and

have gone over it thoroughly. The book is titled "*Concrete*" and was edited in 1982. The author is Thomas Bernhard. It goes like this:

> "I didn't want to laugh or cry anymore, I got up and checked if I had packed enough prednisolone, Sandolanid and Aldactone Saltucin. We loathe chemicals, I whispered to myself. We loathe chemicals and yet, to these very chemicals which we despise more than anything in the world, we owe our lives, our very existence. Without these damn chemicals, we would've been thrown into the cemetery or wherever decades ago. Since there is no more in me that can be removed by surgeons, I depend entirely on these medications. I'm thankful every day to Switzerland and it's industries by Lake Geneva that they exist and through them I exist, as probably many millions of others are grateful for their lives and existence, even though so miserable, these people in glass cases next to Vevey or Montreaux, for the severe criticisms endured from all. Given that almost all of humanity is ill these days and depend on medications, I should have the courtesy to reflect upon this, that I largely if not exclusively exist thanks to these chemicals that I so totally abhor".

Who's the author? I really believe that this author is, from my point of view one of the greatest German writers this century. This author had no idea of what a placebo was, but he suffered from a terrible disease, Boeck disease, a sarcomatosis with pulmonary infiltration and myocardiopathy, which caused his premature death 10 years ago.

Vicente Ortún

I would like to quantify this German text a little, which is what we economists do, put numbers to everything. My intention is to complement both speakers. Perhaps in the last one I wouldn't have become involved with issues concerning the welfare state, I would've left it aside because it does create additional conflict. I won't become involved now.

Putting numbers to things. The issue of the pharmaceutical industry and medical progress. Medical progress can be measured. You either measure it as a discipline or you measure it as a practice. If you measure it as a discipline, you take the Harrison's starting from the first edition and look for things that have changed. You can document the evolution of progress as a discipline. Progress

as a practice: How do you treat otitis/ an infarct/ a fracture today? How was it treated 20 years ago, 50 years ago? You can document this, but it is partial. We're not so interested in progress as such but rather in discipline or practice. We're interested in how this progress has contributed to the quantity and quality of life of people. Again, going deeper into what's been said, you Guillem, may not remember from when we went over it, but these typical quotes such as "preventive medicine in a developed country contributes to quality of life, and curative medicine contribute in two or three years". Antibiotics, surgery, traumatology, etc., demonstrate that this is quantifiable; you could ask to what extent does education, income, inequality and medical services contribute to quantity and quality of life.

There's one more step. If the contribution of clinical services is of, let's say, a year and a half, this year and a half, how much is owed to antibiotics? For example, if we know that the incidence of cardiovascular disease has fallen due to less smoking, control of hypertension and change in diet, how much is due to fibrinolytics? This is the contribution of the pharmaceutical industry.

There's another issue I don't want to complicate, but would be quite critical to mention. We'll find that it's not an all or nothing situation. It'll be two years, three months, that's what it'll be, however, always far from extreme views. Then the aspects critical to economists will arise, but which I'd prefer to omit for the moment, which involves issues of social use, issues of comparison. Is the best way to treat hyperlipidaemia with a hyperlipidaemic drug? I'll leave this for another occasion.

Vicenç Navarro

I'd like to disagree with Mr. Peris' talk. I suppose he's expecting it. I'm not sure how relevant his case is. In this respect, the biographical details he added has both enriched and diluted my criticisms. I reiterate that I'm not sure about the relevancy of his company. Apparently his company is a family owned business, and if that's the case, then it's not representative of the industry on an international scale. My criticisms are directed to the second type not to family owned ones. This then frees me from the awkward position of having to be in disagreement on a personal level. But he should be aware that on an international scale, he is profoundly wrong. The pharmaceutical industry is not one of high risk. It's a highly protected and highly subsidised industry, and this may well surprise him, by the public sector. In the United States as in

Germany and Switzerland, the most important centres for the industry, these have a very privileged relationship with the State, whereby, as I've said in my previous comments, the society does not benefit from these subsidies to the extent they deserve. Concerning this aspect, you affirmed that the pharmaceutical industry has contributed enormously to the production of medications. This is true, but you forgot to point out that in a large number of these products, the background knowledge has come from public institutions. The pharmaceutical industry have acknowledged this given that they'd like to work close with academic campuses, and academic campuses are mainly public. In this sense the pharmaceutical industry have sought out knowledge that has belonged to the public. This is a very important fact as it justifies why the State should intervene more than it has. From AIDS medications to any other type, the basic knowledge behind them comes from the academic world which is financed largely with public funds.

The second observation I'd like to make concerns your detailed statement on generics, which I suppose was in response to my earlier contribution. The urgent need to introduce the use of generic drugs in the Catalan and Spanish markets is due to obvious economic reasons. The Spanish State should not have to pay two or three times the price for a products that it could otherwise get that much cheaper. The fact that they do is exclusively due to the economic and political context of the situation that defines the sort of power it has in relation to the State. We're not talking about if the use of the generic product retards acquisition of knowledge. The acquisition of knowledge is done in other ways which are not the maximisation of profits. You can use generics without it standing in the way of the creation of knowledge. Naturally I don't share your views that this is an industry with risk. In fact, on an international scale, it's now the second most profitable industry. This is also true for Catalonia, by the way. The pharmaceutical industry isn't hard done by. It knows good times, and with the financial backing of public subsidisations. This is what you have to realise, that the vast majority of basic medical activity has been financed with public funds.

Going back, I'd like to take advantage of the opportunity to respond to a commentary you made regarding medical progress. I'm surprised to hear that this sort of "progress" would be considered objective. There's a saying in English that says "Progress is like love, it's in the eyes of the beholder", progress depends on who defines it. Why? Because from the perspective we call

"progress" seen reflected in text books, there could be a lot of progress, but this progress, due to the enormous influence of the pharmaceutical industry on the medical culture of this country, distracts us from analysing the cause of those problems. This encourages the pharmaceutical industry to lean towards "looking after" the problem, and at the same time obstruct their solution. I'm not saying this all stems from one machiavellian sort of plan. No, but I am saying that, as a result of emphasising the "looking after" aspect, the priorities of the system are such that not enough attention can be given to the problems involved in prevention and cure. This is the classic example of big hospitals, of large biological research centres, the enormous biological focus in Catalan and Spanish medicine while public health is virtually ignored. The pharmaceutical industry is also to blame. You know very well that the pharmaceutical industry finances the largest means of communication within the medical culture. I felt it important to point that out. I said this morning that I found the behaviour of the pharmaceutical industry totally understandable in light of its main objective which is the optimisation of profits. You've also mentioned this fact and I applaud you frankness. I think it perfectly logical.

Joan Bigorra

The lack of social support for research carried out by the pharmaceutical industry in Spain and Europe is worrying. Our old continent already said no to biotechnology. The capacity in Europe for biotechnology research is minimal with the exception of the United Kingdom, who has a different culture. Europe might find itself having to buy the products derived from biotechnology within the next few years. And then we'll really have to pay for it. The pharmaceutical industry could go the same way in the next 15 years.

Paloma Fernández Cano

I'd like to make some comments referring to the motivation behind the pharmaceutical industry: true, it's objective is to maximise profits, but with one important focus, not at all cost or at any price. At MSD we have a type of underlying principle that forms part of our culture there which was given to us by George Merck, one of the founders of the company back in the fifties. It goes something like this: "We are never to forget that medications are to help people. They are not for profits. The profits will come in after, and the more we keep this in mind, the greater the profits".

Which is to say that the more efficient we are in developing medications and releasing them to people in need of them, the more success we'll experience as a company. The more we fulfil our mission, the greater the benefits. It's also possible that we get it wrong and not do our job well, but the principal is quite clear and gives specific direction to the way in which we act.

Jordi Camí

I haven't been here for much of this very interesting colloquium although I've had the opportunity of being updated on how it's been going in general. In the first place, I'd like to put forth two or three ideas to change the course of the discussion a little and enter into issues, without diverging from the objective of today's meeting. This is not because I feel that the ideological foundations and ideological components have been exhausted in this meeting, not at all, but I do feel that a lot of time has been given to them. A subject like this is never exhausted, but the Foundation is interested that other areas be looked into, the other faces of the prism, even if it's just so they don't say later that we have been insistent and focusing the debate regarding the ideological issues as a form of alibi.

Amongst my suggestions, I'd like to encourage the bioethics group to put forth their ideas regarding issues of responsibility that have been addressed already, but I'm sure could nonetheless make important contributions to. Secondly, I'd like to focus on not so much the 'what' of public intervention, so that we move on from exclusively critical grounds, but rather I invite you to make suggestions as to how you think this public intervention ought to be, what role should it play, after being satisfied with all the criticisms necessary. Thirdly, and here I would like to make some emphasis, I believe that we could never say that this has been a high level debate because of the people who have participated if we don't give a reasonable amount of time to acknowledging that we're entering the information society and all the repercussions that this carries, as much in the positive sense as in the negative, in that the components thereof probably favour further inequality, etc., but also as an element of total change, even in a conceptual way, of the vision we have of our daily lives. In this respect, intervention is inevitable. Vladimir de Semir, has just joined us and will, in his turn, contribute to the discussion explaining the changed and interestingly warped role the media have and what's ahead of us.

Àngel Puyol

I've taken heed of this call and I'll talk from a bioethics perspective, or at least reveal a couple of concerns within bioethics which are quite interesting. One of them is related to the very concept of progress. I was surprised with the paper of the second speaker where on page one it states that progress has at times been presented as a biblical plague, almost comparable to the concept of sin. I was surprised because, the fact is the concept of progress has religious roots: the idea that we find ourselves somewhere not good, but bad, and that we have to go somewhere else which is better. With the passing of years and with the success of science, we have secularised the concept of progress in our society and it's believed that science will help take us all to a better world.

Regarding your theory on evolution, Darwin himself fell into temptation when he revealed it from a scientific point of view and said that the evolution of species was getting better all the time. I suppose that these days, all scientific authorities, all scientific fields, drink from this idea, which is why I'm not surprised that we talk of progress when we talk about scientific issues, especially in medicine. It's assumed that medicine will make us better. This is the idea of progress.

On the other hand, when the members of the scientific faculty commented on what they understood to be progress within pharmacology or in medicine, I was surprised to learn that the least controversial definition was that regarding the internal progress of the field. We don't know what progress is too well, but we have no doubts that internally progress is writing and producing. We philosophers are not so strange. We also consider that progress is writing and speaking, and we are not so concerned whether what we say has much of an impact in the world or not. However, I believe that more is expected from medicine and pharmacology than what is from philosophers: they are asked to have an impact in the world, that they cause change, and it is expected, for the better.

I know in practise this is both difficult to know and difficult to measure. The reason being that progress, is a value itself. As I said, going to a better world, a better situation, it has to measure something that is also a value – quality of life. Quantity of life can more or less be measured, and probably medicine has already done it, but quality of life, which is where most of this morning's arguments ended up, how do you measure that? Not an easy task

because there are two values at play. It's measured looking for progress, which is a value, and we measure something which is also a value – quality of life. I don't know if it's with utilitarian criteria, as mentioned by Guillem, who isn't here now, but I'm sure that Vicenç will know how to respond well from the academic perspective.

Another issue I'd like to comment on, which has not been mentioned this morning and which worries me as a bioethicist, that's if this category exists, is that of orphaned diseases. Because in the second talk when it was time to mention them, I'm told that there is no solution, nothing more was said. There is no solution because of economic reasons. I know that the pharmaceutical industry is not the ultimate one responsible for attending to these orphan diseases, but then I ask myself who is responsible. The sufferers exist and just because they are small in number, they are not small in value. I don't know who could be responsible for attending to these orphaned diseases, but it worries me.

The fact that university and industry were coming together because research is costly and needs the industry to intervene and provide financial support, was praised this morning. But, the only hope that orphaned diseases or their sufferers have is that basic research belong to the public sector and not be dominated by interests in economic profit. If basic research sponsors are private companies, I'm totally convinced that orphaned diseases will go from being orphan to the cemetery direct. No one will take any interest. I don't know who will be responsible. It's easy to say that we all are. However, in practice someone has to make some decisions. An idea that occurs to me is that basic research be financed by public and not private companies. Something else that occurs to me is that the states with political power intervene in an administrative role and with fiscal measures. The State and citizens do not care for the orphaned sufferer, and I don't know how we could attend to these needs which are as valid as the diseases that effect the majorities. These are the two comments I wanted to make.

Fernando de Andrés

I'm going to be very brief because I just wanted to intervene in response to my friend Joan-Ramon Laporte. The most important thing I want to say is that I totally agree, and I wanted it to be known. It's one of my favourite subjects. I think it's a little ridiculous that the evaluation of medications on a European

scale relies on the industry, even if it's only a question of image. Naturally, the committees try to remain as independent as possible, but in an almost physical sense they're connected with the industry, and don't like to say they depend on it. The solution adopted has been to change the name of the ministry, which is to say, the General Sub-Direction, and perhaps this has solved the problem. It's not called Industry anymore but rather *Enterprise*. I don't know if it's better this way. I do agree that it's not right.

The other thing is that I don't want to respond in name of anyone. Unfortunately, the Spanish Agency does rely on Health. There are several components to this. First, who do they rely on, and secondly, that the organisation work. This European epidemic of creating agencies has preference for efficiency criteria. It's expected that the structures of the agencies can act quicker and more efficiently when it comes to working than the old bureaucratic ones with their elaborate hierarchies and almost immovable passivity. That's what I wanted to say.

María Casado

As a bioethicist I must accept the invitation extended by Jordi Camí, even though I really don't like having the word. I find it horrible and what's more, it raises ideas of a new dictatorship from the experts. Our society tends to increasingly hand over its problems and put them in the hands of experts for solutions. This could be acceptable if we're talking about technical problems where the solution lies in expert knowledge. However, if we're talking about ethics, it's not; here the individual should solve the issue, or society at large should in the need of collective decisions, where they often become legal issues.

I'm a Philosopher of Law and I work these issues from the perspective of the impact this has on human rights. I wanted to put you in the picture of where my area of knowledge lies as this can give you an idea of where I'm coming from regarding the issues we're dealing with. Philosophers of Law are used to being placed in no-man's-land, because even in our own Faculty of Law, we're seen as belonging to philosophy, and those in philosophy don't take us in either. Perhaps more so in a gathering as this one, because what's been said this morning had a large technical component. That's why I first like to listen, then the opinion belonging to the outsider from a different 'tribe' isn't given out of context. One can't reflect on or regulate anything till the facts you want to influence are known.

In any case, there are a few things, underlying all that's been said, that from a conceptualisation point of view, that we've been invited to participate in, I'd like to comment on, or rather ask questions about.

First, I'd like to touch on what Ángel Puyol said earlier about the idea of progress. When a gathering such as this is held under the title *The Pharmaceutical Industry and Medical Progress*, one has to ask one's self: What's this medical progress business? I think this is an important issue because even within the medical profession (and it appears from what I've heard, from within the pharmacy and pharmaceutical industry) that the issue of what are the objectives of their profession are in questions. This is an issue that's very important to us, because behind the elucidation of what are the aims of medicine, there are many of the questions raised this morning; whether the aims of the professional are only curative ones or also care for; today, now that we can extend life, is that the most important thing or is it care; all this obliges us to revise and restate what the aims of medicine are. I'd say that we ought to be careful about considering medical progress as the act of adding to the curriculum vitae of researchers and doctors. This could generate certain mechanisms which could turn out to be rather perverse.

And then we have the idea of justice. In a way we're here invited by a foundation whose final goal, as it's being discussed under the title of today, is the development of ethical behaviour in the pharmaceutical industry and in the world involved with human health. This should have something to do with justice. Why is it that we're asking (it's the underlying cause to many of our contributions) that the pharmaceutical industry develop research lines or that it influences research so that it promotes greater justice and social cohesion? Just because we're saying that we're putting in public funds? However, as I've said to Xavier, this also happens in other industries. There's something qualitatively different here. I think the issue of different research lines is important. Regretfully Vicenç Navarro isn't here as I really wanted to let him know how firmly I agreed with him regarding what he said about the State having a big responsibility. As a legal person, my immediate reaction is: the responsibility sits on the citizens, and we'd have to say collectively in this case. We have to take an interest, we have to prioritise and we have to establish new research lines.

Finally, there's something I can't overlook. It's quite discouraging that we refuse to talk, from the outset, about something that makes us uncomfortable:

the issue of values and our responsibility in regards to the use of the Third World. It's not just that we're going to give the Third World cheaper medications because we're good. It's just that we carry out research there and do quite a few other things.

Victoria Camps

I also protest against the *bioethicist* thing. This word should not become popular because we're philosophers, and not even ethical ones, which I don't think is even an elegant word.

I'd like to address the issue of responsibility. The intervention by Joan-Ramon Laporte has raised it for me. I think it's a concept, which in ethics, is not terribly developed, and that individual responsibility is one of the basic deficits in free democracies, where the left as much as the right are to blame. The right, for being too conservative seeing as when there's a problem, it falls back on the traditional values. The left because it blames the system, or at least it has tended to blame the system for many evils that have not always been its fault. I think we're still dragging these prejudices. I feel it comes out when we talk of defects, problems and the questions we have without answers (and Laporte's contribution certainly raised a few of those), and we immediately look at the industry and say "The industry is to blame for all this". I'd like to be the devil's advocate, and in this case the devil is the industry.

We were asking ourselves how should the State intervene. With more laws? But, who's to blame for lack of regulation? Who does it depend on whether something is more or less regulated; does it not depend on the citizens of the land? It's true that in a market society, in a market economy, industry rejects regulation. However, in all areas (this one and other is communications), when there's an attempt made to regulate a little more, it's the professionals themselves, be they communication or health professionals, that complain about the possibility of being regulated. In the end, the politicians do what's being asked when pressured. Politicians are basically looking for votes in most cases. If there's no pressure, things don't get done.

Another issue that's been addressed this morning is that of medical prescriptions, tied in with the medical culture we have and patient education. The issue of prescription basically depends on the medical culture that doctors

introduce, I think. I don't see why we should blame the pharmaceutical industry for errors of prescription or for the misuse of medications, or for why there's a greater focus on curing and not prevention, or in curative measures more than preventive ones. Preventive measures are more difficult than curative ones to carry out, which means that greater patience is required from the professional to educate the patient and teach them that they shouldn't reach for the tablet, but rather walk more, or swim, or lead a healthier life or give up smoking. Because all this is a much slower process and doesn't produce such obvious results, it's a lot more comfortable not doing it. In other words, we don't support that which we know is better because it takes too much effort.

I myself respect the information society. This morning we also referred to bad press and wrong information and to stereotypes being spread. I wouldn't shoot the messenger here. I also think it's science's responsibility to inform them of what they're doing and of what they know how to do, and make sure that the information published is correct, and protest if it's not.

I don't like to talk about neo-liberalism because fortunately, we are far from it. We still have a social State, which we will probably preserve. We'd have to really be lacking in lucidity and wisdom to do away with it. However, it is true that we're living in a free world, where everything has the same value, where there's fear in holding even slightly strong positions in regards to anything. I interpret that as a lack of responsibility, which is to say, answerable for your own profession and society, and not take on, neither the individual nor the collective he or she belongs to, any problems but rather pass them on to someone else. I think this issue is important when it comes to evaluating the measure in which the industry and science progresses.

Cristina Avendaño

I'll refer to what was being said about the regulation terms we have and work in. The creation of the Agency was alluded to and the separation between the responsibilities of the Agency, in this case the Spanish one (only approving the quality, efficiency and safety of the medication.), and the financing aspects by the system, that are linked to the real evaluation of the benefit or impact on health of a medication, which is much more related to the following section. This type of regulation, which is not exclusive to Spain but to all Europe, is what we have and what links the Agency to the Industry.

In regards to this, I wanted to say that when we've separated the Agency's competencies only in terms of the quality, efficiency and safety of a medication, and isolate it a little more from the measure of relevant impact on health, we (I have rather limited experience, but I've observed this in recent times.) unfortunately get the impression that the standards for approving a medication in terms of benefits are gradually getting lower. I refer to the benefits, in terms of health of these recent new medications. I don't mean the one for erectile dysfunction, because the women here are in minority and I could be misunderstood. Perhaps a better example is this similar compound to melatonin for jet-lag or any of these types of medications we're seeing recently. Those of us that decide how a product qualifies for registration often feel uncomfortable having to apply, as said, the Treaty of Rome or the Community Directives regarding the acceptance of medications, because in terms of evaluating what a medication can contribute, what we would like in terms of criteria for new medications is still far off, and so apply the current regulation which is what we have to do and we can't do anything about it. In other words, meet the current standards and regulations we have. In regards to this I'd like to express my agreement with some of the comments made in relation to the need for this concern, that it seems we all have, to be channelled correctly to change the existing regulations.

Concerning orphaned diseased and the right we assume the sufferers of rare diseases have to medications which are as efficient as the rest, I don't know if I'm being a little optimistic, but I feel here that we've started in the right direction to promote those regulatory measures that will allow us to advance in regards to this. In addition, it seems that the right thing and thing that carries the most prospect of success is what's been done so far, which is to say, not assume that there's going to be any public financial support behind this type of research, but rather make the research of these type of diseases profitable for those who normally research (the pharmaceutical industry). At least we'd be making the most of what we've got, and through fiscal incentive plans and public money, the same research entities would perhaps want to dedicate themselves to this area because there's the chance of making a profit, seeing as otherwise, they won't do it.

Finishing with the issue of regulating agencies and the discomfort felt at times by those of us who are subject to the directives and rules we have, and the perversity talked about this morning regarding the direct or indirect total

mediation of pharmaceutical research by the industry itself. We (the regulating entities) are faced with that pharmaceutical research results be one and only, or rather almost only, those that are in line with the objectives of the pharmaceutical industry, and not any others, which don't exist anyway. Therefore, the field of knowledge acquisition by the regulating entities is again rather limited.

Joan-Ramon Laporte

So many things have been said that I don't know what to say. Regarding the questions related to ethics and issues related to orphaned diseases, which have just been addressed, I've noted down here in inverted commas, using a term Victoria Camps probably won't like, the word "blame". I ask the moderator, is the blame on the industry or who? The question is of the differentiation between market regulation and public healthcare system responsibility.

Regarding regulation, I'll use an example so that you'll understand how I criticise the separation between the regulation of the market and the regulation of health. Medications for obesity, anorexigenes, were removed from the market in Spain and around the world about a year ago, due to some fairly severe side effects. Amongst these side effects, the one that broke the camel's back and initiated the removal of the product was the appearance of cardiac valvular lesions in its users (mainly women). A first study published by the American FDA, which didn't have a very sound methodology, gave an incidence result of 36% of users. This was not a joke. Later, other studies with better methodologies, published after the removal of the product, have lowered the percentages in quite variable ways. However, looking at the most reliable ones, the incidence could be around 8-10%. I called the Ministry and the Agency and asked them what they were planning to do about these medications. The response was "We've removed them from the market. Happy now?" As if I had always wanted everything to be removed from the market. Naturally my concern was not whether this was on the market or not. My concern was, who was now going to examine the hundreds of Spanish users? Who's going to assess the heart of these people? Give a prognosis? Treat? Who's going to look at whether there's been a problem here or not? No one will. When you regulate the market, you don't take people into account. This is what I wanted to say. This still doesn't have an answer. Is it up to an interested researcher to ask the Health Research Fund for help? I think it's incredible. It

can't possibly be. This is the shared responsibility of the State, the Agency, the Ministry and the laboratory that made the product, which by the way, didn't publish the results of the experiments showing that it produced valvular lesions in rats, nor the first reports of valvular lesions that came from Belgium, not the United States. No one has said anything; no one has taken them to court. Whose responsibility is it? If the responsibility is divided, it turns out it belongs to no one.

This is the separation I'm complaining about. You can remove the medication from the market if you want, but one asks himself, what of bad medical practice. Anorexigenes are used to prepare for the beach, especially in the months preceding summer. After the removal of these medications, endocrinologists protested against this: "Why are you saying this against anorexigenes, when they're great for my obese patients?"

"They are not for your obese patients, it's for looking beautiful when you go to the beach". This is a health risk. Who regulates this and who reports it? This is the first issue.

Just a small annotation regarding what Fernando García Alonso said regarding the Third World. The problem with the Third World is that it shouldn't be Third World, and from here things get complicated. If we were all First World and we were all more equal, these things wouldn't happen. Regarding orphaned diseases, I'm not sure if I'm going to state the obvious for those of you in philosophy or law that work mainly in the area of bioethics. From a biological point of view, I think there are some extraordinary arguments in defence of a health system that gives priority to equality and wide spread availability. It's just that, in a few words, we are all a minority. There is no minority that suffers from storage disease, or a minority that have a needle stick injury and from there get AIDS, or even a minority of people (that's if they are a minority) namely homosexuals, that have a higher risk of AIDS. We are all a minority because we all have some genetic, environmental, familial, social or other characteristic that makes us a minority in relation to a given disease. Now with the development of genetics, this is much easier to understand. We could all have the gene that makes us predisposed to cancer of the colon, or breast cancer, which ever. We all fall into the right side of the distribution curve related to blood pressure, and of the distribution curve for tests which let us know how likely we are or not of getting a disease.

Unfortunately this is because medicine only knows how to count to two – you're either healthy or ill, and yet the reality of it is much more complicated. One could be more or less depressed; one could be happy, sad, very sad, a little down, depressed, or with a tremendous depression. There are lots of different depressions, lots of different levels of depression. Each one of us, in one aspect or other, is on the right side of the curve, in the vulnerable area. This is what should make us think that these are not diseases that affect a minority, they are diseases that can affect all of us if we believe that we belong to the same race. I say this in terms of genetic diseases, rare diseases, diseases that are not so rare, diseases classified rare due to their behaviour at some time in history, because things change, and diseases suffered by the people in the Third World. I see all this as a relevant issue and one we mustn't forget.

I'd said this in the morning. I don't know if anyone has an opinion that could shed further light on it. I believe that the social model that tends to create increasingly greater differences between thousands of millions of people and the rest of humanity is not sustainable. Even if we looked upon this with absolute self-interest, viruses don't understand boarders. This is seen in the history of public health. Multi-resistant tuberculosis doesn't understand boarders. It'll come across the Strait of Gibraltar with greater ease than a little boat. No doubt about this. How are we going to tackle these issues? The Third World is not some trendy term used by those with a guilty conscience or because they're leftist, or whatever. It exists and it affects us. There are clear opportunities to do something.

In response to Victoria Camps' affirmation, I wasn't able to note down all she said, because as always, when she exposes these arguments, they contain such rich concepts. However, it's true that there's not just one sector to blame, for lack of better words. There's more that one sector responsible for the things that happen. We all agree that the political system has some responsibility, if not the regulating authorities, as I would personalise. As she said, in the end it depends on the people. But what is also true is that, what I call the 'powerful' have many ways of confusing the people. Earlier it was mentioned that someone said "who has the last word is the patient". However, more so than the patient him or herself, perhaps it should be society, because the patient is a misinformed person. In other words, if they'd asked me ten years ago if I wanted a freeway to get to the airport, I would've said yes. But perhaps some expert in urban planning, communications or transport says: "no, this has a

major impact on the environment, on the people in Sant Boi, on the people in El Prat, on…" and so forth, and so we have to look for alternatives. Therefore, as a citizen, I prefer to choose someone who can give me expert advice in the field.

I assume we agree on these issues, but what's true is that, whoever holds the power (and the power is largely economic influencing the media and other sectors) can influence in matters of self-interest. It's evident from what we see that the dynamics of a company is to generate the maximum benefits, maximum profits. Therefore, the problem (and I apologise as I always seem to end up in the same place as much as I would like to convince myself there's more to it), the all-important problem is the system. A system that approaches issues of health basing itself on purely market criteria is not humanistic. I don't know if that's a valid argument for you. The term humanistic, to me could be subject to a number of interpretations, I believe of high grade. This is something to consider seriously, because it's the defence of the human race as a whole, starting from the concept of minorities.

This is why I believe that the market should be highly regulated regarding health issues, and it's becoming more and more difficult. In times past, you could go to the mayor, then to the Government in Madrid, or that everything was Franco's fault. Now it's the European Union, or globalisation, far more ethereal concepts that make it hard for citizens to know where to go when they want to complain about something. The problems is the system, and somehow or other, should be equipped with resources that defend the vulnerable and weak. When we talk of health, we talk of people who are weak and vulnerable: the patients.

Jesús Conill

I'm going to share some thoughts linked with what's been said both this morning and this afternoon, but I'll make a selection as there are many. Following along the same lines as Jordi Camí, the selection touch on the areas that he's been outlining. Given the material I have prepared, I'm going to concentrate on the idea of responsibilities, as already said.

First of all, we have to give these responsibilities a context, and today we're talking about business and industry. I believe there's something we all have in common today, and has been made rather evident in what we'd refer to as our

economic culture and our general business culture; and that is our particular aversion towards enterprise. We've been bought up this way. It's been hard for all of us to realise what enterprise means. The pharmaceutical industry is an enterprise, and has the advantages and the disadvantages common to all enterprises. We'll look at the type of enterprise it is later, as well as look at its specialty, and then we'll get a better understanding. But I think that the first thing to meditate on is the responsibility enterprise has, and specifically this one, and this within the particular context of modern and contemporary times of organisations. If we're living in an age of organisations we have to understand these types of organisations. We have to even go beyond this because, due to our background, we don't think that what the business goes through, so the political party, the lawyer and everyone who lives in this kind of society goes through too.

What does the politician look for? Votes. And why is it more important to go after votes than after money? These types of reflections that could take us a little further, (but I don't want to waste any time here, just simply mention it) must give us reasons to believe we should put the functions of the systems contained within an enterprise into their right perspective as well as the mediums the enterprise uses in a determined context in a determined system. This doesn't mean we have to justify anything. What I mean is that we should introduce ourselves into this world, which I think not doing so has been the problem all along.

At this point I'd like to stress that looking at such systems as cost-benefit ones for example, you can see them as exclusively mechanical or exclusively commercial, or they can be used and be an ethical system. Who would agree with being wasteful? I don't think being wasteful is ethical. If I have a certain means available to meet an economical objective, as it's been talked about at some stage, this system is not anti-ethical. An ethical perspective has to include and encompass this mechanism, this means , this cost-profit analysis, cost-effectiveness analysis, or whatever, to fulfil the relevant objectives through these mechanisms in a given medium.

This is what I would stress. Also this is what the two speakers have said. We've been told quite clearly that it's all about uniting profit and social good. The point that increasing profits is not restricted to the monetary sense was also included in the talks. Everyone is acting in unclear ways, at least in name.

The politician will from his or her position tell you that what he defends is the well-being of society at large. We shouldn't take any notice of these types of speeches, only in the realisation and implementation of their contents. Therefore, we shouldn't spend our time looking for responsibility, which may not even belong to the guilty, or maybe it does, in a legal sense and in a coercive sense, which would be the most extreme case. We would have to look for ethical components. For example, do we have to move from working short term to long term. This is an option in the ethical culture of a company. One company may say, "No, I'll work in the short term". Fine, it's up to you. This doesn't come under any regulation. You can decide. It depends on your freedom, your competencies, free enterprise – initially. It's up to you, and like this, there are a number of different examples to show that this type of thinking regarding mechanisms, institutions, organisations and the diverse cultures, could help us understand this conflict, that appears to me as needing an appropriate, and even cultural, consideration.

There still seems to be this manner of conflict everywhere I go, which is to say the university and in the classes. To say ethics and economy together still sound the way they do, when they've been together since day one. The remedy is older than the condition, but our culture hasn't yet assumed it.

This takes me secondly to things that have been said this morning. I simply can't see, not in the address given to the issue (and the speakers themselves worked at reconciling the data which has still left me unconvinced), the discord between the data. I believe that without reliable data one can't analyse, and I'd expect you to agree with this. I believe, from what I've been reading, that in Spain and in other countries, but especially Spain, we don't have reliable data on health. Neither do we on this particular issue. You have confused the data yourselves. It's not the same looking at data on consumption and data on expenditure. Consuming and expense are not the same thing. There's considerable confusion here. Faced with this rigmarole, I think it's both necessary and our responsibility to clarify the data. You can't analyse without data.

This takes me to the next point, with which I'd like to finish. I think this is fundamental in three levels, that I think we should extend upon here. Some of these aspects haven't been able to get the exposure deserved, as we have certain limitations, but in order to carry on they should be established. First, regarding

medical culture, specifically the doctor, or rather health professionals (because as always, we tend to refer to the doctor when really there are other health professionals), what sort of medical culture is being generated and promoted? One has to be responsible here, because medical practice isn't born, it's made. You have a lot of power. You're configuring a determined type of culture, a way of cultivating medicine. "This is progressive, this is regressive…" You could say, "resources go into this or that"; you establish these things yourselves, and you say in unison "plenty of resources, not always profitable." These are expressions I've taken from both of you.

Secondly, the same thing occurs regarding public intervention in the area of regulation. In comes the medication reform and in comes public responsibility and then cost reduction is considered. Is it true, or not? How do I know if I should reduce costs or not if I don't have data to clarify the situation? It's all notions because there's not the data to give it the most solid and accurate analysis. Another comes along and expresses it more eloquently, politicising and idealising it. Therefore, data is missing if we're to have public intervention – responsible public intervention, and responsible regulating bodies.

Thirdly, social culture. There should be a commission set up for the reasonable use of medications. It doesn't have to be a single commission. It has to be a commission, which by the way doesn't seem to be working, that does more than speak words to its ludicrous political advantage, but rather it should serve to raise awareness and form practices in society.

Fernando García Alonso

I asked to have the word a little while ago to give an example that has nothing to do with the pharmaceutical industry but has with biomedical research, that I feel illustrates the point well.

I'm the director of FIS (Health Research Fund), an organisation that pours 5,000 million pesetas of public money a year into biomedical research. It would seem a logical task for FIS to not only grant the money, but also to evaluate the outcome. We'll make it easy. We're not talking about the pharmaceutical industry anymore, but of the funds that go into biomedical research. Five thousand million a year. It's a moral obligation, one which is almost automatic, to measure the results of what's been invested.

There's a central problem in what I'm about to say. The big question is: How do you measure these results? The means we have, which seems to fill us with satisfaction, is the 'bibliometric' system. In other words, we measure the scientific output gained from these 5,000 million pesetas, and we justify it before the appropriate ministry, auditor or Parliament, saying: "Look here, I justify that with the 5,000 million we have published all of this." The scientific publishing system is very complicated, sophisticated and perfect. Are these scientific publications medical progress? The basis of what I said this morning is an intermediate factor. This is to say, that publications are a subjected intermediate evaluation parameter. The final parameter for the purpose of evaluating should be, I say, biomedical research, whereby through the research itself we would've changed certain behaviour or workings of the healthcare system, in the broad sense of the word. What's the problem we have? A very difficult problem with methodologies. Measuring research results, remains an unresolved problem.

This is why, Jesús, I'm going to attack you a little, dialectically though. The big conflict in biomedicine occurs when we tend to simplify things by saying: "Well, show us some results, show us the data, and then we'll make some decisions." The big problem in biomedicine is that often the data doesn't exist, or of course, I could load up on figures and slides, and spend eight hours explaining the biometry of FIS, and not have said anything at all or have just given it all an intermediate value that is not definitive.

If you allow me I'd like to caricature this. Now that we're in a new phase, with a new ministry and new cabinet, I find it quite amusing when someone (generally someone who is not from Health, or is a well-known doctor) invariably comes up to me, I, who has lived through six, eight or ten changes of health government, and says: "I'm going to solve this thing about medications, you'll see, all this spending on medications and so; I don't know how people have been so inept in solving this. Give me a list of drugs that are efficient and those that are not, immediately. The efficient ones get finance, those that are not, don't. Besides, I'd be perfectly capable of doing this, and I've talked it over with so and so" And he feels very content with himself.

Where's the conflict here? Where's this list of efficient and not so efficient medications? Who compiles it? Is there a fixed parameter to evaluate with? Naturally, here we have the beginning of the hustle bustle concerning the

conflict of interests, as the minister on duty, or their secretary or the sub-general director are presented with lists that exert their own bias. The great conflict we have in biomedicine as far as I'm concerned is (naturally we won't discuss the fact more data is needed) that all the data we handle regarding the issue being addressed today; medical progress and health outcomes, is tremendously difficulty. I think it's an issue that should always feature in the context you expressed so well, but I would like to refocus this part.

Finally, I'd like to comment on the following. Perhaps there's someone who doesn't belong to the sector or who doesn't know it well, but I would like to make the following affirmation so that there's no mistake, as some of the comments made could have lead some to believe otherwise; but let's not fool ourselves, the pharmaceutical sector is highly regulated by the Government. It's the most regulated sector in existence. It appears that in trying to regulate things more, we're not going anywhere. I think this is a message that should be loud and clear, because just maybe, someone who doesn't know it well could think this was some mad house and that what's needed is an iron fist. The need to govern with an iron fist and that more data is given is provided are two of the usual 'requirements' in neophyte politics that takes everyone six months to realise this possibility doesn't exist.

Carlos Alonso

This morning we've been concentrating on that which seems to nearly always be the centre of conversations: deciding who the 'goodies' are and who the 'baddies' are. One side is good and the other is bad. This is easy to do in discussions, but I really don't think it's this way. I'm actually not a great defender of the pharmaceutical industry regarding its innovative ability, but I am when it comes to the fact it's the only one capable of development which at the same time is research.

Apart from this, I just want to make one last reference to what Juan Bigorra said which worries me, and that is that the pharmaceutical industry, at least in Spain and Europe, less so in USA, have bad press, and this is data. In the theory of communication, what others think, is data. They could be wrong, however what we can't say is that what they affirm is subjective and therefore does not constitute data; it is. I don't know what the pharmaceutical industry has to do to change what seems to be true. What the pharmaceutical industry can't do

however, is say that everyone else is wrong. This is data, and as such forms part of the perception society has. The bad press the industry has and the perception people have are objective data; we've seen it clearly this morning, and it can't be denied. I could have plenty of reasons to say that many are wrong in their understanding of the role of the industry. However we can't deny that in many respects the social perception is a correct one, and we have to accept this fact.

We have created two subtle contrapositions between the pharmaceutical industry as the baddies and research and science as goodies, or rather the researchers as goodies. This dichotomy is unsustainable, and isn't true, because the way science is structured today (and there's a lot of specific studies to support this.), it's being shown that the appearance of a piece of data is more important than a confirmed fact. Fernando García Alonso remarked on it fairly crudely, but there's a lot of truth behind it. For example, what appears in the press and sometimes contained in the conclusions of many a scientific paper regarding the discovery of the keys to old age, after observing the sixty changes in the expressions of certain genes are the keys to unlocking the mystery of ageing, has nothing to do with science, but rather with how it appears or what scientists want there to appear as prominent or important.

There are currently three distinctive phases in scientific development: academic science, post-academic science and industrial science. You could say that academic science was the only branch of science around till about twenty years ago, but now, at least in biomedicine, there's hardly a sign of academic science. Those who study the morphogenesis of a Drosophila wing claim it's an academic activity. I say, however, that their science is not purely academic, because they sell the morphogenesis of the wing saying that the genes have implications regarding the formation of extremities in mammals. This, no longer pure academic science, has passed on immediately to the post-academic phase because what they're after is greater financing, not from the industry but from the State, seeing as the studies are going to have repercussions in the formation of extremities in mammals, and hence in man, where potential malformations will be able to be prevented.

This is a cultural change that the industry can't be blamed for. There are those that easily say the pharmaceutical industry is behind this pressuring the scientists and having science go from academic to post-academic. Possibly the pharmaceutical industry do have some influence but it's certainly not the only

influence exerted here. It's a cultural change that's emerging without us being terribly aware of it. The most serious problem as far as I'm concerned is that academic science is becoming industrialised science, so that we end up only with industrial science. In other words, that field of science which is committed to analysing certain phenomena which in the short term will lead to the development of products of immediate use.

I believe there have been certain elements present in our discussions that could lead to confusion. The graphs presented by Fernando García Alonso and others this morning, I could present them myself without even having a single piece of data on the subject. It's simply a reflection of what's actually happening in science. Currently, almost all diseases, or rather neurodegenerative, cardiovascular diseases and cancer, are not only polygenetic, but are also what is known as polyepigenetic. Therefore, thinking there's a direct relationship between a drug and one of these polygenetic, polyepigenetic or polyphenotypical ones, is a grave mistake. Not that long ago, infectious diseases could be treated with antibiotics, but most diseases today have gone completely beyond the genotype, phenotype and pathology relationship. This relationship has been completely broken, and the sooner we acknowledge this phenomena the sooner we'll advance. So, why are we absolutely stuck as said by Fernando García Alonso? It's because we still continue with the old paradigm of the linear relationship between genes, phenotype and pathology. This doesn't exist anymore. Consequently, when we want to develop a drug that'll cure a particular pathology that doesn't involve mutations, but rather is dependant on the body as a whole into which it's introduced, the cells form part of the social whole that we must take into account; the epigenesis. We know perfectly now that a protein in a neuron can have a particular function, but that same protein in the pancreas can have an entirely different effect. Now we want to move into the field of pharmacogenetics where we say, "I know this gene produces this protein that has this function, so then this protein could be used as a drug." Fine in the neuron, but what about in the glia, the hepatocyte, the fibroblast, etc,? If we don't have a radical change in conceptual paradigms, the pharmaceutical industry is going to collapse, and in fact is collapsing. That's why I say that I could present these graphs without even having specific data, because the curves are derived from a clear logic which comes from the dynamics of science.

It was clearly stated this morning that "medicine doesn't cure but rather looks after". But, isn't looking after curing? If we think purely along the lines of biology, and if the drug doesn't eradicate the disease, it doesn't then cure. However, what does 'cure' mean? Looking after is evidently, as we now know, directly related to curing, and curing is directly related to looking after. We're using terminology that is quite outdated. We have to take a giant leap into a new world, that if I knew where it was, I wouldn't be here today but rather in the front lines of decision making of that place. I at least get a glimpse of it, and I think there are ways to think other than these that could probably be more efficient, and definitely in greater harmony with science.

Therefore, be aware of referring to good and bad, because we'll only get wrapped up in a debate that'll get us nowhere. What does worry me is that the pharmaceutical industry does in fact have bad press. They ought to know why they have it, and they should have the nobility to remedy the situation. I have a very good experience with a pharmaceutical company here in Catalonia, and so know what I'm talking about. I wouldn't have been able to do what I'm doing now (which could have important repercussions) without their financial support. To reiterate, the pharmaceutical industry knows why it has bad press. I could give you much information, but it's not warranted, and with this, I conclude.

María Casado

Picking up from where Laporte left off; the system is to blame. This information is quite interesting. I do like the idea of putting the blame on someone. But, who supports the system? Who does it benefit? Why do we ask for more responsibility on behalf of the pharmaceutical industry? Why do we ask for more responsibility when talking about Health than when talking about other areas? These are the questions that have been posed and continue without answers.

This is why the contribution made by Victoria Camps concerning responsibility is really very interesting, and the reason why we're here. What I feel is somewhat lacking in this field is a different type of protocol. I'm referring to a certain type of morale-lifting, self-regulation. These used to be referred to as deontological protocols. The idea of deontological protocols have bad press, but they could be of use, especially now that there seems to be a

reawakening of ethical protocols in companies, whereby the ethical code of a company or industry gives it a certain identity and expresses what its intentions are. It could simply be like whitewashing, but its use could also have some interesting advantages.

I was questioning here whether this could be a good way to modify public attitudes and perceptions, and consequently the rest. Anyhow, the idea of deontological codes always seem to imply conflict and once again lead to the idea of further regulation, and there's plenty of it as it is, but interesting nonetheless.

With a legal background, I'm quite used to having lawyers accuse us in two ways: on the one hand of regulating everything and binding everyone up so they can't move; and on the other hand, of not giving a specific answer. These accusations are actually the very reverse of the problems we have. "Let's have the law system tell us what we have to do." Let the data tell us what we have to value and what the status of things are. Ihering used to say that this is a particular complex in which there was the search for the father figure, someone who'd tell us what we have to do. I would encourage you all to meditate this.

I'd like to briefly make a small remark concerning the Third World. I'd recommend you read the translation of the article about AIDS, pharmaceuticals, patents and medications in the most recent edition of *Quark*. When I previously spoke about our responsibility towards the Third World, this was the context I was referring to. They were not the sort of words that put your conscious to rest.

Victoria Camps

I really appreciated your contribution, especially coming from a lawyer, because whenever you talk about self-regulation, jurists generally fume. It's like self-regulation is something that's too liberal and doesn't work. I'm glad Maria Casado has captured my thoughts on this. I didn't use the word, but it's what I thought. I feel that self-regulation, keeping in mind what's been said here about commissions that don't work, doesn't just involve deontological protocols. It consists in organisations and commission that work, as protocols in themselves are of little use, but if the protocols have a structure behind them that will follow them up, then you have resources that'll allow society to ask for accountability. It's aware that there are principles it has to adhere to, and at the

same time, there are commissions (partly, ethical committees carry out these functions) that supervise, control and require accountability. I think it's a way to share the responsibility adequately in the future.

Vladimir de Semir

I really feel out of place here, because the journalist - the communicator - is the authentic fish out of water in the history of all this, as I intend on demonstrating. Some of you are already aware of it, and others I won't be able to convince, but I'm not sure if now is the right time to introduce this, as I don't want to introduce new issues and leave others up in the air.

Actually, this fish-out-of-water idea really is nonsense, because as I've been hearing in the course of the morning, inevitably and unfortunately, the messenger, the media, despite what Victoria Camps said, is intervening more and more, in fact to the point where it invades every part of our lives.

Where once we spoke about poor patient education and if the doctor is a factotum and does this, that or the other; this is now a thing of the past. Doctors in seeing their patients know they've lost this. They do still have much credibility before their patients, but the patient now comes loaded with information read in papers, downloaded from the Internet and says: "Listen, I think I'm suffering from this." What the doctor does then is base him or herself on journalistic evidence to work out what's true and what's not, and try to break some preconceived ideas, I won't say received, in the perception people have. I believe now, at this moment in time (Camí mentioned this at the beginning), there's a rather perverse phenomena pervading our society in the omnipresence of the media, and I'm not sure if we've stopped altogether to realise; the media is basically the forger of society's on-going education.

Independently of each other, and more so in a public like we have here today, we ought to have our own sources, look for our own magazines, papers, etc. because we have to realise that regarding the on going general education and health education, who has the pan by the handle, is the media.

The second part of this that I'd like to briefly mention is, if we're ready to take on this role, and independently to that, if there are other factors that intervene in the interrelating interests of the media and of the large groups these days that could possibly make you doubt as to whether you were producing good or bad information quite aside from if you're educating the

public or not. We also have new communicational factors at play here, as some of you will have heard me say, in seeing we've gone from *cogito ergo sum (I think therefore I am)* to *I communicate therefore I am.*

These days, if you want to be somebody you have to communicate, you have to be on television, in the media, etc. Obviously, this is a brief discourse taken from my experience as a journalist, and where I auto-criticise our role in regards to all those things being discussed now.

It's evident that public perception, which could also be ours regarding these problems, comes very conditioned, more so each time, by the media. I don't think anyone could dispute that. There's a certain 'deculturalisation' in this sense, a type of misinformation, because paradoxically, as you well know, when there's excess information (and type of information, seeing as we're all doing this *fast-thinking* that Bordieu mentions), it creates a vicious circle which I don't think we've all stopped long enough to think about. In this respect, were being sucked into the dangerous vortex of the misinformation and deculturalisation of the general public. I'm obviously speaking in general, but this is more pertinent in the area being discussed today, because health, our concerns, our more or less hypochondria when faced with disease, etc., are all burning issues.

Therefore, independently to all other interests mentioned today, there's the emotional element with which the media play, because we don't talk about the sensationalism in the news so much anymore, but rather 'spectacularisation', and obviously any sort of scientific or medical news would lend itself easily to this spectacularisation by the media. Victoria Camps repeated that it's the responsibility of the scientific world to inform. When in the eighties some of us started out here, we had to lure the scientists from their ivory towers so that they would collaborate with the journalists. Nowadays, it seems things have changed for the better, and for the worse, because the reference centres, which are largely the scientific publications, are also joining the perverse game played by the media of transmitting information to society using us, the general media, by sending us information, press releases that induce this spectacularisation of science. Not now, but we could see press releases from the prestigious *Nature* magazine, the filler text as we know it in media circles, that uses us to gain prestige amongst the general public. This could (some argue instinctively) pervert the selection of information published by the very

magazine. I'll give you a rather amusing example, at least I thought it was. Does it make any sense that Nature should publish that the gene for infidelity, longevity or whatever has been discovered, and then, it seems, everyone else does too, on their front page, or in five or six columns (depending on the type of publication)? This is media carnage; we should think about, and so should the scientific world, the sort of influence the transmission of this could have.

I'm going to make my one last point, even though I didn't come especially to criticise the pharmaceutical industry. This communicational game has also changed the role of journalists with modern means for both better and worse. Once upon a time, and we've all seen it in the movies, the journalist would go out with his hat and his card – Humphrey Bogart – and he'd go out into the street in search for his story and he'd bring it in. Nowadays, one doesn't need to do that. You sit at your desk, you have your computer, you have two hundred emails, two hundred press releases. There's Merck invading you on one side and Novartis on the other, and another and facts from somewhere else too, and your problem is a society of knowledge; what do I give them? Well, I choose according to what my company likes the most, which is to create emotion and spectacularity in society. Therefore, even the most rigorous journalists are falling for the infidelity gene. The small piece of criticism I'd like to make regarding the pharmaceutical industry, perhaps not so much here, but more so in the United States, is that they seem to have also discovered this means of communication. The Prozac case is famous, and I don't know if any of you here are involved with it. This case is already famous in the United States where a *best-seller* book, promoted by the pharmaceutical industry, was used to create a need for a drug that was about to be launched; and hence the media game. This is one example, but I do have more which involve good practice and not conflicts of interests. But everyone plays this media game and searches for public emotion, everyone, from *Nature* magazine to the pharmaceutical industry, politicians, etc.

Fernando de Andrés

It's comfortable to blame the system. In fact I think it's the second most comfortable after blaming the pharmaceutical industry, generally speaking.

What I'd like to say is that there's a difference between who controls and who 'does'. Sometimes there are sections of society that have been given the

exclusive task to control and not so much 'do', and yet, it should 'do'. The industry, naturally, does many things, and we can't fault them in doing them well from their point of view. If they answer their own questions with their own research, I think it's their right to do so. The other thing is if they are our questions.

Where I would like to go with this is that society could probably take some initiative, or seek out its own questions, which is obvious, and answer them in other ways. Naturally, I could be wrong, but it seems the way society goes about financing it's research is by waiting around for suggestions, in other words, nice projects that meet certain methodological criteria and maybe match current priorities. They are financed or they stop being financed. One has to wait, that by chance, someone comes up with something relevant to be researched.

Perhaps a more efficient way could be through organisation who are specialised in what the famous unanswered questions are, and who then go about answering them. Organisations that specialise in research like they have in the United States, which we all know examples of. I don't see it as a scandal that public organisations give over some of their questions to private organisations to be researched, but in any case, these should come up with their own questions.

One thing is to control, in other words, ensure that they are carried out correctly and under the most rigorous of conditions, and the other is to look at what we need in accordance with our doubts as to what should be our priorities and our behaviour in relation to health. To this point, health related matters are receptive but not very creative, especially when talking about medications, whereby practically all medications are obviously on the market because the industries ask for them. But it hasn't occurred to anyone that we could need something and then propose that it be commercialised. Examples do exist. The most notable being the abortive pill that Parliament requested be introduced into the market. This is a good example, but as a general rule, we wait for private initiative to produce what it wants and then, at most, it's evaluated.

I don't think we can criticise others, because they do their work. We should do our work, which doesn't only consist in regulating. Going back to the idea of regulating, I'm not sure that by regulating more we'd get better results. Regulation depends a lot on ideology and the difference is clear between the

FDA and European regulators such as the European Drug Agency; it's a rather fiery battle that I believe will finally be won by FDA. I don't know quite why, but that's my prediction.

The FDA often requires that the old criteria of quality, safety and efficiency be met, but they only require efficiency, when possible, compared to a placebo. For example, if a drug shows efficiency superior to that of a placebo, as a general rule the FDA will approve the product. The issue the Europeans have with this is that there's not enough to go by if compared only with a placebo. We'd have to compare it with a placebo, depending on the case, but also fundamentally with an active ingredient, with the standards used today. If it gives at least the same results, then it has a right to be commercialised, if they're superior, not only does it have commercial rights but an almost moral obligation to be. This has been completely answered by the industries, as it's almost logical, and we don't know where it's going lead to, but this demonstrates that regulation is no easy task.

However, if someone came along and posed those questions that the industry doesn't answer on its own, they'd be no need to obligate or regulate them, etc. What can the regulating agencies do? Seeing as the subject of the information society has inevitably emerged, I believe that the least that should be required of them, which they could actually be doing more and more, is to be transparent. Which is to say, the criteria could be subjective, but if it's at least public, things change somewhat, and the reader can form his or her own opinion. This way, sometimes the industry has a better chance of reaching the public because interestingly enough, regulating agencies now, and more so in the past, have a strong tendency to be secretive. We have to counteract the no-information transmitted by the agencies with the yes-information (maybe information wouldn't be here the right word), the yes-data provided by the pharmaceutical industry.

If the criteria were at least clear, then perhaps additional regulation would be different. This is why for example, the press releases of some of the better-known agencies, are literally useless. They approve a drug and then give it a definition, which looks more like a crossword puzzle, and then see if anyone guesses what it's for. Well, it's just wonderful. There's an endless list of numbers and guesses, one after the other, and yet, no one quite knows what's actually been approved. There are some medications approved by the FDA, well defined

according to different criteria that may have been rejected in Europe for reasons unknown due to, in theory, industrial confidentiality. A balance has to be maintained, but what's obvious and perhaps before feeling the need to over-regulate (everything could be over-regulated, and those with the task to regulate, love to regulate), it's to consider increasing transparency. Besides, from what's been said here today, it'll be inevitable. If someone doesn't provide data, someone else will for them, and this is certainly dangerous.

Joan-Ramon Laporte

I'd like to refer to what's been recently said. First, Vladimir de Semir, I know of a more resounding case related to the creation of need. It's the three-year campaign by Merck regarding cholesterol and how bad it was for you. This was in the form of medical supplements in La Vanguardia with photos of fried eggs and so forth, paid for by Merck, saying that cholesterol had to be fought. At that stage statins weren't on the market, but they had them and were about to release them. This has been one of the most extraordinary cases there has ever been.

The other issue is that of regulation or self-regulation, I think we probably all agree that regulation has its limits and self-regulation is a fact of life. Everyone self-regulates, and I agree with it in general terms. However, let's look at a particular experience had by the pharmaceutical industry. It's the only one I know of where self-regulation was evaluated after its implementation, when the deontological code on drug information of the British pharmaceutical industry was approved six or seven years ago. This code was approved by the same industry and was given approval also by the British Ministry of Health, the Medical Association, the Pharmaceutical Association and others. After four years, the 'before' and 'after' effect was compared in terms of publicity and complaints regarding giving biased information about products, and what they saw was that it hadn't had any effect. Laboratories that breached the code changed, but the number of breaches and the magnitude of these remained unchanged. So from here we have the pervading idea amongst the people, who notice these things in Europe, at least from a more medical point of view, that what you read in medical magazines regarding the self-regulation of corporations (and I refer here to both industrial and professional, which I'll be talking about now), is probably a rather limited means for improving conduct.

A very important political debate took place at the College of Physicians in Barcelona a few months ago. It was the first College of Physicians in Spain to approach this issue: Doctors and prescriptions, deontological relationships with the pharmaceutical industry. There was much agreement on many aspects. Some concluded that the system was to blame, as it's also been said here; in this case it was the managers of ICS (*Institut Català de la Salut*) and others. There was an issue that we managed to include into the discussion: Should doctors accept gifts from the pharmaceutical industry? The president of the College of Physicians said it wasn't all too clear. The most that was achieved was the formation of a committee to discuss what would be acceptable. We're not talking about pens here, or a colourful note pad, etc. We're talking about trips to exotic destinations, paying off the mortgage, the El Corte Inglés catalogue, and other extraordinary things offered by some laboratories. It's a question of this, and it's linked to corporativism.

Secondly, the medical knowledge required to work in general practice doubles every ten or twelve years according to recent studies carried out by the Massachusetts Medical Society and the State of Oregon in the United States. There's a European study, German in fact, that tends to indicate the same thing in Europe. This doesn't mean that between the age of 25, when one finishes the degree, and 65-75 years of age, when one retires that their medical knowledge would've increased 12-16 fold. Who is responsible for on-going education for doctors? I can assure you that it's not them, in most cases. Perhaps the system that employs them? Doctors are the ones that decide what basic resources is bought for the system, in the form of diagnostic tests and so forth, but the system that employs them doesn't consider on-going education a priority. An information company, for example IBM, spends about 18% of its annual budget on on-going education for its staff. Who much does ICS spend, how much does it spend on INSALUD (*National Health System*)? It wouldn't even amount to 1%. The pharmaceutical industry fills this gap.

We're not controlling the gifts issue. I once said to a pharmaceutical laboratory director: "You believe that doctors are to be given gifts. Would you accept it the buying director of your company was receiving gifts from your providers of basic resources?" He said, "That's a good argument" So why should they be accepted by the public health system paid for by public taxes?

I'm not blaming the system, I'm just pointing out a few issues that I feel should be improved on urgently. This is a system that prioritises quantity (in

other words, see all who come to you), and certainly not the quality of the service. This is truly how it is, probably because it just follows political priorities.

There's another issue: I think that the pharmaceutical industry performs a certain role, a role directed at the consumer decision-maker, which is the prescribing medical officer who is at the same time a prisoner. Over lunch we were saying that the average salary of a general practitioner in Spain wouldn't make it easy for him or her to buy themselves a 30.000 peseta book, and least of all pay the inscription to a congress and the flight there. The pharmaceutical industry fills the gap that the health system doesn't.

This is to say, there's a medical officer out there that no one trains in any on-going manner, no one informs whether the new drug, the new diagnostic test, etc., is better or worse; and the makers of medical technology, be they medications or diagnostic tests, fill the gap created by a lack of material resources, salaries and information.

In Spain particularly, for each new approved molecule, the regulating agencies allow the commercialisation of up to 15, 17 or 20 different brands, which is what's now happening with omeprazole. In most European countries, they only allow 2 or 3 brands of the same medication. What does it mean when they approve 17 to 20 brands? It means that there are 17 to 20 drug representatives that are going to promote their new drug to the prescriber. Of course, this results in Spain being one of the countries where new drug sales grow faster, percentage wise, than any other country. Great Britain is where they grow the least, because it's where the least number of copies are authorised (only partly, because there are also other reasons).

There's another more general issue. We live in a society that's going through a tremendous ideological crisis in many respects. However, there's one I believe to be rather important, and which many of our thinkers today stress. We've started the century with the promise that technological progress is going to save us from many a thing. And as it was said this morning, there are still those who think, quoting Fernando García Alonso, that we're going to control cancer, ischaemic heart diseases, etc. in the near future. What we do know is that medical technology has brought about good and bad. We can't say it's been an entire failure. Our lives have changed, but we constantly see that with every new innovation, it widens the gap between those who have access to it,

understand it and know how to work it, and those that don't. Look at the Internet, for example, and its number of users according to countries and continents.

When we were talking about innovation and the discrepancy between the figures presented by the two speakers at the beginning of the conference, I thought of a document by the main pharmaceutical multinationals (I think it was the top six or seven that Pep Torrent quoted), that said that if up to now, in the last seven or eight years, there's been an average of 0.5 more or less innovative molecules released into the market per laboratory per year, the intention is to release 3 or 4 new apparently innovative molecules a year starting between 2001 and 2003, let's say 2002.

This is creating a vicious circle, one that needs cooling down. There's a growing rate of innovation, but it's innovation that we're not sure will produce health benefits; or if it's commercial and vague in it's benefits. If captopril had come out onto the market today, it would have died within months because of the undesirable side effects it had initially. Now, when a laboratory releases a new molecule, what it wants is a *blockbuster* that'll sell a thousand million dollars worth in its first year. These are the sorts of records they're after, so hence the enormous amount of aggressiveness to release new products onto the market. There's no rest, particularly the rest so needed by the medical world, the world of medical attention, and not just scientific, to direct all this well, to see how it works, to learn how to use it, to develop opinions on it, and to compare it.

Medications are removed from the market which are not bad, or not worse than any others. What happens is that they produce the sort of adverse reactions so rare that they could attract the press, and so, to look after the laboratory's image, they're removed. Those of us involved in pharmacology know quite a few of these examples, and yet the market is full of products which cause greater harm, but because we're talking about myocardial infarction, GIT haemorrhages and other things people apparently find "normal", then the blame usually goes to the patient rather than the medication. This is the difference. It's all regulated by this same market that continually gives itself new challenges when it comes to speed and apparent innovation. Is there anyway to cool this down? It would do medicine and innovation much good, as I don't think we have time to digest it all.

To illustrate the point using a non-pharmaceutical example: In Spain, a sixteen-year-old boy can go to a shop and buy himself a motorbike, if he has the money earned from his part-time job, or his family are giving it to him or he's worked hard for it, or whatever. However, he needs a driver's licence and I don't how many other things to drive a car, which is actually safer. How can this be? They say: "If you place restrictions on the motorbike factories all these people will be out of work" Who are the victims? They are the youth, and especially the youth from the lower classes who have less of an idea of what is self-control, of what a life is worth, of what it takes to look after oneself. This is social innovation digestion, in this case, industrial. We live in a society where there's no self-regulation for these sorts of things, because while declaring the contrary, they don't place the values which are theoretically superior, like health and education, as top priorities.

Therefore, adopting a constructive position here, when it comes to medications from what I've observed down through history as great proposals regarding pharmaceutical policies, the best, most rational, the one I think most successfully encompasses the problems and the issues is the one launched by the World Health Organisation in the seventies regarding essential medications, and, it's not a limited list for poor countries. It's not what one laboratory representative once said to me: "Of course you can't buy Ferraris for poor countries, you have to give them useful cars, four-wheel-drives and so forth; but for rich countries – anything." No, no, no. This policy does not say which medications they are to use, but rather it says three things:

a) It limits the number of necessary ones to ensure a good supply.

b) It limits to ensure that the medical officer knows the medication well.

c) This policy on essential medications helps identify research priorities.

In my hospital we have a limited list of three hundred and seventy something medications (generic constituents). The number of pharmaceutical forms is somewhat larger, and doctors have the right to prescribe something not on the list, but it doesn't amount to more than 0.2% of total hospital spending at the end of the year. This is to say that needs are covered, and yet it's a complex hospital. Why though? Because there's an effort made regarding information and education, even so, it remains rather chaotic. How can it not be if it's not limited? Why isn't it stopped? An issue not usually referred to is

that knowledge occupies space in people's minds. It's not true this idea that knowledge doesn't occupy space. The superfluous occupies space and distracts us from the important issues.

Vicente Ortún

I've been taking note of those things that have been answered, and there are two that I think no one as answered yet. I'll focus on them, but before I do, I'd like to respond to the last thing Joan-Ramon Laporte said by saying it has an easy answer. A doctor may know 25 or 30 medications, but the information society allows you to install a Vademecum, a pharmacology guide, much like the one he made, into a computer. I'm not talking about training or changing medical attitudes, which appears to be more difficult. We're talking about doctors consulting, whether via sign or symptom, via whatever, a guide. I see this as an opportunity for the information society to do something that'll improve this situation.

I'll refer briefly to the two unchecked items I have. Ángel Puyol spoke about quality of life related to health and made reference to utilitarians, economists, etc. Even though it's a familiar subject, I'd like to dedicate some time to it. Medications and health services in general, what do they produce? Quantity and quality of life. How do we measure quality of life? It depends on what you want to achieve. The measurement of quality of life for a clinician is very different to the measurement used by a philosopher or an economist. For a clinician, psychometric measures usually work well; criteria of validity, reliability, etc. are valid. For an economist, another set of measurements have to be used, originally these were the years of life adjusted to quality of life, and indeed the measures for quality of life incorporate values.

Obviously, quality of life is subjective; it has many dimensions and depends on how you view young and old, those who are worse and those who are better, those who could improve more and those who'd improve less. The answers here are found in research. The researches have developed years of life adjusted to quality of life, but ultimately the answer continues to lie in politics, because the fundamental problem is how one society can collectively express its values and establish priorities. There's work here for everyone, for the 'qualitologists' and for those that measure quality of life, and in finding a better process for social decision-making. Individual decision-making isn't a problem, it's just

you and your money and you do what you want, but it's not so clear when speaking of a group.

The other issue I wanted to address will be briefer still. The 'how' of public intervention. There are a few issues to consider here the first being a network of rules. The rules of a society are not the formal ones; it's not the Law as such. That's the least of it. The rules are formal and informal, and societies are their own set of rules, formal and informal, as well as their own control mechanisms. In the case of professionals, most of the protocols are unwritten. They're not deontological codes. What a profession considers unacceptable is met by various sanctioning mechanisms: ostracism, reward, and eponymous, none of which are written anywhere. The values and the hopes shared within a profession are not written anywhere, and yet are very important.

Regarding the 'how' of the matter, there are lots of issues. I'll only address the first one, the how of public intervention. Knowing that we depend on who we were yesterday and who we are today, we have to collect all those things that don't work, and know it, and better them. The first thing that doesn't work is democracy. Where there's a greater focus on extension rather than on thoroughness. How do you improve the democracy in health? With transparency. It's not acceptable that you're offered utilisation-cost data by American and English hospitals and yet not access this data concerning Spanish hospitals. It's the same situation regarding the consumption of pharmaceuticals, adverse reaction to certain medications, and bacterial resistance rates. Therefore the solution is quite easy. First, transparency, as we don't have it. Transparency helps us be more efficient and democratic. We have much more data than information and, as you said in your presentation, more information than knowledge.

Regina Revilla

I'll be very brief because mine is a background related comment. We've been listening to so many things that it would be impossible to answer each point made here, as each was a rich contribution. What I've been left with from today's meeting is firstly, that the problem we're dealing with here is so complex, it requires so many people, so much knowledge, there are so many decisions to be made, and so many, let's say, guilty and responsible parties, those that perform and those that don't, etc., that we should conclude after the

meeting today that the subject has to be approached with great depth, because this is very serious. I think health is a very serious issue and the relationship brought together by the object of today's meeting, progress in health or healthcare and the pharmaceutical industry, are very important indeed. The perception we've seen is had, even of the companies we represent here today (and I think these have been selected from a number of companies because of their better image) is not good. The criticisms have been very tough. We'll have to meditate on that to see what can be done to change that perception, if indeed it's true, and if it's not true, look at changing our behaviour and what we contribute to society, but we must do something to have things go differently. I'd like to express my appreciation for this type of debate. I believe there's now need for a change. Various meetings have been mentioned: Joan-Ramon Laporte has just mentioned an important one. The other day we were also in one on ethics and business held by the European Society of Ethics; Paloma was also at one were the subject was one we've been trying to develop on the ethics of prescription, etc. From many different perspectives, a lot of us here are worried about something that isn't working as it should, and at least those of us who are here, want it to change somehow and get ahead. When I see the clock tick on it truly saddens me, because the debate becomes richer as more issues are brought to the surface and there's less time to address them. I would ask that in all the issues we've been looking at, that we could, at least partially, resolve. See how we could address them from a multi-sector perspective, and even a multi-approach one, with all sorts of opinions, thoughts, conditions and positions in favour and against, like the two that have brought us here today.

Jesús Conill

I was about to retire from today, but I would like to highlight something along the lines of what Victoria Camps and María Casado have said. There are some important aspects: we shouldn't confuse deontology and ethics. I simply wanted to make that known. Nor is it enough to stop at protocols and restrictions. I believe examples have come to the fore that demonstrate that the idea of self-regulation and so forth, is a more positive and purposeful position.

Secondly, when I mentioned the importance of the data, Vicente Ortún confirmed it and know I'd like to touch upon this. From what I know, comparatively speaking in Spain, they are quite precarious. The first

responsibility involves actually having the data, not too solve anything, as just having the data is enough. I wasn't going to refer to the political aspect regarding solving this problem, as said by Fernando García Alonso. What then, if we don't have the basic information available that tells us what we consume, what we spend, what percentage do we dispose of, and then one says one things, the other says another, and so then, we can't make any responsible decisions. This is the second point I wanted to make.

The third point, which I think is terribly important but won't go into depth, is implicit in the contributions of many today, but especially that of Joan-Ramon Laporte. I believe it's a deep and open subject. As he said, how can this economic war vicious circle in which we find ourselves be moderated? How can it be moderated or cooled down in the times we find ourselves in the pharmaceutical industry, in the fierce competition between Europe and the United States? Should we regulate more if at all? We do have examples. We used to have a lot of regulation, but it was quite deficient. What sort of regulation is needed to help Europe resist the competitiveness with the United States? If there's a type of regulation that would prohibit competition, they'll simply say: "I can't work with that". This is a future scenario that we should reflect on.

Joan Bigorra

I'd like to refer to the question posed by Carlos Alonso regarding why the industry suffers from bad press. Obviously I don't have the answer, but two factors do occur to me. One is the lack of transparency. I believe that the pharmaceutical industry is not a very transparent one. It is improving, but historically speaking it hasn't been. The other factor, in my opinion, is due to a certain neglect in objectivity regarding the health implications and repercussions of its contribution. The industry has gone to great lengths to release a medication onto the market. It has managed to register it, a price, it has launched it, but in many cases it hasn't followed it up in the evaluation process to measure its impact in the various dimensions (technical, patient satisfaction and quality of life and economical).

In order to be constructive, I think debates such as these put neurons to work in finding a better way. I feel we have a great deal of data, because every time a doctor uses a medication, it generates data, but whether that data is put into objective terms or not is quite another thing. Maybe the data is collected

but only in mind, in intention, in what is expected of the medication, and when the patient comes back, in the perception of what's happened. The challenge comes in making information out of the data, and knowledge from that information. This would be the only way to introduce greater information if we were to have another similar debate in the near future. This can be done. In fact, in the United Kingdom for example, there are databases with more than four million patients that are followed up for ten years, Canada has its experience and Catalonia has a centre that makes this sort of information available in Vic.

It's a matter of putting in the resources and a question of institutions and industry working together to generate this sort of information, which is what I believe society expects from us. For this to happen we have to break away from a certain myth. The myth of controlled clinical trials. It's been said here that the controlled clinical trials are the golden rule. I'm a clinical pharmacologist by profession and so know that clinical trials have their limitations. There are different levels of classified evidence. It seems like when we move away from the first level classification and go to the second level, we don't value it so much, and down from there all is promotion and information of little value. If we really want to gather information about medications, I think we have to de-myth the ideas surrounding clinical trials and work also with the rest of the different levels of evidence, applying them the best possible way.

Margarita Boladeras

I'd like to highlight the fact that all social agents indeed work in a system, with system dynamics, stressing within that the dynamic aspects, and therefore, its changing nature, especially today.

I think the current dilemma is: Are we using these processes of change, the information society, globalisation, etc., to highlight deficiencies, dysfunctions and perversions or do we try to use them to improve and eliminate or solve problems? I definitely think that the communication society can be just one more instrument in the hands of manipulators, giving rise not to information but rather misinformation, chaos, etc. However, it can also be an instrument whereby relationships between the various social agents and institutions can be improved and made more flexible. In other words, apart from enjoying the

communication between myself and a friend in the States or Japan, the relationship would be more fluid between institutions for example, between companies, between companies and institutions, between the Government and all the other social agents.

I feel it very advantageous in this respect, following along the lines of Fernando de Andrés, where perhaps we should leave behind talks of intervention, regulation and legislation and focus on dialogue, communication and see what the problems are and how we can solve them.

I think this confrontation between companies and public should be resolved. Society needs companies and needs elements of co-ordination, cohesion and institutionalisation which come through public routes. What is not sustainable is that each side goes his own way. I believe that everyone, all social agents and the State too, should concern themselves more with organising, stimulating, co-ordination and attempts to solve problems, rather than controlling bureaucratically (as I call it) in such a way that, as we all know from the beginning, it ends up generating more problems than it solves.

I know this is thwart with problems and I'm not sure what specific measures can be taken to change direction, but I believe we should think about alternatives. Apart from critical type of analyses, as done here today, we should look for alternatives, and I think those alternatives can come in various forms and levels. I feel today we have already started to close the distance between university and private enterprise for example. I'm trying to collaborate with companies, and this, which is nothing really, just a drop in the ocean, could be the way, as long as there's the transparency spoken about.

In this context, I believe I'm in total agreement with Ortún; some of the problems come from a certain deficiency in the democratic system. This is why I talk about transparency, the need for transparency, the need to talk about real problems and look for appropriate actions and collaborations that will overcome problems.

Carles Vallvé

I'm just going to be brief. I've been thinking all along that I'll have to be brief because what I have to say is quite below the level of this meeting. I'm used to working with the basics and with things I can touch with my hands. I was waiting before the meeting that someone would come forth and introduce

a particular issue dealing with medical progress and the pharmaceutical industry. I'm absolutely amazed that no one has addressed this issue. Fernando de Andrés was about to start on the subject. When Vladimir de Semir spoke, I was sure he was going to. Anyhow, I will talk about Viagra. Have the marketing department of the creators of Viagra discovered a new disease? Have they invented cavernous bodies, for example? I wonder if this molecule was developed in a university or a pharmaceutical laboratory, if the profits generated will create more employment or not, or if the gentleman suffering from impotence should instead get himself off to the psychiatrist, where he really needs to go. I really am amazed that this issue hasn't been addressed. I'd be grateful if someone could give me a reason for this.

Paloma Fernández Cano

I have to acknowledge my thanks to Joan-Ramon Laporte regarding his mention of the cholesterol campaign, because it's an increasingly recurring element found in drug information. It's also related to what Carles Vallvé has just said.

I believe that in the history of pharmacology, the pharmaceutical industry has been very successful in bringing medications into our realm, but not so much, neither the industry nor the entire health system, when it comes to benefiting a society susceptible to these advances, which are continually added to the therapeutic arsenal. There are now a number of diseases or risk factors that are not adequately treated. We do have knowledge about these, even though you could say a lot of uncertainty also, but overall we are gaining terrain over them, and yet, the knowledge gained is not being applied. Cholesterol being a clear example, we think of how many people suffer from dyslipaemia and are not being adequately treated. Like this one, we could name a number of diseases: hypertension, osteoporosis and many more.

What happens in this situation? This is where the media intervenes. I believe that the most efficient way to remedy this social information deficit is through the use of the media, without a doubt. I also think it's the riskiest way as there are certain risks attached to this method. Nonetheless, in the health system as we know it today, with two-minute appointments with the doctor mentioned before, or even five or seven minutes, it's difficult in that time to give much of an explanation about risk factors or disease to the patient, not to mention a particular high risk population or whole general population.

Therefore, I believe the media can play a useful role here. I think it's perfectly legitimate, and not only legitimate but beneficial for society for there to be campaigns that educate the public about certain diseases, otherwise society wouldn't have access to this sort of information. Fortunately, this information is becoming more and more available everywhere, and always thanks to the work of the media in diffusing it. I believe that it's not so much a question of whether a campaign of this type, which is totally legitimate and beneficial, is carried out or not, but rather what approach should be used.

For the very reason of risk and all the problems it can generate; deception, hypochondria, etc., it's precisely these reasons that we have to carry this out with the utmost accuracy and care. This doesn't mean we shouldn't do this, but rather quite the opposite.

Xavier Carné

Using a parable. When I was younger and studying medicine, we'd do the rounds with the professor who wore a long white coat. He'd have a disease before him and he'd say: "This gentleman, as you will observe, has short eyebrows. This, dear friend, take note, is leprosy, treated with such and such because that's what my experience tells me".

Then when I was a little older I was told that this 'my experience' thing doesn't take you anywhere. They told me about the scientific method that could also be used by doctors, and that there were nine or ten levels of evidence too. The highest level was clinical trial and the ones that followed gradually lessened in validity. Everyone knows about it these days, even the doorperson at my apartment talks to me about evidence. She's a very respectable person, but not highly educated. We talk about her son's illness, where she gets her information from the papers, *El País*, *La Vanguardia*, Vladimir de Semir, her sister's internet and so on. How are we going to fix this? With the Pharmaceutical Index put together by Dr. Laporte, that includes 365 medications which are virtually the same as those published in the WHO's list of essential medications? Now get this, the last version of the list put out by WHO contains 305 medications. In the AIDS section there's only one medication – zidovudine. The reason given is that the rest are very expensive, and what has to be done with poor people (not in those words) using means of cost-effectiveness, the only thing that can be done is to try and reduce

mother-to-child transmissions, because everything else is a lost cause. This is what the latest list of essential medications put out by WHO says.

With the type of access we all have to the Internet and the panorama as explained by Vladimir de Semir, we can't afford to play around with information, limiting, structuring and organising it. The information given must be of quality and then, as Bigorra said, medicine based on evidence has to be 'de-mythed', or in other words, we have to take the myth out of clinical trials. It has to be said to all of you that clinical trials give an overview of the population, but that people are ill individually. Perhaps that individual man is on the right hand side of the curve, and maybe for that other man, the information contained in *Nature* is totally useless and needs to see someone for advice.

In some way, this reminds me of that professor that would base himself on his experience. Perhaps we've swung too far on the pendulum. It's a reflection and a parable.

Vladimir de Semir

The thing about the pendulum is quite to the point, as of course, I was rather quick before in being so brief. Regarding the pendulum, we've gone from one extreme of there not being any available information and having to go looking for it (and I think this was both good and bad, because there has to be information), to the other extreme where there's excessive amounts of information and where one type of information takes precedence over the rest. This is, obviously, a serious problem.

A statement was made before which I link to the media and which made me think. It was said, and everyone made a gesture of acquiescence, that more power means greater responsibility. I've applied this to the media and to the powers that be, and I think certainly more responsibility, but also a greater opportunity for irresponsibility, and obviously quite powerfully. For example, the media and multimedia groups wield a great amount of power and they create a certain reality in society. Let's not forget that we're creating reality. Reality is not necessarily truth, but that created through the media, and there's no one to control it. Well, except simply the interests of the large groups which are, forgive the repetition, increasingly merging and where we journalists are becoming facilitators of contents, filling space and curtailing, sorry, I mean

capturing the public's attention,… and if I may, curtailing social knowledge and critical thinking, and I shall finish with that.

Jordi Camí

In answer to the question posed by Carles Vallvé regarding Viagra, I have a hypothesis, which is only relevant to our society. Due to cultural and environmental factors, intimate, loving and sexual relationships have undergone some decline. I'm referring exclusively to heterosexual relationships here. I believe that Viagra is a sign of social progress. I don't think it's any medical progress, but indeed social progress, because most of Gauss' curve shows that when heterosexual relationships are had, she (I don't know to what point the analysis can be seen as more feminist or chauvinist, or neither) wants more time and he wants greater rapidness. Whatever the case may be, Viagra, with all its undesirable side effects, danger and price, etc., has managed to give him a little more time. Therefore, if I were to ask something of the pharmaceutical industry (not in terms of medical progress, but rather the more frivolous context of social progress that I'm referring to) it would be to hasten the discovery of a drug that will, at least in terms of harmony, come closer to the above mentioned in, let's say, the simple mechanics.

Fernando García Alonso

Of everything that's been said, there's something that stands out for me, perhaps for having finished earlier in the piece. What's drawn my attention the most (it was playing on my mind before, but now it's been completely reaffirmed) in what's being addressed today, the pharmaceutical industry and medical progress, is that we have a basic lack of information, I'm sorry to say.

We have, in theory, a lot of data regarding medications and their consumption as spoken about today. Since the seventies up to the present, we have data on consumption. We have an abundance of information that could fill pages and computers, but this information doesn't tell us a thing except what we spend in medications. There have been legions of researchers, some present here today, and at times even myself, that have tried to extrapolate a number of things from data concerning the consumption of medications. In my opinion, it's one of the most futile investigations that we've ever become involved with. Really, the type of data we have here in Spain on the consumption of medications is only good for adjusting the expense accounts

and saying that we've spent more than we should. In this vortex which is the madness of handling this data, we always seem to be faced with headings like "There has been a reduction in spending on medications in Galicia thanks to new management policies." You then look into this and see that the rate in the last year was 12.3% compared to the 12.9% of the year before, and in relation to the annual average, 10.7%. In other words, it's an absolutely political way of handling data, totally repulsive in some cases, as the data is used as is most convenient.

The other data hasn't contributed in the slightest towards knowing more about our therapeutic reality and medical progress, if there's been any. The data is simply there to tell us what we've spent, and for political use by the Government or by the opposition, for whoever it's most advantageous, and always in quite a demagogic way, which is quite pathetic. I sincerely believe that between the politicians (neither between those in Government nor opposition) there has never been even the slightest morality in the use of data. They've always been used in the most pathetic of ways.

As far as I'm concerned, the message is quite clear. In reference to what we're discussing today in the context of Spain, a greater effort should be made to obtain more information along the lines Juan Bigorra was talking about and encompassing what was said regarding clinical trials. We need a significant methodological overhaul. We need the information society, but we need to previously ensure all our doctors are computerised. In my understanding of things, while we continue to lack an information network for doctors, we'll continue to run on shortage of information and we'll find ourselves, as I've done myself, in a situation of having to speculate. I shall limit myself to this issue to facilitate things.

Xavier Peris

The truth is that, at this moment, there's a lot to reply to from the position of the pharmaceutical industry, and in the course of the afternoon a number of reasons have come to light that make the criticisms of society towards the system, and in there the pharmaceutical industry, understandable.

Faced with the impossibility of being able to reply to everything, I have taken notes and I'd be sincerely happy to deal with many, if not most of them, from Salvat, where I work. In any case, at the end of this meeting I'll leave my

business card with my contact details to anyone who wishes to continue with these issues, as I find them very pertinent.

I'll be leaving this meeting grateful for the opportunity to partake in it, and truly satisfied with the time spent with all of you. It's quite refreshing to get away from the office, breaking away from routine and from obligation, despite the feeling of getting involved in more work. I do think it's positive, and the most rewarding part is being able to go back to the office and continue to reflect on all this. I don't consider this to be a digression but rather a path towards progress, just simply progress, and then perhaps towards medical progress.

Nonetheless, there are some issues I should like to reply to. There are some things that when you consider the future are tremendously worrying, the model, the system, and there are those (Joan-Ramon Laporte mentioned this) that attempt to regulate the system and namely the pharmaceutical industry. I believe this was noted down before, however, I really don't think there's another industry subject to such levels of regulation and pressure than the pharmaceutical one. Therefore my question is not whether we have to regulate or what do we have to regulate, but rather who should regulate. I think I'll leave this question open perhaps, and then in rounding up my talk I could answer it.

Another of the points made this afternoon referred to the resources used up by the pharmaceutical sector, and that many of them (both papers include this from clearly different perspectives) are not fully profited from. The only thing I'd like to say to that is that I don't think it's subject to criticism. Jesús said this, and I'd like to reiterate that it's not subject to criticism. This is why I was saying this morning that it's a high-risk industry. You have to be brave to invest a large amount of resources without any guarantee of benefits, unlike other economic and business sectors, where there's a clear return. There has to be a strong vocational element in the pharmaceutical industry to consider investing in a health project, when you really don't know how far it'll take you.

Carlos Alonso was perhaps putting forth something more. The pharmaceutical industry has bad press, and we should know why. Then what's the pharmaceutical industry going to do about it. I'd like to humbly affirm (I believe these to be personal opinions and perhaps one in the context of company director), that perhaps there is an answer to why a good like medications have bad press. We purchase most things with excitement and

anticipation: the flat, the car, the suit, and food, but not medications. I think this is the fundamental reason behind the bad press of medications and the pharmaceutical industry, with some exceptions. Evidently, I feel that, from a broader concept of medications, everyone thinks of the investment made in something that is not going to have the repercussions expected from such an investment and such an expense.

What is the pharmaceutical industry going to do? For me, doing something means integrating solutions. Follow the path of greater social collaboration than what's been possible till now. I believe we need greater social integration (as I've expressed at the end of my paper where it's written) where the academia, the consumers, and even the consumer associations are more involved as where political power is much more involved with the pharmaceutical industry. I think there's a way to solve a number of problems.

Above all, I think the pharmaceutical industry is right in much of what they say, even though they sometimes don't express it well, shedding little light on many of the problems. Perhaps some part of the solution lies in the statement about it not all being the pharmaceutical industry's fault. Given I'm here representing the pharmaceutical industry, I sincerely hope I haven't contributed, through my arguments, towards this feeling that we expound on things rather badly.

PARTICIPANTS IN THE SEMINAR

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Xavier Peris, General Director of Laboratorios S.A.L.V.A.T.

Moderator: **Jordi Camí,** Director of the Barcelona Municipal Institute for Medical Research.

1. **Carlos Alonso** – Centre for Molecular Biology, Universidad Autónoma de Madrid
2. **Cristina Avendaño** – Spanish Drug Agency
3. **Pere Berga** – Almirall Prodesfarma
4. **Joan Bigorra** – Novartis
5. **Margarita Boladeras** – Faculty of Philosophy, Universidad de Barcelona.
6. **Xavier Carné** – Pharmacology Department, Hospital Clínic de Barcelona
7. **María Casado** – Bioethics and Law Observatory, Parc Científic de Barcelona
8. **Jesús Conill** - Faculty of Philosophy, Universitat de València
9. **Fernando de Andrés** – Faculty of Medicine, Universidad Complutense de Madrid
10. **Vladimir de Semir** – Director of the Scientific Communication Observatory, Universitat Pompeu Fabra de Barcelona
11. **Paloma Fernández** – Merck Sharp & Dohme
12. **Joan-Ramon Laporte** – Clinical Pharmacology Department, Hospital de la Vall d'Hebron de Barcelona
13. **Guillem López** – Dept. Business and Economy, Universitat Pompeu Fabra
14. **Vicenç Navarro** – Dept. Political Science, Universitat Pompeu Fabra
15. **Vicente Ortún** – Dept. Business and Economy, Universitat Pompeu Fabra
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