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LABOUR/MANAGEMENT PROGRAMME

FINANCING INNOVATION IN HEALTH CARE (INCLUDING BIOTECHNOLOGY)

Report on a meeting of management experts held under the OECD Labour/Management Programme

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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(Paris, 27 June 1996)

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FOREWORD

Under the OECD Labour/Management Programme for 1996, a meeting of management experts on "Financing Innovation in Health Care (including Biotechnology)" was held in Paris on 27 June 1996. The meeting was prepared in collaboration with the Business and Industry Advisory Committee to the OECD (BIAC).

Below is an overall report of the discussions of the meeting of experts, prepared by Mr. William Looney, who was designated as General Rapporteur for this activity.

FINAL REPORT ON THE MEETING

by Mr. William Looney
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I. Introduction

The commercial impact of expenditure controls on suppliers of medical goods and services has been obscured by a preference among government policy-makers to evaluate the progress of these controls in the broadest macroeconomic context. Viewed in this manner, initiatives to curtail growth in expenditures do show real evidence of success: despite a strong inducement to spend to meet the demands of their ageing populations, most OECD countries in the past decade have been able to keep the ratio of total health care spending to GDP at a figure below the "crisis" threshold of ten percent.

However, it is important to consider the effect of cost controls from another perspective -- one that carries equal weight in terms of societal value. Specifically, has the progress in controlling health system costs sown the seeds of a long-term decline in the number and range of innovative products introduced into the health care marketplace?

Repeated surveys of private investors have shown that the chief legacy of the tighter cost-containment environment many producers now face in health care is a loss of flexibility in new product pricing. The erosion of price freedom for health care products and services is a deliberate outgrowth of government efforts to manage the supply of such products and services to the patient. It evidences a declining "public interest" commitment in underwriting the success of new product introductions through open-ended policies on coverage and reimbursement.

Hence the commercial justification for expensive investments in research-intensive products has in many cases been weakened. Such attitudes are hardening despite accumulating evidence that the introduction of new innovative products has enhanced productivity and efficiency in the delivery of health services, contributed to lower system financing costs, and yielded progressive improvements in the indicators of quality and convenience most prized by the patient.

It may reasonably be argued that the public interest would be better served by a more supportive mix of policies that recognise the financial burden and lengthy developmental risks borne by inventors. This is a frequent topic of discussion within the biotechnology community as well as in other producer groups. Concern about the long-term climate for health care innovation is evident even in the United States, where new product pricing remains relatively free of government intrusion but still faces intense downside pressure from managed care providers that rely on capitated payment arrangements.

The particular elements of the public policy environment that most concern investors in innovation are:

- the conditions of financing, which in the case of health care are determined by the unique solidarity aspects of public budgets and insurance;

- the porosity of social interactions among private firms and between the private and public sectors, which stimulates the flow of ideas and creates synergies to overcome constraints on the capabilities of individual firms and inventors; and

- regulatory conditions relating to new product approvals, including the length of safety and efficacy review periods as well as the procedures for publicly subsidised coverage and reimbursement.

II. Rationale for the meeting

Growing international interest in the question of how to build a public climate that fosters innovation is also evident in the work of the OECD, where it has emerged as a principal focus of research at the Directorate for Science, Technology and Industry, and particularly within the Unit on Biotechnology. The Business and Industry Advisory Committee to the OECD (BIAC), in a discussion paper submitted to the "High-Level Conference of National Experts on Health Care Reform" held in November 1994, stressed that the need for health expenditure restraint should not be pursued to the extent that it inhibits valuable investments in innovation, a practice which is "fundamental to continuous quality improvement and cost reduction." There was general support for the BIAC position among member country delegations attending the Conference, but no real discussion took place concerning specific strategies that might best accomplish the goal of achieving a balance between these two policy objectives.

Soon after, BIAC proposed to the OECD that a series of informal exchanges between OECD staff and management experts be organised to build on the results of the High-Level Conference. The first such exchange, "Health Care Reforms in Light of Changing Funding, Incentives and Production Patterns", took place on 4-5 May 1995 and included a discussion of the impact of conventional demand-side expenditure controls on health spending as well as the success of new cost-containment strategies based on the application of incentives and other forms of market-based competition.

A principal conclusion of the May 1995 meeting [see OCDE/GD(96)57] was that few OECD governments have an adequate understanding of the impact that health expenditure restraint measures have on the potential for innovation in technology-intensive industries like pharmaceuticals, biotechnology and advanced medical equipment. Hence BIAC sought and obtained an agreement with the OECD Secretariat to organise a second meeting of management experts on 27 June 1996 to focus attention on the special market and financing conditions encountered by innovative producers in health care. Specific objectives of this meeting, which was given the working title "Financing Innovation in Health Care (including Biotechnology)", included:

- assessing the contemporary and long-term competitive climate for innovative sectors like biotechnology, pharmaceuticals and advanced medical devices;

- evaluating the effects of current health care cost-containment measures on prospects for timely development of new technology-intensive products and services; and

- identifying the optimum mix of public policies to promote increased research and development geared to meeting consumer expectations for continued access to breakthrough health technologies.

The date for this one-day meeting was chosen to complement a separate management experts consultation held on 26 June in coordination with staff from the OECD Directorate for Science, Technology and Industry, and which examined general issues involved in financing innovation, from a broader cross-industry perspective.

III. Agenda Item 1: Introduction and main conclusions of the LMP experts meeting on Financing Innovation

The Chairman opened the meeting by noting the existence of a paradox: while the market for health care is dynamic and buoyant due to the impact that innovation has had on medical progress, the social policy arrangements that determine access to health care remain fixed and inflexible. To resolve this paradox, significant changes must be made in the financing structure of health care markets.

One solution that has been advanced is to simply stop further public subsidy support for innovation through a refusal to list new products for medical reimbursement, or by granting a market price that is too low to generate the return needed to recoup development costs. Health care industries in the 27 OECD Member countries are experiencing the full adverse effects of these policies, so a discussion on how public policy reforms can nurture the growth of the innovative enterprise -- the topic to be analysed today -- could not be more timely.

The Rapporteur for the previous day's meeting on “Financing Innovation”, Professor Colin Mason from the University of Southampton, summarised the discussions as consisting of four principal themes. The first was the appropriate role for government in financing innovation, a subject on which there was a divided opinion -- some participants contended that rational economic behaviour dictates that the best or most feasible projects will always find a sponsor from the private market, and that government intervention to support innovation can only distort this process. Others referred to the special characteristics of small businesses, which in most OECD countries provide the bulk of new jobs but without government support might lack the financial resources to cover the risks of new product development.

The second theme focused on strategies to foster innovation. There was a consensus that not enough is known about the exact manner in which intellectual property (IP) protection influences the climate for innovation, particularly in light of the diverse approaches taken by national court systems in defending patent rights. The relationship between IP and innovation was deemed an excellent topic for further intensive research by the OECD.

The third theme consisted of an analysis of the current state of financing mechanisms. It was agreed that reliance on venture capital has faded as a means of covering start-up operational costs, a trend which has created a "financing gap" for innovation precisely at the point where the risk is greatest. A partial solution to this problem has been provided by the intervention of wealthy

individuals or "business angels," who lend their own capital in return for a portion of the venture's equity. Other ideas raised included the increased use of targeted tax credits.

The fourth theme centred on issues linked to the size of the innovative enterprise, with emphasis on the particular needs of large, medium-sized and small companies. OECD research on rates of job creation was cited in making the point that only a small minority of firms grow quickly enough to become major sources of employment. It was agreed that more could be done through the tax and regulatory systems to improve the survival rate of start-up ventures. However, there was also a consensus that medium-sized enterprises are frequently ignored when public policies to promote innovation are being drafted.

IV. Agenda Item 2: New biological knowledge and the potential for innovation

Mr. Mark Cantley presented an overview of economic issues confronting the biotechnology sector and how this relates to the Unit's current research priorities. Referring to the extensive research on health expenditure reform conducted by his colleague, Mr. Jean-Pierre Poullier, Mr. Cantley suggested that it might best be summarised in two words: "incentives work." Government must continue to play a crucial role, however, since the manner in which market incentives are applied will determine whether their ultimate effect from a public policy standpoint is "for better or worse."

Mr. Cantley said the biotechnology sector was both a source of solutions to the goal of improving productivity and efficiency in health care as well as a problem for those policy makers who must make short-term decisions on how to apportion health financing priorities within a limited resource base. Draconian cost-control regimes can inhibit innovation, and there is little doubt that this has its most disproportionate impact on new and emerging areas of innovation in biotechnology; but it is also true that without real cost-control, national health systems that provide the reimbursement for new medicines will eventually become insolvent.

A further difficulty for innovation in biotechnology has been the high level of public concern -- at least in some countries -- about its conjectural risks. This has led to pressure for onerous regulations which can also inhibit research and investment.

Tackling this question effectively depends on the capacity to maintain a climate of public trust. Trust is particularly important in biotechnology, because a substantial portion of the citizenry in Europe believes that investment in biotechnology is environmentally hazardous and ethically imprudent. There is also broad scepticism about the merits of scientific research in general, while public confidence in the institutions that conduct and regulate this research has been diminishing for some time.

A recent book by Newsweek columnist Robert Samuelson, *The Good Life and Its Discontents*, presented United States statistics that reveal how sharp the decline has been: in 1966, some 73% of the public was able to express confidence in medicine as an institution; the equivalent figure for 1994 was only 23%. The Commission of the European Union (EU) is so alarmed at the erosion of support for biotechnology and science in general that it has committed one million ECU's behind a programme to advance public awareness and understanding of the contribution of biotechnology.

The OECD has an important role to play as an intellectual bridge between the national institutions and overall public opinion. The mandate of the Biotechnology Unit is to serve as an honest broker

for governments as well as a source of impartial policy-linked information. The Unit hopes that this information will also serve a larger purpose by stimulating useful internal debates that governments can use to educate their citizens. Ultimately, only education can overcome the shift in attitudes and raise the level of public trust.

The OECD has a long record of work on biotechnology issues dating back to the 1970s. A list of its research efforts includes *Biotechnology: International Trends and Perspectives* (1982); *Biotechnology and Patent Protection* (1985); *Recombinant DNA Safety Considerations* (1986); and *Biotechnology and the Changing Role of Government* (1988). Many individual directorates -- on environment, agriculture, and employment, labour and social affairs, as well as science, technology and industry -- are involved in biotechnology issues. As a result, an Internal Coordination Group for Biotechnology (ICGB) has been established to enhance transparency and promote greater coherence between the biotechnology-related activities pursued by different OECD bodies.

Indeed, as biotechnology moves into ever more areas of application, a correspondingly wider range of policy issues arises. Over the years, OECD research has uncovered no less than 11 different working definitions for biotechnology.

The most pressing areas of inquiry continue to be regulatory, safety and intellectual property issues related to the invention, use and commercialisation of products and services derived through modern biotechnology. In a book published in 1981, *The DNA Story: A Documentary History of Gene Cloning*, Nobel prize-winner James Watson and co-author John Tooze wrote that "politics and politicking preoccupied the first years of the recombinant DNA story, but that phase is fast becoming history."

Unfortunately, that judgement has proved premature.

The Biotechnology Unit is currently working on a wide-ranging study addressing the entire economic case for biotechnology in health care. Publication is planned for 1997. The report will combine case studies with discussion of market and regulatory issues that influence the innovative process in this sector, including the impact of national regulatory regimes on R&D outlays for new biotechnology drugs; the financial context behind the development of national biotech industries in the United States, the United Kingdom and Japan; the role of intellectual property rights in encouraging biotech research; and the human resources implications of new technologies in medicine.

With specific regard to IP, the study presents a special analysis of the changes wrought by Canada's decision to rescind provisions of the Patent Act providing for the grant of compulsory licenses to manufacture or import patented brand-name pharmaceuticals. Our report also analyses regulatory conditions required to encourage development of orphan drugs, which is now the focus of a new initiative by the European Commission.

It has long been the opinion of the OECD that adequate patent protection is an important element in promoting a positive climate for biotechnology investment. A study issued by the OECD in the mid-1980s warned that the state of intellectual property protection in Europe was disadvantageous for industry compared to the and Japan, where conditions were more flexible and transparent in terms of the level of protection provided.

In response to this analysis, the European Commission put forward in October 1988 a proposed Directive on the Protection of Biotechnological Inventions, clarifying certain key issues on patentability and promoting a more harmonised approach to patenting rules. However, eight years later, after political disputes involving the European Parliament and the Council of Ministers, the proposal has still not been adopted.

Another of the Unit's activities concerns the organisation, with volunteer host countries, of workshops on leading-edge biotechnologies related to health care. These combine a commitment to first class scientific exchanges with the opportunity for biotech specialists to discuss relevant public policy issues with national officials.

For example, in November 1993, the German government sponsored an OECD workshop at the Paul Ehrlich Institute in Langen on the environmental safety effects of recombinant vaccines. On 28-30 June 1995, the Unit held a workshop in Ottawa, Canada, in partnership with Health Canada and the Department of Health of the United Kingdom, on the issue of gene delivery systems. Both workshops highlighted the challenge that the emergence of gene therapy poses for the national regulatory process. Many other challenges are imminent as a result of the rapid progress in mapping and sequencing human and other genomes. The common genetic basis of all living systems means that the progress of understanding is no respector of traditional institutional structures, whether these be administrative mandates, industry sectoral divisions, or scientific disciplines.

Discussion and Comments

Participants agreed with the perception that the entire discussion on how best to regulate biotechnology had been thrown into disarray by the multi-disciplinary nature of the science. The challenge to traditional jurisdictional lines posed by genomics, in particular, raises potentially serious problems in defining an adequate level of IP protection to promote innovation as the biotechnology sector moves into this new area of science -- can the traditional patent system survive the genomic revolution?

V. Agenda Item 3: The role of governments in creating incentives to innovation

Professor Henry Grabowski presented a summary of market conditions that make the process of innovation in pharmaceuticals unique.

The industry is today facing a major reorientation in the techniques of drug discovery, which in many aspects has been fuelled by the scientific revolution in biotechnology. Research-based companies are employing drug discovery methods based on anticipatory computer-based designs of disease-bearing molecules rather than through random screening of endless chemical combinations. Many new drugs for cancer and AIDS are being developed using the techniques first used in biotechnological research.

The social benefits to be derived from this new approach to drug discovery are enormous, but reaping the full reward in the form of new cures and treatments depends on a sympathetic public policy climate. Government and the public must recognise that, even with advances in technology, the drug development process is becoming longer and costlier. Clinical development time frames have risen from an average of five years in 1960 to more than nine years today. The

overall process from synthesis to market approval takes well over a decade and costs several hundred million dollars for each new drug introduction.

Duke University is presently contributing to a new research project to identify average costs per new drug from synthesis to market launch and one preliminary estimate is that the price tag has risen to somewhere between $400 to $500 million.

More than the figure itself, the important point to make is that these costs have been rising at a rate much higher than inflation.

Market risk is a key element behind the escalating costs. There are many drugs on the market, practitioner expectations as to the therapeutic performance of new drugs are high, and the chronic diseases that are prevalent today are more resistant to simple biochemical solutions. The practical consequence of these trends is that fewer products are surviving the transition from clinical development to final market approval: in the United States, for example, only one of every four new chemical entities survives to attain a final FDA authorisation for sale.

The conditions facing conventional pharmaceutical manufacturers have also begun to impact the level of innovation in biotechnology. During the 1980s, biotechnology companies had a relatively higher success rate in producing new drugs than conventional pharmaceutical firms. More recently, however, the biotechnology industry's introductions have slowed to a level equivalent to that of their larger pharmaceutical counterparts.

The lagging pace of new drug introductions has potentially significant long-term implications for the profitability of both the pharmaceutical and biotechnology industries. Analysis of the returns on pharmaceutical R&D for successive time cohorts of new drug introductions in the 1980s reveals that the capacity to develop and commercialise a few top-selling products -- those that land within the top 10% of sales revenues -- hold the key to funding future research. Revenues from these "blockbuster" drugs are not only sufficient to allow the company to recoup the fixed costs of R&D for that product; they also cover the fixed costs borne by products that fail to find a large market and thus never earn back what the company spent to develop them.

Government policies are crucial to ameliorating these and other market pressures confronting the pharmaceutical and biotechnology industries. A supportive public policy climate is particularly important to biotech firms due to their high level of dependence on external sources to fund investments in innovative product development. Public policies that combine to push down the prospective rate of return for investments simply means that fewer firms will be able to find partners willing to share their start-up costs.

Adequate patent protection is the most important support that governments can offer to the industry, but the regulatory conditions that must be met before a new drug can be introduced to market are increasingly pivotal as well. The growing interest of governments in requiring evidence of "cost-effectiveness" before a product can be approved for sale is an example of how well-meaning attempts to manage costs can inhibit innovation by placing another hurdle in the way of selling in the open market. Perhaps a better way to resolve the problem of keeping health care costs down without destroying the incentive for industry to innovate is to promote disease management on a capitated, risk-sharing basis.

Mr. Etienne Barral presented the results of a report analysing data on new pharmaceutical product introductions over the past twenty years. The data base consisted of all new chemical and

biological entities introduced to market in the United States, Canada, Europe and Japan between 1975 and 1994. The report classified the 1,061 products surveyed on the basis of two criteria: the level of product internationalisation and the level of product innovation.

The survey found that a direct correlation exists between the regulatory environment for innovation in each country and the number of "breakthrough" products originating there. For example, countries with strict price control regimes -- like France and Italy -- have seen a sharp drop over the 20 year period in the number of breakthrough products discovered and marketed by locally-based manufacturers. Conversely, products that provide no therapeutic advance and consist of a known chemical structure have tended to proliferate in these markets.

Pharmaceuticals classified as being inherently innovative, with both a new chemical structure and evidence of providing clear therapeutic improvement, have won the most rapid acceptance in international markets. Three countries -- the United States, the United Kingdom and Switzerland -- account for two thirds of the top "category A" drugs during the period surveyed; over the past five years that percentage has grown to 87%. The three countries are also considered to have the most positive regulatory climate for R&D.

If there is a single message that emanates from the data in the study, it is that "the future is being paid for by the present." The ability to generate revenues from sales of the successful drugs of today is the only viable method of funding the costly research needed to produce the next generation of breakthrough products.

The danger in pinning hopes on the future is that government policies are cast in the fiscal realities of the present. Increasingly, assessment of the "value" to be derived from access to an individual drug is founded on economic indicators. Even in the case of an unquestionably innovative "category A" product, defining an acceptable price is a highly judgmental task because if the product cannot be compared to existing products because of its high level of innovativeness, then how can governments decide what price is appropriate? This issue is likely to prove particularly troubling to the European Commission, which is struggling to draft a formula to provide a fair compensation for developers of so-called orphan drugs, where the market is by definition quite small.

There are plans to extend this research approach to the biotechnology market, where the impact of public policies on research output and innovative potential is even more pronounced. Many biotechnology firms appear to be vying to develop the same types of products, with an average of three companies competing within the same therapeutic category.

Discussion and Comments

Participants stressed that it was vital to address the perception of government and insurance payers that innovative pharmaceuticals are "budget busters," whose costs exceed their overall value to society. Successful innovative drugs are exposed to much negative publicity because their very innovativeness tends to generate demand, which leads to strains on the financing side. One observer noted that the United States Food and Drug Administration (FDA) was moving to try to regulate industry claims concerning the effectiveness and innovative potential of its products, which if approved would impose yet another hurdle in the path of the time-to-market process.

It was also agreed that industry needed to place more emphasis on the role that multiple therapies, combined with genuine price competition, can play in keeping health care costs down. "Me too"

products have repeatedly served to erode the position of a single market leader, bringing prices down without requiring complex government intervention in the form of price controls.

VI. Agenda Item 4: Evolving business strategies for financing innovation in the health care sector

Dr. Alain Sommer highlighted the special conditions encountered by suppliers of medical services in their efforts to promote the development and use of innovative new technologies. The terms of financing constitute the principal source of risk in the medical services market, and these terms are governed largely by the manner in which governments organise and fund national health insurance systems.

It is important to accept that in nearly all OECD countries, government continues to play the leading role in financing medical innovation, from the academic research phase to clinical adaptation, marketing authorisation and eventual product reimbursement. Third party payers are also important and the trend is for them to follow the lead of government in determining how much they will pay for innovation. Uncertainty about the level of payer support for a new medical product or service creates a "vicious circle" to inhibit the innovative process: uncertainty raises costs, which in turn raises uncertainty, triggering an almost exponential increase in risk.

Government has accentuated the perception of risk by expanding its role in assessing the "value" of an innovation for purposes of reimbursement. This role is eclipsing the many ways in which the public sector provides support for innovative product development, through the underwriting of basic research or by reliance on various forms of fiscal subsidies.

Three conditions are essential to improving the climate for investment in innovative medical services. These are:

- speeding up the time it takes to develop and diffuse innovations, which would therefore lower development costs;

- encouraging risk-taking by those involved in the innovation process in order to overcome the reticence of participants and reduce the risk of failure; and

- making medical innovation projects less opaque and thus more attractive to participation by private investors.

With specific regard to the first objective, governments might wish to develop new regulatory mechanisms that would permit multi-country approvals of new medical service technologies. This would acknowledge what has become a central fact: the market in which such technologies are developed is now a global one. Another promising approach is to facilitate the establishment of global consortia -- on a cross-border, cross-industry basis -- that would share and disperse the development risks of a new medical services technology. The key attribute of such consortia is that more financial and logistical resources can be mobilised, resulting in a lower level of risk for each of the participants.

VII. Agenda Item 5: Innovation in financing

Mr. Ullrich Hoffmeyer discussed how the current desire to promote market-driven competition on the purchasing side of health care can be reconciled with the obligation to preserve the social contract as the central unifying element in the national health systems of most OECD countries. One strategy now being employed by four governments in Europe -- including the Netherlands, Switzerland, Germany and the Czech Republic -- is the incorporation of formal risk-adjustment mechanisms to maintain equity and solidarity as national insurance systems are being deregulated to allow choice for consumers.

Simply defined, risk-adjustment is a mechanism that ensures equity of health insurance coverage regardless of health status, within the framework of a competitive health insurance market. Under a risk-adjustment approach, all insurers in the market pay a portion of the premiums or contributions they collect into a central fund. The relative financial risk of each insurer is calculated by the fund administrator based on a profile incorporating the health risk of each member of each insurance plan. Insurers with a larger proportion of less healthy, high-risk plan members receive from the fund an amount that compensates them for the higher financial risks involved in insuring their members. In effect, insurers with healthier plan members subsidise those with less healthy members, thereby evening out the financial risk.

Risk-adjustment also removes much of the economic incentive that insurers in a competitive market have to "cream-skim" the enrollee pool, through sophisticated risk selection techniques that eliminate the sickest people from enrolment in favour of healthy people. This practice enhances the cream skimmer’s capacity to offer lower rates than those insurers with a more medically diverse membership, compounding irregularities in the market for insurance and presenting the prospect that the sickest people in society will be forced to seek coverage from a few chronically insolvent funds that provide inferior care.

Although derided as a "utopian" concept, the appeal of risk-adjustment is that it provides a countervailing benefit to the structural weaknesses inherent in all types of health systems. In the United States, for example, a risk-adjustment programme would clearly enhance the equity protections that are lacking in what is a predominantly competitive market for insurance; in Europe, however, where insurance is a solidarity-based construct applied by public mandate to cover all citizens, risk-adjustment introduces a measure of competition and consumer choice but with no erosion of the existing commitment to equity.

Risk-adjustment also has much unanticipated value as a source of efficiency and cost savings in the delivery of health care. By allowing for enhanced competition, insurers are able to vie for customers on the basis of lowered premiums and the need to compete on price in turn provides an incentive for the insurer to negotiate better financial terms with providers. The savings created here will pass through the entire health system to lower costs.

In addition, the enhanced capacity to compete should induce greater attention to quality among insurers. Poor levels of customer satisfaction means that enrolees will simply take their business elsewhere. The tendency of risk-adjustment schemes to even out gaps in premiums among individual insurance plans will also force insurers to come up with new strategies to differentiate themselves from the competition, such as enhanced benefit packages.

Mr. Paul Belien continued the discussion with an analysis of the current state of the health care financing reform process in Europe. Despite the enormity and sheer scope of the effort to control

the rise in health care costs, no government in Europe has succeeded in achieving permanent structural changes to lower overall expenditures; costs have risen inexorably at an average rate of 4.1% in the past decade.

Such efforts are indeed doomed to failure because governments insist on retaining an outmoded "pay as you go" approach to financing health care, where deficits in the health care account are balanced with monies from general taxation. Europe's ageing population as well as the enormous cost of developing new cures and treatment technologies ensures that providing even the most basic health care under current financing conditions is going to be unsustainable in the long-term.

The most worrisome aspect of this trend is that the quality of health care obtained by patients is declining even as costs are rising. Waiting lists for necessary surgeries are growing while the capacity of the consumer to exercise choice in access to therapies is being constrained by introduction of practitioner budgets, and other new forms of cost containment aimed at suppressing the supply of care.

A practical solution to the gap between financing and demand is to give the European consumer an incentive to earmark more of his or her own individual resources to meeting the cost of health care. Examples of this approach include medical savings accounts, in which contributions accrue on a tax-free basis until needed to meet a specific medical emergency or to defray the cost of less urgent types of care. Reliance on such fiscal incentives will create a huge pool of capital that can in turn serve as the seed money for the development of new health technologies. Only in this way can Europe move from the perception that health care is a social cost to one that sees health care as a contributor to investment and economic growth.

Embarking on this course will require governments to abandon the post-war tradition of central control over the health care system. If a health care capitalisation scheme is to increase fiscal resources and expand consumer choice, it must be implemented within an administrative framework that is flexible and decentralised. Governments in Europe must end the "quest for mediocrity" that leads them to emulate each others' bureaucracies in strangling market incentives within a web of ever-expanding regulation. Bureaucrats talk endlessly about introducing more competition, but the competition they propose is always "managed" competition, which is regulated from above.

VIII. Conclusions

The Rapporteur summarised the main conclusions of the meeting, noting that all participants had agreed that:

(i) Government has an overt supportive role to play in nurturing a set of essential pre-conditions for a productive innovative process in the health care industry.

These preconditions include a commitment to strong levels of patent protection, covering both products and processes; a generous stance on the reimbursement of clinical trial costs; continued financial aid for fundamental academic research as the seedbed for advanced commercial applications; and a willingness to address the phenomena of "regulatory creep," marked by a slow but inexorable increase in the compliance burden on industry in obtaining necessary market approvals.

(ii) There is a danger that what has been observed as a more constructive and positive approach to patent protection will be marginalized by the addition of new regulatory hurdles imposed as a consequence of the need to limit the dissemination of costly new technologies for public reimbursement.

The prospect that more governments will demand evidence of a technology's cost-effectiveness prior to market launch could compromise the potential that innovation has as a source of cost savings to the health system. The true prospects for an innovative product are often unknown at the time of market launch -- this is why the best test of an innovative success is the breadth of acceptance by the marketplace, over time, under real world rather than prospective market conditions, and in multiple delivery settings.

(iii) While the costs of new drug development are rising, so too is the level of competition for existing products.

Although there are variable estimates as to the precise cost of developing a pharmaceutical from discovery to clinical trials to final market launch, the important point is that costs are rising at a rate well above inflation. With fewer new products being approved for sale, the financing of R&D in pharmaceuticals depends more than ever on the revenue stream from a small number of breakthrough products whose uniqueness as therapies has enabled them to captured a major share of the market. It is important to emphasise, however, that the period of market exclusivity for new pharmaceutical products is increasingly short-lived -- less than three years, on average.

(iv) The uncertainties involved in managing innovative risk are growing worse, and this is not due to financing problems alone but is also founded on a pervasive public scepticism concerning the social merits of scientific investigation in general.

Participants agreed to continue the dialogue between industry and the OECD professional staff on the process of health care reform, with a third meeting planned for 1997 on the need for broad-based structural changes among government and private sector institutions that serve as insurers of health care.

ANNEX -- LIST OF PARTICIPANTS

MANAGEMENT EXPERTS

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Mr. Josef Kubicek	President JOK Instruments	CZECH REPUBLIC
Mr. Alain Sommer	Directeur Administratif et Financier CLININVEST Compagnie de Suez	FRANCE
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Mr. Daniel Whitaker	Senior Consultant National Economic Research Associates	SPAIN
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Mr. Michael Owen	Director of Economic Affairs Corporate Strategy Unit Glaxo Wellcome plc	UNITED KINGDOM
Dr. Ullrich Hoffmeyer	Associate Director National Economic Research Associates Economic Consultants	UNITED KINGDOM
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