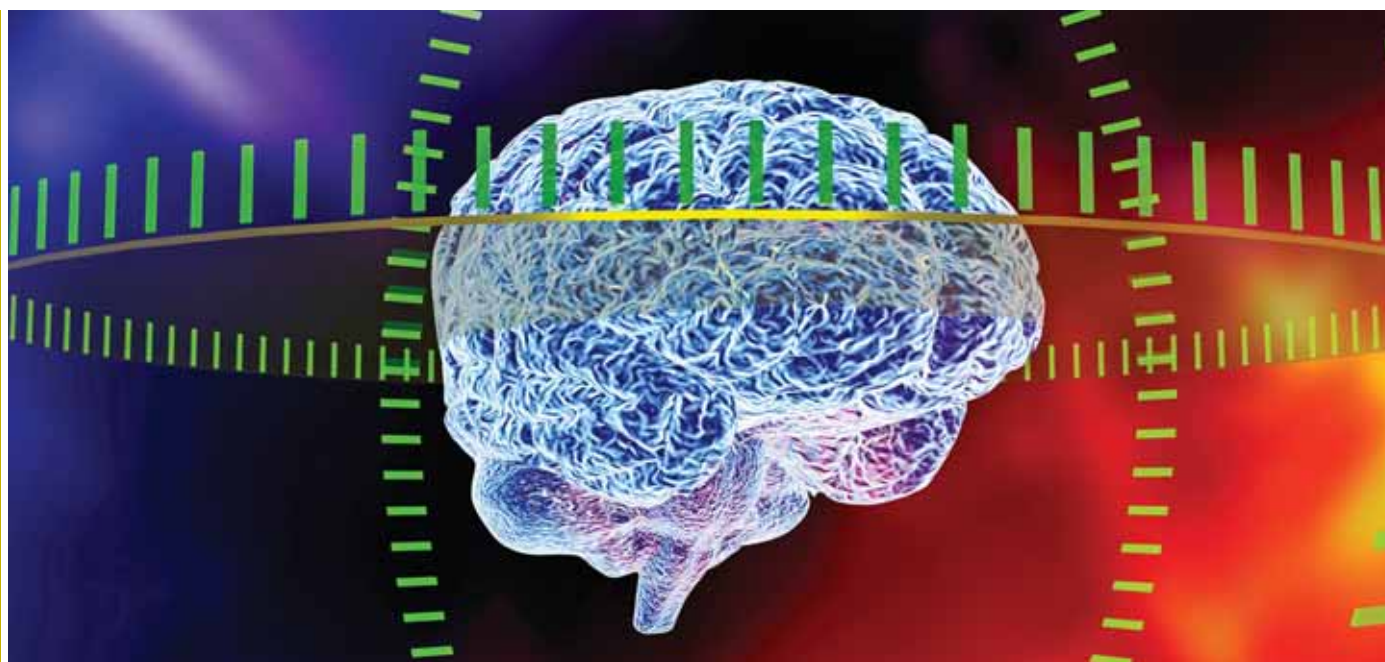


# BRAIN RESEARCH

## A PRIORITY FOR EUROPE





## EUROPEAN BRAIN COUNCIL

THE EUROPEAN BRAIN COUNCIL (EBC) IS A COORDINATING COUNCIL FORMED BY EUROPEAN ORGANISATIONS IN NEUROLOGY, NEUROSURGERY, PSYCHIATRY, BASIC BRAIN RESEARCH (NEUROSCIENCE), AS WELL AS PATIENT ORGANISATIONS AND INDUSTRY.

It is a unique structure that therefore encompasses a vast network of patients, doctors and scientists, working in partnership with the medical devices and pharmaceutical industries. The EBC's comprehensive scope makes it eminently suited to working closely with the European Commission, the European Parliament and the World Health Organization (WHO), as well as other decision-making bodies.

The EBC is determined to eliminate the discrepancy between the huge impact of brain diseases and the implications of understanding normal brain function on the one hand, and the modest financial and time resources allocated to brain research, teaching and the care of brain diseases on the other.

***The mission of the EBC is to promote brain research in Europe and to improve the quality of life of those affected by brain diseases.***

# BRAIN DISEASES – THE FACTS

- The burden of brain diseases in Europe is approximately twice that of cancer <sup>[13]</sup>
- Cancer and brain research received roughly the same amount of funding in Europe in 2005 – €4 billion, or €9 per capita <sup>[13]</sup>
- In the same year, the USA spent around €14.5 billion on brain research, or €48 per capita <sup>[13]</sup>
- Over the next 20 years, the number of people suffering from brain diseases could grow by as much as 20% <sup>[17]</sup>
- Migraine is one of the most prevalent brain diseases in Europe, affecting 41 million people in 2004 <sup>[17]</sup>
- Alzheimer's disease, the most common cause of dementia, affects 1 in 20 people over the age of 65, and as the population ages the number of cases is set to grow <sup>[20]</sup>
- Parkinson's disease affects 1.2 million people in Europe, a number which is also set to grow as the population ages <sup>[17]</sup>
- By 2020, major depression is predicted to account for the second highest burden of disease worldwide, after ischaemic heart disease <sup>[6]</sup>

## EXECUTIVE SUMMARY

BRAIN DISEASES ACCOUNT FOR 35% OF THE BURDEN OF ALL DISEASE IN EUROPE, AT A COST OF €386 BILLION PER YEAR.

As the population ages, that burden is set to grow. Public funding of brain research in Europe amounts to 0.2%, and industry funding to 0.8%, of the annual cost of brain diseases. If Europe is to meet the challenge of brain disease, it needs to invest more in brain research, and to

promote greater collaboration between countries, as well as greater collaboration between industry, academia and patient organisations. Brain research has been specifically identified in the EU's Seventh Framework Programme, FP7, which will run from 2007 to 2013. In order to show what can be achieved with increased resources, the EBC has developed a Consensus Document on European Brain Research. In this document, brain research is described under 45 main headings, each spanning from a human disorder to its basic mechanisms. We suggest that the document serves as a foundation for the development of national plans for brain research, so that these can be coordinated with that of the EU and with those of other countries.

The present document summarises three publications produced by the EBC since 2005: Cost of Disorders of the Brain in Europe, Resource Allocation for Brain Research in Europe and Consensus Document on European Brain Research. Anyone wishing to read these documents in full can find them at:

<http://www.europeanbraincouncil.org/publications/>



Over the next 20 years, the number of people suffering from brain diseases could grow by as much as 20% <sup>[13]</sup>



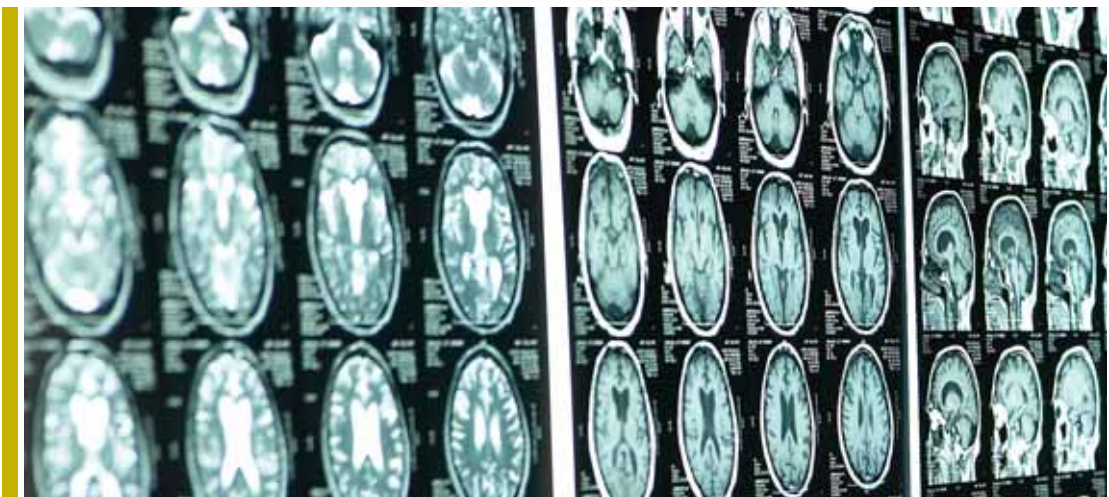
## BACKGROUND

BRAIN RESEARCH IS ALL RESEARCH – BOTH BASIC AND CLINICAL – PERTAINING TO THE CENTRAL AND PERIPHERAL NERVOUS SYSTEMS AND THEIR DISEASES.

It is also called basic and clinical neuroscience. Brain diseases are all those disorders that affect the central and peripheral nervous systems, including neurological and psychiatric diseases, half of all traumatic injury and half of all congenital abnormalities that cause disability. The EBC

has adopted these definitions in an attempt to unify the various disciplines whose interest is the brain, the spinal cord and the peripheral nerves.

Over the last few decades brain research has advanced dramatically. Our knowledge of the normal brain has progressed and many common and chronic diseases, for which there was formerly no treatment, can now be treated more or less effectively.



# BURDEN OF BRAIN DISEASES

## BRAIN DISEASES ARE A MAJOR PUBLIC HEALTH PROBLEM IN EUROPE AND BEYOND.

Using measures accepted by the WHO [1], in 2003 the EBC calculated that they account for 35% of the burden of all diseases in Europe [2, see also 3].

An analysis of all epidemiological and health economic studies in Europe, published by the EBC in 2005 and called 'Cost of Disorders of the Brain in Europe' (CDBE), measured the impact of brain diseases differently [4]. It took a holistic view of costs, including healthcare costs, private and public costs outside the medical sector and indirect costs, such as the cost of absenteeism. The analysis found that across 28 European countries with a total population of 466 million, 127 million people or 27% of the population are affected by at least one brain disease. The total cost of brain diseases per year amounts to €386 billion, or €829 per European inhabitant. **Figure 1** [4] shows the 12 most costly brain diseases, as calculated by the CDBE study, together with their prevalence. The study is incomplete; there are gaps in the data and many important diseases were not included. It is important to get a more accurate picture and the EBC is planning to conduct a field study of the cost of brain diseases in Europe, to complement the retrospective findings of the CDBE study.



The burden of brain diseases in Europe is approximately twice that of cancer [13]

The cost and burden of brain disease in Europe are almost double those of cancer, and are set to grow as more and more people live longer than 80 years [5]. The first Global Burden of Disease study [6], published in 1996/7 by the WHO, World Bank and Harvard School of Public Health, predicted marked increases in the burden of non-communicable diseases, and of brain diseases in particular, to the year 2020. Over the next 20 years, the number of people with brain disease could grow by as much as 20%. **Figure 2** compares the research funding, costs and burden due to cancer and brain diseases in Europe, and shows that in terms of funding, brain diseases are given a lower priority than they deserve.

FIGURE 1 [4]: THE 12 MOST COSTLY BRAIN DISEASES IN EUROPE IN 2004

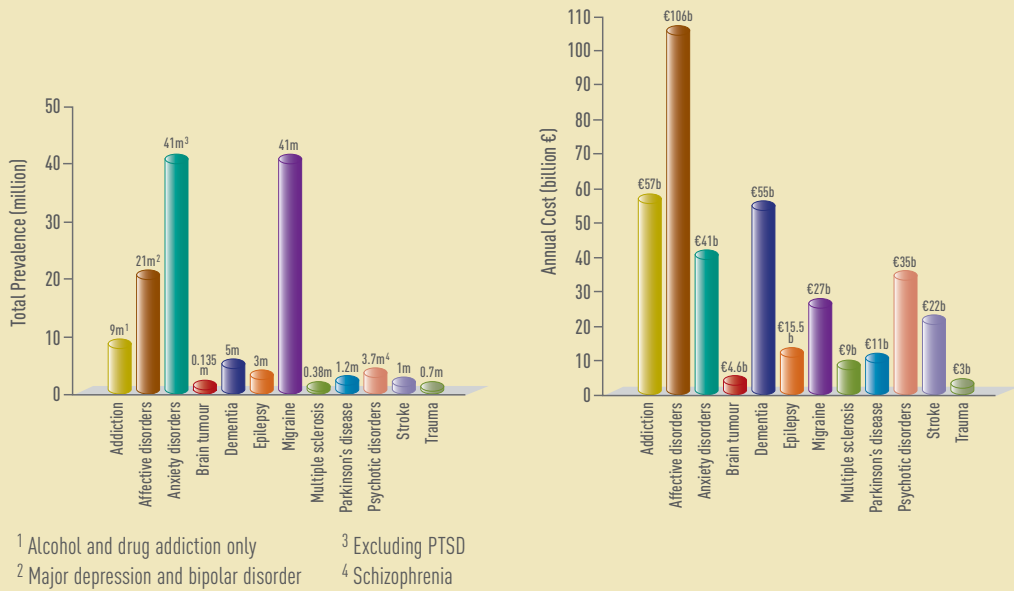
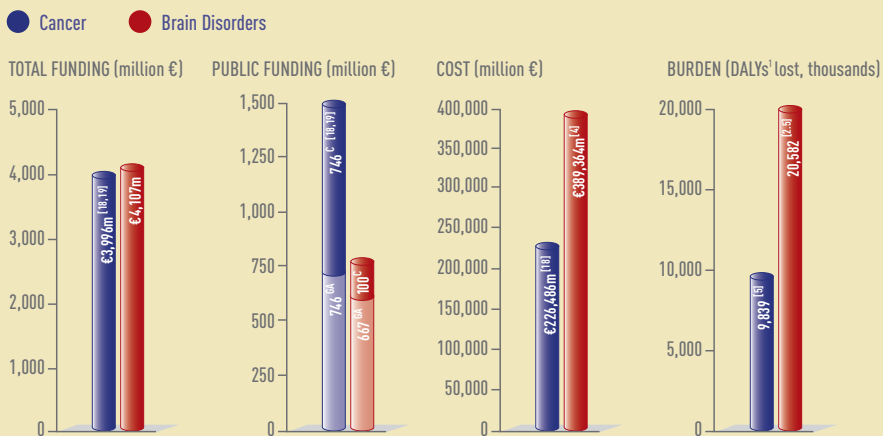


FIGURE 2:  
RESEARCH FUNDING, COSTS AND BURDEN DUE TO CANCER COMPARED TO BRAIN DISORDERS IN EUROPE (2005)



Note: The cost estimates are based on 19 European countries as stated in Wilking et al [18] for comparability. The cancer cost estimate assumes that indirect costs are three times the direct costs, giving a relatively high estimate (see discussion in Wilking et al [18]). The cost estimate is inflated to 2005 values. Death estimates exclude Cyprus.

<sup>1</sup>DALY – Disability Adjusted Life Year. <sup>GA</sup> Government Agency, <sup>C</sup> Charity.

## LOSING THE EDGE IN R&D

HISTORICALLY, THE PHARMACEUTICAL INDUSTRY HAS BEEN ONE OF THE STRENGTHS OF EUROPEAN SCIENCE AND TECHNOLOGY, BUT NOW THE USA IS LEADING THE FIELD.

A survey of the pharmaceutical industry commissioned by the European Commission (EC) in 2004 described the implications of the changing costs of R&D for innovation in the EU as 'potentially alarming' [7]. It highlighted two significant threats:

1) The lower R&D costs in lower income parts of the world and 2) A loss of competitiveness to the USA, despite a cost advantage in undertaking trials in Europe. Europe is losing that cost advantage, however, as India and China are becoming increasingly attractive locations for low cost, large scale clinical trials. Europe is suffering a brain drain to the USA. Meanwhile, for some of the diseases which threaten to become more prevalent as the population ages, a 'pharmaceutical gap' is opening up because there are no effective treatments for them, or because current treatments are inadequate.



Cancer and brain research received roughly the same amount of funding in Europe in 2005 – €4 billion, or €9 per capita [13]



## THE IMPORTANCE OF UNDERSTANDING THE NORMAL BRAIN

The complexity of the brain is such that if we do not understand its integrated functions in health, we cannot hope to disentangle the extra layer of complexity added by disease, or to design therapies to correct it. Studying the normal brain is also very important if we are to understand the behaviour of humans, how we interact with each other and how we adapt to a changing environment – the arrival of the information technology age, for example.

### THE IMPORTANCE OF COMMUNICATION

Language defines humanity, since only human brains are able to produce language, and out of language grew culture. The question of why the brains of other animals – particularly primates – are unable to support language remains unanswered. One theory is that the human brain is uniquely equipped with neural networks which allow it to construct meaning through a hierarchical arrangement of subordinate clauses, obeying the rules of syntax and grammar. These neural networks are shaped by both genes and experience. One of the major discoveries of the last decade, in the language field, was that of the FOXP2 gene in 2001. A point mutation in this gene was found to be linked with a disorder in the KE family, half of whose members had severe articulation difficulties, as well as linguistic and grammatical impairment. Although nonhuman primates such as chimpanzees share the vast majority of human genes, the activity of those genes differs in chimp and human brains – perhaps explaining why language is supported by one and not by the other. Other genes associated with language are sure to be discovered in future, throwing more light on what it is to be human.

A better understanding of the normal brain could lead to the design of environments (e.g. toys, TV) that are more cognitively stimulating for children. It could also influence teaching methods by indicating how the brain receives and retains information best, and therefore how information could most effectively be delivered.

Brain imaging techniques such as functional Magnetic Resonance Imaging (fMRI) are proving extremely useful for studying the normal brain. fMRI detects metabolic and vascular responses that are coupled to neuronal activity. This complex relationship is not yet understood, though it is the subject of intense investigation. When it is understood, it will provide crucial information for interpreting imaging signals, both in health and disease.

## BRAIN RESEARCH: A MULTIDISCIPLINARY EFFORT

### ADVANCES IN BRAIN RESEARCH ARE BEING DRIVEN BY COLLABORATION BETWEEN MANY SCIENTIFIC DISCIPLINES.

For example, basic research on the brain now needs physicists, chemists, computer experts, biologists and doctors. For clinical research, the skills of bioinformaticians and experts in data analysis and database architecture will be required, as well as those of clinicians and basic scientists.

For many of the major brain diseases, researchers lack large, well-characterised patient cohorts who can be followed up over the long term. Such patient populations are crucial for systematic, large-scale, prospective studies.



Migraine is one of the most prevalent brain diseases in Europe, affecting 41 million people in 2004 <sup>[17]</sup>

## A ROLE FOR INDUSTRY

DESPITE THE LOSS OF ITS COMPETITIVE EDGE TO THE USA, EUROPE STILL HAS GREAT RESOURCES, PARTICULARLY IN BRAIN RESEARCH, AND IT POSSESSES FIRST CLASS BIOTECHNOLOGY CLUSTERS WHICH COULD FORM PARTNERSHIPS WITH INDUSTRY TO EXPLOIT NOVEL IDEAS.

In parallel with the search for innovative therapies, four technological areas need to be targeted: 1) New techniques for delivering medicines to the brain and monitoring the fate of these non-invasively over time; 2) Diagnostic tools for brain diseases and for monitoring disease

progression and recovery, particularly brain imaging techniques; 3) Intelligent computers and brain machine interfaces; and 4) Nanotechnology.

In the future, traditional approaches to the treatment of brain disease will give way to personalised, patient-centred medicine for which more complex, combination therapies will be required that affect the course of the disease and provide a wide spectrum of support for the patient [8]. In addition to pharmaceuticals, these therapies may encompass treatments based on stem cells and gene therapy, and will need to include psychological and social support. For pharmaceuticals, the current design of clinical trials and regulatory procedures do not yet fully reflect this trend, but the door has been opened to more radical ideas by the European pharmaceutical directive and the roadmap of the European Agency for the Evaluation of Medicinal Products. The EC's 2004 survey of the pharmaceutical industry [7] made several recommendations to aid this transition, including encouraging more cooperation between the public and private sectors in Europe, as there is in the USA, and improving communication between industry and regulating authorities.

These and other innovations would speed up the journey of a new drug to market and reduce failure along the way, thus bringing down R&D costs and stimulating more innovation in Europe. One initiative with these goals has already been launched. The Innovative Medicines Initiative [9], a cooperation between the EC and the European Federation of Pharmaceutical Industries and Associations, has created a €2billion public-private partnership within FP7 that will tackle the major impediments to drug discovery in five important areas: brain research, cancer, inflammatory disease, metabolic disease and infectious disease.



## A ROLE FOR PATIENTS


OVER THE PAST DECADE  
PATIENT ADVOCACY IN EUROPE  
HAS UNDERGONE ENORMOUS  
POSITIVE CHANGE.

Previously, patient representatives relied on the 'emotional' approach in their attempts to influence policy makers and others, by exposing the burden of pain, trauma and disability which governs their lives. Now, most patient advocates take a professional approach which translates the emotional burden of the disease into objective data on the real cost.


This more clinical approach has much more in common with the public health agenda and the people who manage it. It also harmonises more easily with the approach of medical and scientific experts. Patient groups have become professional lobbyists and some have established offices with permanent staff, to ensure the effectiveness of their activities.



Parkinson's disease affects 1.2 million people in Europe, a number which is also set to grow as the population ages <sup>[17]</sup>



This scenario has been most obvious at the European level, where patient organisations have pursued their aims more and more effectively by working in partnerships. Such alliances have been formed not only between patient advocates for a single disease, but also between national groups representing each illness, who have come together in the European Federation of Neurological Associations (EFNA), for neurological disorders, and the Global Alliance of Mental Illness Advocacy Networks (GAMIAN-Europe), for psychiatric disorders. In turn, these 'super-umbrella' groups are working successfully with political decision-makers, the medical and scientific professions and the pharmaceutical and medical device industries, to promote their cause. EFNA and GAMIAN-Europe are founder members of the EBC.



AT EVERY OPPORTUNITY, POLITICIANS AND CIVIL SERVANTS NOW WORK TOWARDS SYNERGY IN THE RELATIONSHIP BETWEEN SCIENCE AND SOCIETY – A SCENARIO WHICH THE EBC EXEMPLIFIES IN ITS BREADTH OF MEMBERSHIP AND THE SUCCESS OF ITS PARTNERSHIPS.

Already, in a number of European countries, neurological and psychiatric patient groups are forming similar alliances to influence and work with public health authorities at the national level, while National Brain Councils are also being established on the model of the EBC. Patients form an influential lobby in the constituencies of policy makers, who see them as an 'emerging resource' in medicine. At every opportunity, politicians and civil servants now work towards synergy

in the relationship between science and society – a scenario which the EBC exemplifies in its breadth of membership and the success of its partnerships. These developments are already showing a beneficial effect on the historical lack of understanding of the function of the normal brain, as well as on ignorance about the burden that brain diseases impose on society and the vast improvements in diagnosis, prevention and treatment which have come about in recent years.



## ETHICS

THE ESSENCE OF WHAT IT IS TO BE HUMAN LIES IN THE HUMAN BRAIN. IT IS THEREFORE NO WONDER THAT BRAIN RESEARCH RAISES MORE ETHICAL QUESTIONS THAN ANY OTHER BRANCH OF THE LIFE SCIENCES.

Brain research must benefit humanity, not harm it, so guidelines for the ethical application of knowledge about the brain must develop in parallel with the research itself. Those guidelines must be decided by society at large, not by the scientists who conduct the research. Here are just a few examples of the ethical questions that brain research is currently raising:

The definition of 'normal' brain function is changing as our understanding of the brain deepens. That has implications both in terms of defining 'abnormal' behaviour and treating it ('normalising' it) and in terms of envisaging how normal behaviour could be enhanced [10]. It also touches on the question of free will, because a person who is accused of a crime can claim brain disease as a mitigating circumstance. As science provides better diagnostic evaluation, more effective therapies and better predictive power, the way we think about criminal justice will have to change [11].

Patients who are unconscious, comatose or in persistent vegetative state cannot consent to or refuse treatment, or volunteer to take part in research programmes. Living wills and advance directives, in which people specify what treatment they want or do not want in such situations, are increasingly popular, but are not yet legally enforced in most European countries. The patient association Alzheimer Europe is in favour of the use of advance directives among patients with dementia [12], but recognises the inherent difficulties with it – notably, who decides when the patient is no longer able to behave autonomously or to take decisions about his or her future treatment?



Alzheimer's disease, the most common cause of dementia, affects 1 in 20 people over the age of 65, and as the population ages the number of cases is set to grow [20]

## THE NEED FOR FUNDING

IN COLLABORATION WITH THE COMPANY STOCKHOLM HEALTH ECONOMICS (NOW PART OF i3 INNOVUS), THE EBC HAS CONDUCTED THE FIRST EVALUATION OF PRIVATE AND PUBLIC FUNDING OF BRAIN RESEARCH IN EUROPE.

The results of the EU-funded Resource Allocation for Brain Research in Europe (RABRE) project show that total spending on brain research in Europe in 2005 was approximately €4.1 billion, of which €855 million came from the public sector (governments and charities) and

€3.3 billion from industry [13]. Public funding of brain research therefore amounts to 0.2%, and industry funding to 0.8%, of the cost of brain diseases per year. Funding of brain research in Europe is low compared to funding of cancer research, and low compared to funding of brain research in the US. The RABRE results strongly suggest that funding of brain research must be increased in Europe, particularly public funding. The study's authors also predicted that, even using very conservative estimates, increased investment in brain research would bring a high financial return, conceivably within as short a time as ten years.

There are some encouraging signs that the importance of brain diseases is finally becoming recognised. The WHO published its study 'Neurological Disorders: Public Health Challenges' in 2006 [14]. In FP6 (2002-2006), €157 million was allocated for brain research, almost double what was allocated in FP5. This more positive attitude to brain research is further reinforced in FP7 (2007-2013), in which brain research has been specifically mentioned under the Co-operation programme. Furthermore, the Health and Consumer Affairs Directorate of the EC has mental health as a priority area of its 2008 Work Plan [15] and finally, the EU launched its European Pact for Mental Health and Well-being in June 2008 [16].



## CONCLUSIONS AND RECOMMENDATIONS

**BRAIN DISEASES ACCOUNT FOR 35% OF THE BURDEN OF ALL DISEASE IN EUROPE, AT A COST OF €386 BILLION PER YEAR.**

This burden and cost are set to grow as the population ages. Public funding of brain research currently amounts to 0.2%, and industry funding to 0.8%, of the cost of brain diseases per year. In order to meet the challenge of brain disease, the EBC believes that Europe needs to increase investment in brain research, and

promote greater collaboration between countries, as well as greater collaboration between industry, academia and patient organisations.

In recent years, the EU has shown an increasingly positive attitude to brain research. It is now crucial that every nation in Europe follows its example and makes brain research a priority. With the aim of ensuring that research is coordinated across Europe, the EBC has developed a Consensus Document which describes 45 research themes [17]. Each theme contains a proposal for future research, spanning from a specific brain disorder to its basic mechanisms. For example, one is entitled, 'From Alzheimer's disease and other dementias to basic mechanisms of neurodegeneration'; another, 'From addiction and normal pleasure-seeking to animal models, signalling mechanisms and genetics'.



**By 2020, major depression is predicted to account for the second highest burden of disease worldwide, after ischaemic heart disease [6]**

In drawing up this document, the EBC aimed to cover all branches of brain research from a European perspective, while avoiding duplication of national programmes. It set out to obtain the highest possible degree of consensus across Europe, and to apply, for the first time, a bottom-up approach, consulting scientists from academia and industry, as well as clinicians and patient representatives. The Consensus Document should be seen as a guidance document for use by all relevant policy makers, particularly the EC but also other stakeholders including national governments.

In order to help raise awareness of the issues and the possibilities for brain research, the EBC has been fostering the creation of National Brain Councils, a number of which have now been formed or are in the process of being formed. These organisations, while independent of each other and the EBC, are nevertheless aligned in their desire to see greater importance attached to brain research. They share the EBC's view that increasing funding in brain research would bring not only enormous economic benefits, but also inestimable human and social returns.

**THE TIME TO ACT IS NOW.**

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**European Brain Council – Florence Office**

University of Florence  
Department of Pharmacology  
Viale Pieraccini, 6  
50139 Florence, Italy  
Tel: +39 055 436 2098  
Fax: +39 055 427 1280  
[evelyn.sipido@unifi.it](mailto:evelyn.sipido@unifi.it)

**European Brain Council – Brussels Office**

Fondation Universitaire  
11, rue d'Egmont  
B-1000 Brussels, Belgium  
Tel: + 32 (0) 2 513 27 57  
Fax: + 32 (0) 2 513 64 11  
[info@europeanbraincouncil.org](mailto:info@europeanbraincouncil.org)  
[www.europeanbraincouncil.org](http://www.europeanbraincouncil.org)