

28 July 2006

Sir David Cooksey
Cooksey Review Secretariat
H M Treasury, 4th Floor
1, Horseguards Road
London SW1A 2HQ

Dear Sir David,

REVIEW OF UK HEALTH RESEARCH

The British Pharmacological Society (BPS) is pleased to have the opportunity to submit comments on your review of the most effective institutional arrangements for the new single fund for health research.

The BPS is the primary UK learned society for scientists and clinicians involved in the study of drugs and how they work. We have about 2,500 members in academia, industry, the health services, and regulatory authorities. Our members are involved in the full spectrum of pharmacological and clinical pharmacological research, ranging from the basic mechanism of drug action, through clinical trials to pharmacoepidemiology and pharmacovigilance. Our international membership also gives us a global perspective. Our responses to the questions you pose in your letter of 4 May 2006 are below. We are members of the Biosciences Federation, and also support its response.

1. What are the strengths and weaknesses of the MRC and NHS R&D programmes at present? How do each of these support the research and training needs of the NHS, social care, industry and academia? Does more need to be done?

MRC

The MRC has international status for its cutting-edge supported basic research. Its funding of the Laboratory of Molecular Biology in Cambridge alone would be enough to make it internationally renowned. It has made major contributions to translational research e.g. monoclonal antibodies and the confocal microscope, as well as important contributions to clinical research through support for major programmes and funding work on clinical trial design.

One of the greatest strengths of the MRC is that it can make decisions on the funding of scientific research without being unduly influenced by the day-to-day pressures of changing political

priorities. The BPS considers that it is vital that any new funding arrangements should respect the Haldane principle and maintain this arm's length relationship with Ministers. The MRC also has a rigorous peer review system for judging funding applications, and the maintenance of this system is essential to retain confidence in funding decisions. It provides major support for biomedical research response mode funding in the University sector but has recently suffered from under-funding - 20% of applications were funded in 2004 / 5. MRC studentships/fellowships are very important in training researchers and supporting them during the early stages of their careers. MRC participation in the Capacity Building Initiative in Integrative Mammalian Biology (with the BBSRC, HEFCE, SFC, DTI and BPS) will be very important in maintaining the ability of UK academia to work in this area, and its ability to train researchers for industry in an area where the ABPI has identified a major skills shortage (Sustaining the skills pipeline, ABPI, 2005).

NHS R&D

NHS R&D has made important contributions to academic medicine. It allows clinical research of wide application to health care to be supported at a local and regional level. However, its organisation is weak and funds initially destined for research infrastructure have been diverted to support direct patient care. A big problem has been the lack of incentives for NHS Trusts to support research leading to a culture where research is not valued. Also, lack of funds to set up basic laboratory provision has impeded the use of research funds provided by charities. The process of allocation of NHS R&D funding has not appeared as transparent as that of the MRC. Some NHS funded research is of lower quality than MRC funded research. A substantial part of the NHS R&D budget is spent in support of MRC and other projects.

A merger could potentially produce a system that would continue to support world-class basic research but would be able to facilitate experimental medicine and satisfy the needs of industry for epidemiology and post-experience studies.

2. What do you believe are the key scientific and organisational challenges facing health research, and underpinning training, in the UK over the next decade? How might the UK Government best help address those challenges? What do you believe should be the Government's objectives for health research, and why?

Key challenges for health research and training include:

- attracting enough bright young people into academia/clinical research posts, given the relatively poor economic rewards and in some cases working conditions compared with other jobs that need similar intellectual resources.;
- ensuring that medical students have enough exposure to the science underpinning medical practice so that a proportion of them will be attracted to research (Clinical Pharmacology and Therapeutics, one of the few specialities that requires formal training in research, is shrinking. Problem-based learning by medical students has reduced the amount of underpinning science they study, and means that many of them rarely see any clinicians who are involved in research, who otherwise might act as role models);

- increasingly complex legal and ethical governance (e.g. the new COREC form, which discourages research by creating another barrier);
- bringing together people in different disciplines and those doing research at different points of the drug life cycle.

They could be addressed by:

- improving financial rewards and working conditions for academics;
- re-introducing some more underpinning science (e.g. pharmacology) to medical courses;
- reducing the bureaucracy affecting research;
- improving the career structure for academics, including clinical academics;
- as suggested by the Royal College of Physicians, providing opportunities for basic scientists and clinician researchers to train and work together;
- reaffirming the NHS objective of putting 1.5% of its turnover into research.

For the new merged fund, the key scientific issue is likely to be ensuring that all areas of the broad remit of the new body are given appropriate priority. It would be counter productive if more areas were funded yet none or few of them were able to achieve the critical mass to ensure success. In the clinical context there would need to be a balance between regional 'seed corn' funding and centralised centres of excellence. This leads to the organisational challenge of how to distribute the money in the best way to support research, whether to have priority areas for funding or to rely on curiosity driven research proposals, how to select the best scientists and clinicians to support and how to institute metrics to ensure that the money is being spent in a way that makes a difference.

We cannot better the Academy of Medical Sciences statement of the desired objective as '*Generating knowledge through excellent biomedical and clinical research, transferring that knowledge into medical practice and ensuring that UK research is internationally competitive*'.

3. What should be the Government's priorities for health research? Is there anything it should stop doing or funding? What is it not doing or funding that it should do, and, in the absence of further sources of support, what can it lower in order to release the necessary funds?

The maintenance of a powerful and competitive research base with appropriate capacity building and support for outstanding individuals (gifted scientists or clinicians who can identify the important questions and know how to answer them). The efficient translation of this research for the benefit of patients and society.

The Government's health research priorities must not be confined to the short-term, but must include a broader strategic focus. Clearly it is essential to address practical, clinically important problems (e.g. the treatment of leg ulcers), but this must not be at the cost of reductions in the basic biomedical research that will underpin the practical advances of the future. Excellence must be a pre-requisite for funding.

Merging MRC and NHS research funding would allow investigator-led research to be complimented by designated research initiatives in areas of unmet medical need.

4. How should decisions be taken on the balance between the long-term economic and social benefits of a high quality biomedical research base; and the needs for research to improve healthcare and other public services? What is the appropriate balance between public funding for investigator-led and priorities led research? How do we balance funding for basic science, translational science and applied science? Is this something that should vary over time? What mechanisms should be used to make judgments about this balance?

Without a high quality biomedical research base there will be no meaningful research to improve healthcare and other public services. Basic research into the mechanisms of disease and of drug action underpin all other research relating to improving prevention, diagnosis and treatment of disease. It is therefore vital that any new funding arrangements should ensure that sufficient funding is available for basic as well as applied biomedical research. It is understandable that Government should want to focus public funds on its priority areas. However, these priorities are often driven by short-term political expedients, whereas much medical and health services research requires a much longer time-scale. The new funding arrangements must not be subject to the “target-driven” approach taken to NHS service delivery.

The key driver should be the availability of creative ideas, talented researchers and advances in enabling technology. Any top-down prioritisation must take into account scientific feasibility and the input of innovative ideas from the scientific community although it is acknowledged that certain areas (e.g. mental health) are currently neglected. The NHS is currently driven (out of necessity) by short term priorities but would benefit from a longer term perspective.

5. In your experience, how have the results of publicly-funded health research in the UK been used, both in the development of new treatments and to influence / change wider policy and healthcare practices? What lessons can usefully be learned to improve the uptake of advances in science and medicine?

The best single example of practical benefit is probably the monoclonal antibody therapies arising from the work of Milstein *et al* and Winter *et al* at the Laboratory of Molecular Biology. An example of a different kind is the influence of systematic reviews for NICE and the subsequent NICE guidance on prescribing practice.

Many of the targets which the pharmaceutical industry has used to discover new drugs have come from publicly funded research done in the Universities and again this is sometimes many years after the initial scientific discovery (e.g. SRSA work done at the Royal College of Surgeons in the 1960s and 1970s led to leukotriene receptor antagonists for asthma in the 1990s).

Much research does not have immediate deliverables in terms of health care benefit but is part of a body of work that eventually transforms the way we think about a field or disease. It is important to remember that some research has a very long gestation period before healthcare benefits are seen.

6. How might better links be forged between 'basic', translational and applied researchers, working across the whole field of health research, from the laboratory bench to the front line of the NHS? How might better links be forged across disciplines, e.g. with engineers, physicists, and social scientists?

A single health care fund should be able more effectively to support research that crosses traditional boundaries. One danger is the creation of a barrier between healthcare research and everything else. The Society shares with the Biosciences federation and some other bodies a concern for the effects of the proposed changes on the BBSRC. It is very important that full consideration should be given to this in order that no adverse unintended consequences result.

The learned societies have a role to play in linking researchers across the spectrum. They bring together people working in the same discipline in different types of research. BPS scientific meetings for example bring together basic scientists working at the level of investigating disease mechanisms, through applied researchers, clinicians treating patients, those working in regulatory authorities and those working at a pharmacoepidemiological level. The shared discipline means that the scientists share a language, but work at different stages of the drug life cycle and can inform each other's research.

Disciplines like pharmacology and clinical pharmacology, that have excellent links with industrial research, can also be of great benefit by linking all stages of research (as recommended in the Report of the Biosciences Innovation and Growth Team). Consideration should be given to using mechanisms like the RAE to encourage cross-disciplinary working, by providing more recognition and credit for it.

7. How can the Government encourage translation, entrepreneurship and innovation in health research to improve public services in the UK?

Putting a strong culture of healthcare R&D together with a productive interaction with industry is the best way to achieve this. This has already been done successfully by CRT and MRCT. Focussing on pre-competitive areas e.g. predictive toxicology and putting public money together with an industrial consortium could be of value as a stimulus.

The Government needs to ensure that the basic infrastructure for effective research is provided and that there is a sufficient supply of well-educated young people capable of meeting the challenges of biomedical research in the future. In order to attract the right young people, problems of career structures and rewards need to be addressed. Opportunities for interaction between academia and industry need to be facilitated. The ABPI/NHS training scheme for Clinical Pharmacology and Therapeutics is an example of a creative approach to training specialists with an understanding of the needs of both clinical medicine and drug development in industry, and schemes like this should be encouraged as they will facilitate translation, entrepreneurship and innovation.

8. How can UK health research funding be most effectively used to provide the appropriate infrastructure for basic, translational and applied research, whether funded by the UK public sector or other sectors? How can UK health research funding be most effectively used to support the work of NICE, facilitate innovation and collaboration with industry, and address market failures in the application of healthcare?

Resources for local seed corn funding of research would be helpful so long as this could be done without reducing the amount of funding elsewhere. The provision of an infrastructure (the well-found laboratory) so that full advantage could be taken of charity funds would be helpful. The interfacing of the new NHS IT network with research initiatives would maximise the value of this investment. Pharmacogenetic work to improve treatment options with new and existing drugs could combine basic and applied objectives and would interface with NICE. The Clinical Research Networks could be used to facilitate the work of NICE and other decision making.

Methods such as the ABPI/NHS training scheme mentioned above, and the BBSRC's Industrial Partnership grants facilitate translational research. The pharmaceutical industry recently identified serious recruitment problems with *in vivo* pharmacologists and clinical pharmacologists, disciplines they find important in translational research, so the Government could help by funding training posts (Sustaining the skills pipeline, ABPI, 2005). This would also facilitate the work of NICE.

9. What lessons should the UK learn from other countries in making the proposed changes to the institutional arrangements for the funding of health research?

The United States has spent most and has been most productive although not all initiatives have been successful. Most European countries have been much less successful than the UK and many of them have top-heavy, very traditional, systems that make it hard for young researchers to get funded.

It might be more productive to look at those areas within the UK that have been most successful to use as examples of best practice.

10. In implementing the single fund for health research, to what extent should the MRC and DH / NHS R&D be merged or brought together? And to whom should the single, ring-fenced fund be accountable? Please provide reasons and any supporting evidence for your response.

A full merger of healthcare R&D is needed to achieve full benefit of an integrated approach to funding and to ensure the correct balance between response mode funding and therapeutic area initiatives. If the UK is to remain at the forefront of biomedical research, it is very important to ensure that the research budget is not subject to politically driven targets. These are too short-term and change too often to be the basis for sustainable research. This suggests that the new fund should not be directly accountable to the Secretaries of State for Health and Trade and Industry (nor to the Ministers in the devolved regions). A suitable over-arching board or council with strong leadership is needed and should be put in place. The relationships with the DTI and the DH should

be preserved in the new scheme to ensure interdisciplinarity, to recognise the essential nature of the links with the pharmaceutical industry and a degree of ownership by the NHS Trusts.

Overall funding needs to be enhanced not reduced to see the benefit of a merger. It is very important that the amount of money available to fund high standard basic research should not fall. The new structure should ensure that rigorous peer review is in place for all research proposals. Some transitional arrangements are likely to be necessary, as the MRC and the Department of Health have had different structures and different cultures, and they will need some time to adjust to change. It will have to be clear that resources allocated to the new single fund for research cannot be diverted into NHS service provision, as has been the suspicion in the past. Without this assurance, confidence in the fund will be lost.

We are concerned that £300 million seems to have gone missing in the Government statements on the size of the joint annual funding as around £1billion compared with current joint spend of £1.3billion.

11. To what extent does the success of recent innovations in health research (e.g. Clinical Research Networks) and the proposed structures rely on the new Connecting for Health NHS IT system, and to what extent should it do so?

This is a unique opportunity but it has not yet shown it to be successful. The potential benefits and the unique position that the UK may be able to occupy in healthcare research are unquestioned, provided the technical and legal/public confidence obstacles to the use of the data available to the NHS can be overcome.

12. Given that NHS R&D is currently devolved, but that the work of Research Councils is not, how can these functions work best together to maximize the health and economic benefits to the UK?

This is undoubtedly a challenge and there is no easy solution. As mentioned above, an overarching board of some kind may be necessary.

Please contact us if you would like us to enlarge on any of these responses. We are happy for them to be made public.

Yours sincerely,

Professor G Henderson
President

