Daejung Kim, Alistair McGuire and Margaret Kyle
Korean pharmaceutical industry policy: lessons for Korea

Report

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Forward 《

The global pharmaceutical market, valued at USD 1,057 billion, is almost three times the value of the international smartphone market. The best-selling pharmaceutical product in 2014, a treatment for rheumatoid arthritis called Humira, generated USD 11.8 billion in sales in that year alone. Can a latecomer like South Korea catch up with, let alone surpass, successful pharmaceutical industries in such a massive global market? Korea might be the world's leading producer of electronics, smartphones, and other such high-tech products, beating the competition in the United States and Europe, yet its pharmaceutical industry lags far behind the standard of its American and European counterparts. Korea's pharmaceutical industry is struggling, and the reason why, as Chandler (2005, p. 5) explains, is the high entry barrier to the global pharmaceutical market. I hope this study enhance our understanding on the industrial policy in pharmaceutical industry and provide valuable insights to the policy development in the industry. I give great thanks to Prof. Alistair McGuire and Prof. Margaret Kyle in participating in this research.

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Sangho Kim, President
Korea Institute for Health and Social Affairs

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Abstract 《

Chapter 1 introduces Korea's pharmaceutical industry development since the 1970s. The Korean government began to recognize and grant patents on substances in 1987, which opened the industry's eye to the R&D investment. Korean pharmaceutical companies began to develop their own new drugs, starting with Sunpla, in the 2000s. The majority of these drugs, however, exclusively targeted the domestic market and resulted in little competitiveness on a global scale. The Ministry of Health and Welfare of Korea launched the R&D Projects since 1995, As the amount of government R&D investment has been steadily rising in Korea, many have criticized the redundancy of investments made by multiple departments and agencies and the lack of interdepartmental cooperation it reflects.

The key to the competitiveness of a nation's health technology lies first and foremost in the strength and caliber of its research institutions, The factors limiting or promoting the success of academic-industrial collaboration are relatively clear. According to various studies, limiting factors include the disagreement among the involved parties over the objectives, the smallness of Korean pharmaceutical companies and their pools of experts, the lack of accurate valuations of technology, and the inefficiency of the system for distributing rewards of

collaboration. Furthermore, The health insurance system plays a decisive role in the innovation and spread of health technology in a given society.

Naturally, as pharmaceutical innovation is complex, incentive driven, and involves R&D efforts from both the public and private sectors, outcomes differ from nation to nation. Nevertheless, pharmaceutical innovation and policies remain under-analyzed topics in the research community. Following chapters will discuss the economics of direct investment in pharmaceutical R&D by the government, academic-industrial collaboration, and insurance benefits and pricing.

Chapter 2 summarizes the economic case for innovation policy, describes how innovation policy is implemented in practice, and describes the evidence on the effects of innovation policy. First, We investigate the "pull" policies aiming to increase the private benefits associated with innovation and "Push" policies targeting the costs.

The most widely used "pull policy" around the world today is the granting of intellectual property rights, particularly patents. However, the long-run dynamic efficiency (incentives for innovation that contributes to welfare over time) yielded by patents comes at the cost of short-run static costs. In the extensive (mostly theoretical) literature on the economics of patents, it is generally accepted that patents do not provide optimal

incentives. Alternatives to patents include govern-ment-sponsored prizes for innovation or ex ante commitments to purchase a minimum quantity at a specified price.

"push" policies encourage greater investment in R&D by re-ducing the costs of that investment. Such policies include tax credits for R&D investment, grants for research performed in universities or other organizations, and the establishment of government research centers that perform research internally. Most governments in developed countries employ some mix of these. Push policies have a number of weaknesses, however. First, the information burden for a policymaker is considerably higher than for pull policies. Second, push policies also require policymakers to confront potential moral hazard on the part of grant recipients. The section 3 of this chapter begins with a discussion of economic models of how best to allocate funding across diseases and their shortcomings, and provide an over-view of empirical studies in this area.

Under some conditions, pull and push policies can be de-signed to achieve identical expected outcomes at the same ex-pected costs. In practice, pull policies are more attractive in situations where the information burden is particularly large, where capital markets function well, and where government funders are risk averse. Push policies are favored when the promotion of spillovers is especially important and if capital markets undervalue R&D.

Chapter 3 overviews on the regulatory reform in healthcare sector in general and its impact on R&D. Worldwide, health sector regulation has extended beyond traditional concerns with safety and efficacy, to evidence of performance and value. Such changes directly impact on the ability of a health sector to innovate, as DRGs tend to benchmark the average practice and value based pricing attempts to restrict new technology diffusion.

Value-based pricing looks to estimate the value of a drug based on available evidence of performance. The value-based pricing (VBP) approach can be widened to incorporate factors such as the burden of illness in society, the unmet need addressed, the budget impact of up-take, the degree of innovation judged to be associated with the drug and the wider social benefits derived from the drug.

In the pursuit of static efficiency through price regulation all the major European markets now appear to support some form of value-based pricing (VBP) where value and subsequent product reimbursement price is explicitly linked to the incremental health benefit produced (OFT, 2007; Moise and Docteur, 2007). As reimbursement is increasingly tied to product value, some have argued that all dimensions of value must be taken account off, and that the highest levels of reimbursement should be given to the most innovative products. In France and Germany many product reimbursements reflect innovative value, where

innovative value is aligned with health benefit within a given therapeutic area. While England appears to be implementing a reimbursement system, like Canada and Sweden, based on health benefit as determined largely through implementation of cost-effectiveness thresholds.

Little is known about the interaction between patent protection and price regulation. If price regulation distorts expected revenues, then there will be an adverse influence on R&D investments. If there is strong patent protection this may offset these distortionary effects, but if patent protection is too strong this provides incentives for over-investment in R&D. One form of regulation thus influences the other. Efficient regulation should reward both innovative R&D and products achieving high health benefits.

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Korean Pharmaceutical Industry and its policy

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Korean Pharmaceutical ≪ Industry and its policy

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Session 1 Introduction

Every new technology that is successfully commercialized creates a formidable barrier to the market in the form of piling knowledge. The increasingly distant entry barrier in pharmaceuticals had its origins in the 1880s, when numerous enterprises began developing and producing chemical and biological technologies and products. Keun Lee and Franco Malerba (2014) has argued that it is relatively easy for a newcomer to catch up with rivals in industries with short technology lifespans. However, in industries such as the pharmaceutical industry, where the speed of change in the knowledge base of a technology tends to be quite slow, it is difficult for newcomers to catch up. (Conversely, latecomers have a much better chance of success in industries in which old knowledge is regarded as obsolete, and so investors would be better off investing in these industries.)

How do government's policies on the pharmaceutical industry facilitate and promote a leapfrogging ahead by means of

technological innovation? Thomas (1994) noted that the French pharmaceutical companies' share of the export market remains stagnant, while at the same time UK companies' have been growing. He identified the causes for their success in the UK government's policies on the approval of drugs, prices, and the national innovation system. The United Kingdom imposed far more rigorous criteria for the approval of pharmaceutical products than did France, which tended to be quite lenient toward the French pharmaceutical companies. The United Kingdom also adopted a business-friendly policy on pricing and actively encouraged foreign investment by loosening regulatory requirements as part of its active foreign competition policy. France, on the other hand, kept strict control over pharmaceutical prices and maintained a strict protectionist policy to shield French pharmaceutical companies against competition from American, Swiss, and other rivals. Finally, in the interest of innovation, the UK government ensured effective cooperation among the government, hospitals, and pharmaceutical companies. By contrast, French pharmaceutical companies depended upon governmental research institutions extensively, while their networks with the medical community weakened.

Pharmaceutical industries worldwide have undergone dramatic changes since Thomas (1994)' study was published. With the declining productivity of pharmaceutical research and de-

velopment (R&D) and the rising average cost of drug development, pharmaceutical companies no longer attempt to produce best-selling products in-house, but rather research and develop new products via a virtually integrated network of open innovation worldwide. Forming partnerships with universities and other research institutes for R&D, these companies outsource pre-clinical and clinical tests to contract research organizations (CROs), production to contract manufacturing organizations (CMOs), and sales and distribution to contract sales organizations (CSOs). In adopting such a strategy, the companies are able to minimize both costs and development risks. In the meantime, with the age of personalized medicines dawning, genetic screening and molecular marker technologies are beginning to allow medical practitioners to formulate customized prescriptions for individual illnesses with reduced side effects, enhanced patient safety, and better adaptation to new treatment regimes.

Examining how governments of advanced economies are adapting to these changes on the pharmaceutical market and what factors latecomers like Korea should consider in developing their pharmaceutical policies are surely fertile fields of research. Yet little research on these areas has been done to date. This study therefore discusses some of the issues involved.

Session 2 Korea's pharmaceutical industry today

Until the late 1970s, the Korean government played a large role in fostering the pharmaceutical industry with strong protectionist measures, such as a ban on the imports of drugs that were made locally. Yet the industry lacked competitiveness due to a critically dearth of investment in R&D. In the 1980s, with the ban on pharmaceutical imports lifted and the pharmaceutical market liberalized, Korean pharmaceutical companies were forced to compete with foreign counterparts that possessed far more financial, technological, marketing, and management resources and expertise. Over the years since then, the imbalance of pharmaceutical trade has worsened. Once the Korean government began to recognize and grant patents on substances in 1987, pharmaceutical companies could no longer produce active substances without patent permissions. This situation led them to realize that the key to survival was the development of new drugs, which in turn opened their eyes to the central importance of R&D investment.

However, it was not until the 1990s that the Korean government began to foster and support the pharmaceutical industry systematically as a source of significant wealth and employment. In 1995, the Ministry of Health and Welfare launched the first of a series of Public Health and Medicine R&D Projects, and in 1999 it established the Korea Health

Industry Development Institute (KHIDI). In 2011, the National Assembly enacted the Special Act on Supporting and Fostering the Pharmaceutical Industry, and then in 2013 the Korean government announced its first five-year plan for advancing the pharmaceutical industry according to that Act. The five-year plan envisioned making Korea one of the seven global centers of pharmaceuticals and raising the value of its pharmaceutical exports from KRW 2.3 trillion in 2012 to KRW 23 trillion by 2020. The plan also aimed to increase the number of Korean companies among the world's top 50 pharmaceutical companies from zero in 2012 to two by 2020 and to develop globally best-selling new drugs from zero in 2010 to three by 2020. To these ends, the plan called for increasing government investment in R&D projects, raising a public fund for fostering the pharmaceutical industry, developing specialized workforces, providing strategic support for exports, and developing cutting-edge industry clusters and other infrastructure.

Korean pharmaceutical companies began to develop their own new drugs, starting with Sunpla, in the 2000s. The majority of these drugs, however, exclusively targeted the domestic market and resulted in little competitiveness on a global scale. Although the government and the private sector continue to increase investment in pharmaceutical R&D, the road to successful commercialization remains long and winding. There is thus a need to develop a new and more effective model of pharma-

ceutical innovation.

As of 2014, the Korean pharmaceutical market amounted to KRW 19 trillion in value. However, this estimate was based upon production data and not sales data. The actual market may therefore be bigger. Based on financial statements published by Korea's pharmaceutical companies, Yuhan Corporation was the highest grossing in 2014 with KRW 1 trillion in sales. According to the IMS, the top 10 pharmaceutical companies in Korea collectively account for 28.7 percent of gross revenue on the pharmaceutical market. Multinational corporations like Pfizer, MSD, and Novatis still top the list. We may surmise, then, that the Korean pharmaceutical industry is sufficiently globalized and subject to fierce competition among a great number of companies.

Korean pharmaceutical companies have occupied 0.2-0.3 percent of the global export market since 2000. Germany is the leader on the global pharmaceutical export market with a market share of 11.4 percent, followed by the United States (7.8 percent), China (2.6 percent), and Japan (0.7 percent).

[Figure 1-1] Changing Nation-by-Nation Shares of the Global Pharmaceutical Market
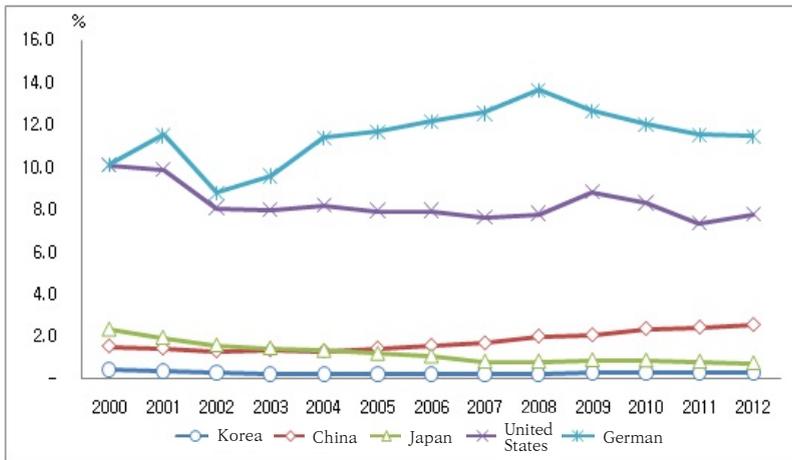
Source: ISTANS (based upon UN Comtrade data)

From 2000 to 2012, the aggregate amount of R&D investment in the Korean pharmaceutical industry multiplied from KRW 138.1 billion to KRW 1.0445 trillion, but the R&D cost as a share of manufacturing only increased from 1.6 to 2.8 percent. In comparison, the R&D cost as a share of manufacturing in other leading pharmaceutical countries were 22.8 percent in the United States (2011), 12.2 percent in Japan, 8.8 percent in Germany, and 4.1 percent in China.

[Figure 1-2] R&D Investment in the Korean Pharmaceutical Industry and Its Share in Manufacturing
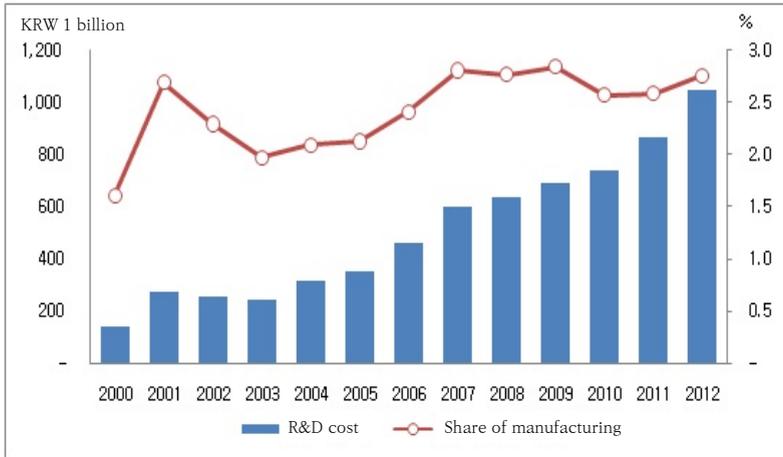
Source: ISTANS (based upon UN Comtrade data)

Session 3 Direct investment in pharmaceutical R&D by the Korean government

Both the amount of R&D investment and the size of the research workforce in Korea's pharmaceutical industry have been increasing steadily, yet they are still far from matching what is occurring in other advanced countries. As of 2013, a total of KRW 1.2333 trillion had been investedin the Korean pharmaceutical industry, with KRW 258.7 billion comingdirectly from the government. Of the government's budget for investmentin R&D, the pharmaceutical industry received 1.6 percentin 2014.

[Figure 1-3] Governmental Support for Pharmaceutical R&D and Its Overall R&D Budget Share
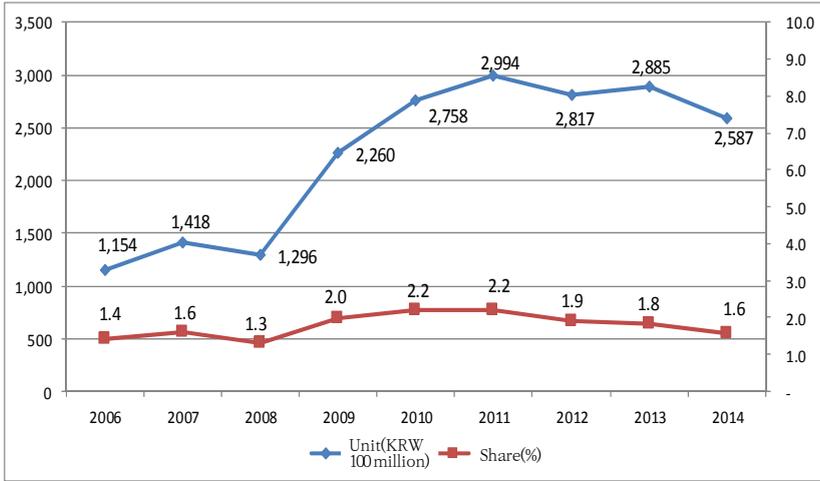
Source: NTIS

The distribution of the government's R&D support by recipient type (governmental/public research institutes, universities, corporations, and other) reveals that universities were the largest recipient in most years, except for 2006, 2009, and 2013, when corporations received the most. In other words, the Korean government's support for pharmaceutical R&D tends to be concentrated in universities and corporations, favoring the former over the latter.

[Figure 1-4] Distribution of Government Support for Pharmaceutical R&D by Recipient Type

(Unit: %)
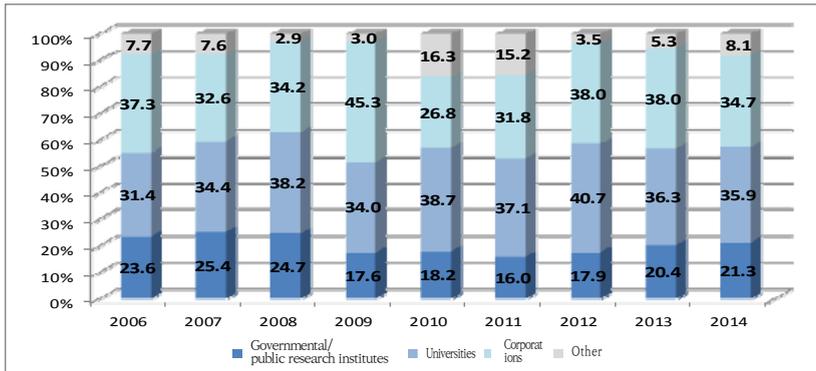
Source: NTIS

Governmental support for R&D development has far-reaching effects that are not limited to the receipt of funding. Inclusion in the government's R&D support scheme often serves as marker of the quality of a project, which enables researchers involved to receive additional investment from other investors with greater ease. Governmental support can also affect and shape corporations' R&D portfolios. Of course, we need a more rigorous economic theory to determine how government R&D investment affects each industry or sector.

Even though the amount of government R&D investment has been steadily rising in Korea, many have criticized the redundancy of investments made by multiple departments and agencies and the lack of interdepartmental cooperation it

reflects. A more prudent system is needed. Japan, a country with a public R&D support system similar to Korea's, launched a Japanese version of the National Institute of Health (NIH), modeled after the American example to oversee Japan's health-care system. The new public corporation is meant to centralize the budgets, investments, and commercialization processes of all health-related R&D projects, which have until recently been supported by such Japanese government agencies as the Ministry of Culture and Science, the Ministry of Welfare and Labor, and the Ministry of Economics and Industries.

The NIH of the United States and the Medical Research Council (MRC) of the United Kingdom are public agencies that support R&D. Yet they also operate their own research labs and design their own portfolios to guide important R&D projects. In developing penicillin, for instance, the MRC formed a penicillin committee with representatives of pharmaceutical companies and research centers serving as members, and it filed patents on the product via that committee. Whereas the NIH and the MRC consist of multiple labs, the Japanese version has no research functions of its own. The Japanese experiment will therefore provide important implications for Korea. However, before creating anything akin to Japan's NIH, it re-mains to be seen whether Korea's governmental departments and agencies will relinquish their R&D-related privileges and powers to such an institution.

Session 4 Academic-industrial collaboration

The world of health technology is fragmenting at an astonishing pace today, forcing universities and other advanced scientific institutions, hospitals, market organizations, and regulatory regimes to enhance their competitiveness. The key to the competitiveness of a nation's health technology lies first and foremost in the strength and caliber of its research institutions, which, in turn, require an effective education system for the teaching and training of researchers. Hospitals should also be given incentives to focus more on research activities than services. A study which traced back the R&D processes of 32 pioneering new drugs concluded that the pharmaceutical industry itself had contributed 53 percent to the drugs' success; universities, 28 percent; hospitals, 13 percent; and governments, six percent (Maxwell and Eckhardt, 1990). Consoliet al.(2009) analyze the innovation and spread of medical technologies as a result of interactions of diverse factors (or of innovation systems) that are interdependent of one another.

The factors limiting or promoting the success of academic-industrial collaboration are relatively clear. According to various studies, limiting factors include the disagreement among the involved parties over the objectives, the smallness of Korean pharmaceutical companies and their pools of experts, the lack of accurate valuations of technology, and the in-

efficiency of the system for distributing rewards of collaboration. Promoting factors, on the other hand, include strong partnerships, appealing subject areas of R&D, mutual respect among the parties involved, and effective incentives.

The Korean government has been implementing its bio-cluster policy in an effort to foster academic-industrial collaboration. Since the 2000s, it has invested extensively in developing the Osong Bio Valley, the Daegu Bio Valley, and other such bio-clusters, with the Osong project alone receiving almost KRW 7 trillion.

Tavassoli and Tsagdis (2013) have identified 14 factors that determine the success or failure of a cluster, two of which are the effectiveness of the supporting organization and the focus and vision of the organizing committee. The following table summarizes more of the common characteristics of leading bio-clusters around the world. The most notable characteristic common to these bio-clusters is that two top universities—the University of Cambridge and the University of Oxford—are at their centers. This indicates that the success of an industry cluster crucially depends upon both the quality of researchers working there and the effectiveness of the re-training system the cluster offers. Another key characteristic is that successful bio-clusters are centered on corporations. The UK government promotes academic-industrial collaboration by supporting the

networking among cluster-tenant businesses. The French government requires tenant businesses of clusters to form their own councils, so as to make their own decisions on how to improve their clusters.

⟨Table 1-1⟩ Key Characteristics of Leading Bio-Clusters Worldwide

Cluster	Characteristics
Cambridge Science Park (UK)	- Led by Addenbrooke's Hospital and University of Cambridge. - Funded systemically by local banks. - Supports university/research-based entrepreneurship.
Cambridge Biomedical Campus (UK)	- Led by Fulbourn Hospital, Rosie Hospital, Addenbrooke's Hospital, Papworth Hospital, Cambridge Department of Medicine, MRC Laboratory of Molecular Biology, Cancer Research UK Cambridge Institute, and other renowned hospitals and research institutes. - Fosters networking among tenant institutes with a support system. - Provides a system for re-training and recruiting researchers. - Cluster has its own re-investment process.
Oxfordshire Bio Cluste (UK)	- Led by Rutherford Appleton Laboratory, QinetiQ Nanomaterials Limited, and University of Oxford. - Fosters networking among universities, research labs, and tenant businesses with a business-centered and bottom-up R&D support system. - Provides an integrated system supporting the entire process from R&D to production.
Lyonbiopole (France)	- Provides a decision-making body in which tenant businesses, research labs, and local governments participate. - Supports a business-led cluster association.
Medicen Paris (France)	- Tenant businesses, research labs, universities, and local governments can decide cluster's policies in a bottom-up manner.

Session 5 Insurance benefits and pricing

The health insurance system plays a decisive role in the innovation and spread of health technology in a given society. A new health technology might be developed, but it may never be commercialized as a product or service if investors perceive the future prospects of the technology to be uncertain. Therefore, the coverage, the extent, and the cost of insurance-covered health products or services play a central role in deciding the pace at which new health technologies (e.g., stem cell technology, genetic treatments, and the like) spread. That is why policymakers must revisit the current system of evaluating health technology and the governance of insurance benefits to consider ways of improving the efficiency and accuracy of the technology valuation process.

In Korea, a new drug is only included in health insurance coverage after the Health Insurance Review and Assessment Service (HIRA)'s Drug Benefits Evaluation Committee decides on its appropriateness for the health insurance scheme. Once the drug is deemed appropriate, the National Health Insurance Service (NHIS) launches negotiations with the pharmaceutical company over the price of the drug. The Drug Benefits Evaluation Committee determines whether a new drug is appropriate for insurance coverage on the basis of the relative clinical utility the drug offers over previous drugs, its cost-ef-

fectiveness, and its possible impact on the fiscal system. Clinically useful and cost-effective new drugs are admitted into the insurance coverage scheme based on coverage by health insurers elsewhere around the world, the coverage price and benefits ratio, and the fiscal resources available for insurance benefits. Drugs that have no alternatives, that treat small groups of patients suffering from fatal and rare diseases, and that have shown clinical benefits (e.g., significant extension in life expectancy) may be included into the insurance coverage scheme without proof of cost-effectiveness.

Since December 2006, Korean law has required that all new drugs be registered (included into the health insurance coverage scheme) based on selective review and economic analyses. Economic analyses involve determining the cost-effectiveness of new drugs and presenting the results in the form of incremental cost-effectiveness ratios (ICERs). The ICER is a measure of how much a unit of a given drug improves its effect per cost. The cost estimation process involves listing the appropriate items of expenses associated with a treatment based on the given drug; measuring the amounts of resources spent on the given items in natural units (e.g., the number of hospitalization days required and the number of hospital visits required); and multiplying the amount of resources spent under each item by the unit cost to estimate the final cost. In general, these analyses use the quality-adjusted-life-years (QALY) as an

indicator of cost-effectiveness but do not recognize techno-logical or pharmacological innovation as meaningful indicators. In other words, the current health insurance review system's focus is largely on the improvement of clinical effect. An innovative new drug is unlikely to be included into the health insurance scheme based only on the innovation it has made possible in the treatment/administration process. In the future, however, the review system will have to account for technological or pharmacological innovation as well.

The price of a drug reflects the cost of the R&D process to bring a final product to market and determines the profit ex-pectations of the pharmaceutical company involved. In most industrialized societies, the pharmaceutical market is subject to the health insurance system, as this system determines the pri-ces of drugs. Increasing drug prices may lead corporations to invest more in R&D by allowing them to earn greater profits. However, macroscopic observations and analyses of the corre-lation between the pricing policy and the pharmaceutical R&D activities in Korea over the last few decades reveal that this correlation has not always been positive or proportional. If anything, the contents of the pricing policy rather than the ab-solute pricing level may exert a greater impact on R&D activities. To date, no empirical study has been conducted in Korea to demonstrate the correlation between the pricing poli-cy/level and the R&D productivity of pharmaceutical

companies. Korean pharmaceutical companies differ significantly from their multinational counterparts in terms of the scope and scale of R&D. It is therefore difficult to apply the conclusions of empirical studies on the R&D activities of these multinational counterparts directly to Korea's situation. As a consequence, stimulating pharmaceutical R&D in Korea in the future will require support for empirical studies on how pricing policy actually affects Korean companies' R&D activities.

Session 6 Conclusion

Given the need to ensure and improve public health in changing times, it is critical to understand how innovations and progresses occur in the pharmaceutical industry. The pharmaceutical market is expected to achieve exponential growth worldwide in the coming years. Promoting innovation in the Korean pharmaceutical industry will therefore significantly benefit the national economy. Numerous governments worldwide have already launched diverse policies that explicitly or implicitly support the pharmaceutical industries in their respective territories.

The United Kingdom provides an example of a successful and effective policy for fostering a nation's pharmaceutical industry. Its pharmaceutical industry is experiencing new

growth, thanks to advancements in information technology, engineering, and genetics. Yet the productivity of its R&D has been on a steady decline, just as it has elsewhere around the world. In response to this paradox, the UK government announced its Strategy for UK Life Sciences in December 2011, a strategy for the development of the country's life sciences over the course of the next decade with innovation led by the Department for Business, Innovation and Skills (BIS). The strategy envisions the UK as becoming a global leader in life sciences and maps out specific steps that will be taken toward that goal[1].

Naturally, as pharmaceutical innovation is complex, incentive driven, and involves R&D efforts from both the public and private sectors, outcomes differ from nation to nation. Nevertheless, pharmaceutical innovation and policies remain under-analyzed topics in the research community. This may be because innovation in healthcare tends to be varied and

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[1] According to the strategy, the UK government will play a leading role in raising a Biomedical Catalyst Fund for academic-industrial collaboration, developing the National Biologics Manufacturing Centre (NBMC), and creating the "Cell Therapy Catapult." The UK government has also launched a policy for enhancing patients' access to latest-technology medicines and increasing opportunities for them to participate in clinical trials; and it distributes clinical test data, on the condition of the anonymity of test subjects, for the purposes of drug development and research (Clinical Practice Research Datalink, CPRD). As part of its efforts to encourage medical institutions to adopt the latest innovations, the National Institute for Health and Care Excellence (NICE) actively publicizes and advertises information on new technologies, while the government encourages academic-industrial collaboration groups to adopt innovations by removing all possible obstacles.

sweeping in scope. I have addressed four areas to be considered in the policy perspective; 1) Direct investment in pharmaceutical R&D by the government, 2) Academic-industrial collaboration, 3) Insurance benefits and pricing.

2 R&D Policy and Pharmaceutical Innovation

2　R&D Policy and Pharmaceutical Innovation 《

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Session 1　Introduction

Knowledge and innovation have long been recognized as critical to economic growth. Particularly for developed economies, which no longer have a competitive advantge in manufacturing due to high wages, sectors that rely on intangibles like knowledge have increased in importance. Can government policy promote innovation, and under what conditions? Focusing on the particular case of pharmaceutical innovation, this chapter summarizes the economic case for innovation policy, describes how inovation policy is implemented in practice, and describes the evidence on the effects of innovation policy.

The economic justification for a government role in promoting innovation is to ameliorate a particular type of market failure associated with the production of knowledge and innovation. Specifically, ideas and knowledge are non-rivalrous (or public) goods. A pastry, for example, is a rivalrous good: if one person consumes the pastry, no one else can enjoy it. However, the recipe used to create the pastry is non-rivalrous. Its use by one chef does not preclude its use by other chefs. It

is, in fact, a public good. Not only can other chefs use it, but they might develop new recipes by modifying this one, yielding even better desserts; economists refer to this as cumulative innovation. The non-rivalrous nature of knowledge and the potential for spillovers imply large benefits for society.

Unfortunately, knowledge can be costly to produce. Returning to the example of a pastry, the creation of a new recipe may require substantial investment in specialized training and equipment. Because many attempts to create a new pastry yield nothing useful, this investment can be risky. Any chef contemplating this investment weighs these costs against the potential benefits. But rather than considering the total benefits realized by himself as well as all other chefs, who might produce the same pastry and develop new recipes based on this one, the chef considers only the profits he might realize himself. Another way of describing this problem is that the inventor, or producer of knowledge, cannot appropriate all of the benefits because of its non-rivalrous nature. This calculation means that he will invest far less in finding new pastries than the social optimum. Paradoxically, the fact that knowledge can be easily used by many can result in insufficient investment in its production.

In order to prevent spillovers, the inventor may attempt to keep his innovation secret (or at least the means of producing

the innovation). Secrecy is a means of appropriating the benefits, but also reduces the social benefits. In addition, if the inventor wanted to sell the information, he would face the disclosure problem, or Arrow's information paradox. Because few buyers would be willing to purchase the information without some proof of its quality, the inventor is forced to disclose some details in order to guarantee that the information has value. But once disclosed, the price of the information is zero. Information is non-rivalrous, so the inventor can't take it back from the buyer; since the buyer has the information already, he may feel no obligation to pay for it. Technology transfer may be impeded.

The production of ideas, information, or knowledge is therefore difficult to manage. The greater the spillovers, which are social benefits, the lower is the investment by for-profit organizations and the less likely is technology transfer or sharing of knowledge. Innovation policy seeks to correct this market failure.

Session 2 Push and pull policies

Broadly speaking, innovation policy may be classified into two approaches. "Pull" policies aim to increase the private benefits associated with innovation. "Push" policies instead tar-

get the costs. In both cases, the assumption is that innovators will respond by increasing their innovative efforts, and the total level of innovative efforts will be closer to the social optimum.

Before describing these in more detail, it is important to realize that while the social returns from innovation may be large, they are not infinite. More is not always better, once costs are considered. Few would argue that it makes sense to spend trillions to develop a new pastry. As delicious as it might be, that money is likely to be more usefully deployed elsewhere. Social welfare is maximized when the additional expected benefits resulting from investment are equal to their costs. Innovative efforts with a small probability of success are justified only if the benefits are very large. For a given benefit, we should spend more where success is more likely.

Because the benefits from innovation are considerably harder to quantify systematically than are the costs, policy debate often focuses mostly on the latter. For example, a factor in rankings of countries in terms of their innovative capacity by the Organisation for Economic Cooperation and Development (OECD) and others is the percentage of gross domestic product (GDP) spent on research and development (R&D) (OECD (2014)). Implicitly, these rankings assume that the socially optimal percentage exceeds what we observe in practice. However, we do not have particularly reliable estimates of the socially

optimal level. This almost surely varies across industries and over time.

2.1 Pull policies

The most widely used pull policy around the world today is the granting of intellectual property rights, particularly patents. Patents allow an inventor to prevent others from manufacturing a good based on his idea for a limited period of time. During that period, the knowledge underlying the invention is less non-rivalrous, in some sense. Consequently, the inventor is able to appropriate a greater share of the benefits resulting from his efforts.

Patents have a number of appealing features as a policy instrument. First, they do not require a policymaker (or government agency, or expert committee) to measure the benefits from a potential innovation. Rather, inventors form estimates of their expected profits, and invest accordingly. Under some conditions, markets can efficiently aggregate disperse information; patents are one means of using markets to acquire information about the value of an invention. If inventor profits are correlated with social benefits, then the signals provided by the market induce investment that targets appropriate goals. Note that this link is essential, and is not guaranteed. However, the preponderance of evidence shows that patents are linked to

increased investment in pharmaceutical development, on average (see, among others, Qian (2007), Kyle & McGahan (2012)).

Second, patents require some disclosure by the inventor. For example, a granted patent generally must include sufficient detail about the invention so that an expert in the field would be able to understand it. In most countries, patent applications are published after 18 months. While it may be incomplete, disclosure allows spillovers of knowledge to others. In contrast, trade secrets, another mechanism by which inventors may attempt to protect their profits, do not provide these spillovers. In the case of pharmaceuticals, secrecy is limited due to other regulations to assure the quality of manufacturing. Numerous studies have established that patents generate important spillovers through disclosure (Jaffe (1986), for example).

Third, patents appear inexpensive to many politicians.[2] Other than the direct costs of running a patent office, they require no budgetary outlays. Of course, patents are costly in other senses, discussed below.

Fourth, patents are relatively strong policy commitments. Particularly in recent decades, trade agreements require signatory countries to provide minimum patent terms and to en-

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2) This is not usually the case in developing countries, where politicians are more likely to view patents as benefitting foreign inventors at the expense of the local population.

force them. Consequently, inventors are mostly shielded from variations in policies from year to year, which introduce uncertainty and complicate investment.

Fifth, patents reduce the disclosure problem through establishing property rights around knowledge. These property rights enable inventors to sell their ideas directly, and to profit even if he does not engage in manufacturing or production on the downstream market. The development of a "market for ideas" or market for technology enables vertical specialization. Different actors in the market can focus primarily on the activities in which they are strong, whether that is R&D, manufacturing, marketing, etc. This can yield a lower total cost of innovation. In fact, the pharmaceutical industry is now characterized by this vertical specialization. Small biotechnology firms focus on early-stage research, and license their products to larger firms with global sales forces. In recent years, the number of new pharmaceutical treatments that originated in smaller firms and were licensed to multinationals has continued to increase, evidence of the importance of these licensing markets (Economist (2006)).

Unfortunately, the long-run dynamic efficiency (incentives for innovation that contributes to welfare over time) yielded by patents comes at the cost of short-run static costs. Because patents grant market power to an inventor, the inventor may

sell at a price higher than would be the case with competition. Consequently, access to the innovation may be reduced, because some consumers may not be willing to pay that higher price. This trade-off is particularly acute in the case of pharmaceutical treatments. In the short run, some patients may die because they cannot afford access to patented treatments. Consequently, other policies to counteract these less desirable aspects of patents are often employed, such as pharmaceutical price controls.

Patents have other shortcomings as well. They are rather blunt policy instruments, applying a "one-size-fits-all" term of 20 years of protection regardless of technology field or the importance of an invention that meets the minimum criteria for patentability. Products with long development times, such as pharmaceuticals, receive the same duration of protection as those with much more rapid lifecycles, such as computers or mobile phones. Since the period of protection begins from the patent application date, rather than the date at which a product based on that patent reaches the market, the effective period of protection can be much shorter than 20 years. Recent research (Budish et al. (2013)) has demonstrated that this variation in effective patent life may distort innovative efforts in pharmaceuticals, in particular away from products with longer development periods (and therefore with less time remaining on patent, once marketed). Other more flexible policy instru-

ments may complement patents, such as patent extensions (to offset time lost in development) or market exclusivity periods (which date from product launch, rather than invention).

In addition, the link between profits and social value does not always exist. For example, diseases that primarily affect those living in developing countries, such as malaria, have long been neglected by for-profit firms. While the social value of curing malaria is high, the profit potential is low, even in the presence of patents, because patients are unable to pay prices that would allow a firm to recover the fixed costs of development. Kyle & McGahan (2012) found that while increasing patent protection stimulated research efforts for global diseases, it was not sufficient for attracting research on diseases that primarily affect poor countries. Vaccines for infectious diseases are another example. An individual who takes a vaccine benefits not only himself, but all with whom he might come into contact. Since individuals are likely to ignore the benefits to others, demand for vaccines is lower than what is socially optimal. Consequently, investment in vaccine development may also be too low. Finally, other government policies such as price controls can distort the relationship between profits and social value. For drugs that treat very important diseases that affect a large number of people, governments may be tempted to set relatively low prices in order to maximize access. However, that may depress the profits associated with

socially valuable treatments and distort research incentives.

In the extensive (mostly theoretical) literature on the economics of patents, it is generally accepted that patents do not provide optimal incentives. Alternatives to patents include government-sponsored prizes for innovation or ex ante commitments to purchase a minimum quantity at a specified price. Kremer & Glennerster (2004) proposes these policy instruments for addressing neglected diseases, in particular. These tools explicitly consider the link between profits and social value, and they avoid the short-run static inefficiencies of patents. However, they can be difficult to implement in practice. They require an estimate of social value, which may be difficult. They may require coordination among multiple funders, and the commitment must be credible. Wright (1983) provides a useful summary of several pull policy alternatives: patents, prizes, and research contracts. He emphasizes that in environments with asymmetrical information about the costs of performing R&D and its value, patents may be preferable to prizes. Because of the limited use of prizes to date, we have little empirical evidence on their efficacy in pharmaceutical development[3]. However, there has been growing interest in expanding their use.[4]

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3) Only one advanced market commitment has been implemented, for the pneumococcus vaccine. Brunt et al. (2012) examine inducement prizes in agriculture from 1839-1939 and find large effects.
4) See Stine (2009) for a summary of federally funded prizes in the US. Democratic presidential candidate Senator Bernie Sanders proposed a

In a global market, R&D investment will only respond to pull policies that create a large shift in expected global revenues. Few countries have sufficient importance to implement such policies. For example, if a small country were to double (or halve) the period of patent protection, it would be very surprising to observe a response in the R&D efforts of private firms. If it accounts for only 2% of the global market, and almost no pull policy introduced by this country alone would make a difference. In fact, all countries for which this is true (including large but poor countries, which account for only a small share of total pharmaceutical revenues) have reason to maximize access in the short run and to ignore the dynamic incentives for innovation. For this reason, foreign free-riding on the incentives created by US pull policies is a complaint often heard in Washington. For example, former FDA Commissioner Mark McClellan noted "Americans, who account for a fraction of prescription drug use worldwide, will pay for about half of all pharmaceutical spending worldwide. By contrast, citizens in the world's third largest economy, Germany, paid less than five percent. The same kind of drug payment disparity is true for many other developed nations who have about as much ability to pay as Americans do...The United States is now covering most of these costs of developing a new drug to the point where it can be used by the population of the world."5)

"Medical Innovation Prize Fund Act" in 2011, though the Senate never voted on it.
5) http://www.fda.gov/NewsEvents/Speeches/ucm053614.htm

International trade agreements that include intellectual property rights can at least partially address this issue. They commit countries to minimum patent terms, which may reduce free-riding. In aggregate, if all small countries coordinate on patent policy (or another pull policy, such as prizes), the dynamic incentives for investment should be higher. In practice, this coordination has been extremely controversial in the case of patents, although the result of a series of multilateral and bilateral trade agreements has been an increase in the length and breadth of patents on pharmaceuticals in many countries.

2.2 Push policies

Rather than changing expected revenues in order to induce supply, push policies encourage greater investment in R&D by reducing the costs of that investment. Such policies include tax credits for R&D investment, grants for research performed in universities or other organizations, and the establishment of government research centers that perform research internally. Most governments in developed countries employ some mix of these.

If the government requires that the results of funded research are placed in the public domain or made available through low-cost non-exclusive licensing, the resulting knowledge potentially generates greater spillovers. No intellectual property

blocks its use, and the information is disclosed through publications or other means. For example, the National Institutes of Health (NIH) in the United States typically ask that recipients of grants publish the results in open access journals in order to maximize the availability of the knowledge. In addition, the static losses associated with patents and market power can be avoided. The production of a successful treatment can be licensed to many firms, ensuring competition and reducing prices.

Like prizes, push policies rely less on market signals of social value to drive investment than the use of patents. Particularly in situations in which profits are not linked to social value, this "de-linking" is appropriate. A number of scholars affiliated with non-governmental organizations working in global health have advocated such a model (Love (2011)). Relatedly, another advantage of some push policies (and prizes) relative to patents is their responsiveness to social need. The size of the cost reduction can be adjusted to reflect the relative importance of the research, while the patent term is fixed.

Push policies have a number of weaknesses, however. First, the information burden for a policymaker is considerably higher than for pull policies. Not only must a policymaker have an estimate of the social value associated with the R&D, but the policymaker must also be able to identify the most capable

performer of that R&D. For example, is a government agency more likely to succeed, or to succeed at a lower cost, than a forprofit organization? The former faces little competition, while the market may punish poor performance of a firm. If the government chooses instead to fund research performed in universities, how does it select the best researcher? The cost of acquiring the information necessary for selection may be significant, and failure to do so may result in inefficient funding of unproductive researchers. When grants are restricted to domestic researchers, the capacity for "crowdsourcing" research is also reduced.

Push policies also require policymakers to confront potential moral hazard on the part of grant recipients. In order to ensure that recipients spend grant money efficiently, funders typically stagger the financing over several years and condition it on evidence of successful efforts. However, an academic researcher may be reluctant to disclose the failure of his research efforts, particularly if doing so means losing the grant. In addition, placing restrictions on how grant money may be used in order to avoid wasteful spending may limit the flexibility to address changes in need. For example, the cost of laboratory equipment may suddenly fall, but if the recipient is prevented from reallocating any savings towards another use, he may nevertheless buy additional unnecessary materials. Kremer (2002) points to the example of a program funded by the US Agency

for International Development in the 1980s, in which some funding recipients defrauded the government. These problems are also present in for-profit research, of course, but economists usually have faith in the market to address them more easily than government.

Research is fundamentally risky, and failure is common. Push policies therefore require some tolerance for failure on the part of the government (and the electorate). Because push funding may be sensitive to the electoral cycle or changes in political leadership, it may be unreliable. For example, during a period of economic downturn and tightened budgets, it may be tempting to cut investment in research that has not produced tangible, obvious and important results. In contrast, the efficacy of pull policies depends to some extent on the development of capital markets and investors' willingness to finance risky development efforts. The risk under both patents and prizes is borne by these investors, rather than by the government or policymaker.

Under some conditions, pull and push policies can be designed to achieve identical expected outcomes at the same expected costs. In practice, pull policies are more attractive in situations where the information burden is particularly large, where capital markets function well, and where government funders are risk averse. Push policies are favored when the

promotion of spillovers is especially important and if capital markets undervalue R&D.

Session 3 Government funding of R&D in pharmaceuticals

In this section, I will focus exclusively on the use of push policies, primarily grants, to fund R&D efforts in drug development. Although important, I will abstract away from most details of grants, such as their optimal scope, length, etc. and instead consider only their objective: to advance drug development in a particular disease. I begin with a discussion of economic models of how best to allocate funding across diseases and their shortcomings. I then provide an overview of empirical studies in this area.

3.1 Theory

A simple model of government funding is presented in Lichtenberg (2001). This model is based on the premise that government allocates research funding in order to maximize social welfare, and that the probability of curing a disease is an increasing function of funding: the greater the funding, the more likely it is that research will generate a cure. The level of funding for each disease that maximizes social welfare is such

that the marginal benefit is equal to the marginal cost, subject to a budget constraint. The model predicts that funding should be greater for diseases with more serious burdens, and for diseases where scientific productivity is higher. These predictions are also consistent with NIH descriptions of the funding process.

While very appealing in its simplicity and predictions, the model considers only a single country and its government or social planner. For a very large country such as the United States, or in a world in which countries are quite isolated from each other, this is not an unreasonable approach. However, national economies are now much more tightly linked together. Diseases do not respect national boundaries, and nor does information about how best to treat them. The large sunk costs associated with drug development are usually amortized over sales in many countries by large, multinational pharmaceutical firms.

If each national government considers only its local disease burden and local scientific productivity, inefficient allocation of funding is a likely outcome. First, each government underestimates the total benefit of curing a disease, because it ignores the spillovers to other countries. For example, the burden of malaria in the United States is very small; this model would suggest that the US NIH spend very little money on ma-

laria research. In fact, the global burden is large, and countries where the local burden is high may face more severe budget constraints, as they are generally poorer. Second, if funding is allocated only to local scientists, there also a potential loss of efficiency in countries where local science is less productive. If there are economies of scale in R&D, then small countries may be unable to match the productivity of research programs in larger countries with higher levels of funding. In other words, the outcome achieved by many individual countries is probably inferior to that obtained by a single social planner taking global decisions.

Indeed, this model is especially problematic for small countries. Just as pull policies are unlikely to shift incentives, their research funding may also be insignificant compared to global spending. Often, policies that appear to have an effect do so only at a local level, rather than a global one. For example, generous tax credits for R&D may induce firms to relocate their laboratories, but not to shift the level of their research activities.

Perhaps each national government instead recognizes that diseases affect people in other countries and that the benefits of research can be shared globally. Unfortunately, rather than improving the situation, this recognition may lead to free-riding on the research supported by other governments. For ex-

ample, if the NIH considers the global malaria burden and allocates additional funding for malaria research, it is possible that all other government funders reduce their own spending on malaria. In this sense, countries behave as in an alliance for defense, such as NATO. Since deterrence of a shared enemy's aggression is a public good among alliance members, each is able to free-ride on the defense budgets of their allies (Olson & Zeckhauser (1966)).

A separate concern is that this model neglects the behavior of the forprofit sector. It is sometimes argued that health is too important to be left to private firms CITE, and that governments should instead finance or perform all pharmaceutical R&D. Proponents of this approach point to two advantages. Governments focus on burden instead of profits, and distribute the resulting treatments in order to maximize access, rather than profits. If profits (made possible by patents, for example) are higher for diseases with greater burdens, then firms would also choose to spend more R&D money on severe diseases, for a given level of scientific productivity. Indeed, a multinational firm would consider the global burden, not just a local burden, and would also have the capacity to tap into scientific talent around the world. This could mean a more efficient allocation of R&D, with a temporary reduction in access associated with patents.

Of course, as discussed previously, it is easy to identify examples of diseases with high burdens but low profits, which the private sector is likely to ignore. It is precisely these diseases where the case for government funding is strongest. In fact, there exists a risk of crowding out private investment in diseases with high profit potential.

3.2 Empirical evidence

Many researchers have empirically examined government funding of pharmaceutical R&D. This interest reflects in part its budgetary importance (the NIH budget alone exceeded $US30 billion in 2015, for example), as well as the availability of good measures of output or results.[6] These studies consider several different questions, discussed below.

Despite my emphasis on the importance of considering a global market above, most studies use data from a single country, most often the US. Given the outsize importance of the US in funding medical research, this is not surprising. However, it may limit the applicability of some of the conclusions to other countries.

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6) Governments fund research in many other fields as well, but pharmaceutical research generates countable outputs such as the number of new chemical entities and is unlikely to be kept secret for national security reasons.

1) Political economy of funding decisions

Motivated by the model of funding allocations described above, Lichtenberg (2001) estimates the determinants of NIH funding across diseases using data on grants from 1971-1995. Lacking a good measure of scientific productivity at the disease level, the main focus of his work is disease burden. He finds a positive relationship between the level of disease funding and measures of disease burden, such as life years lost before age 65. While this is encouraging evidence that the NIH behaves in a way consistent with societal interest, Lichtenberg also presents some nuanced results on whether this relationship varies with the demographics of disease. Specifically, he finds that diseases that are relatively more prevalent among the non-white population receive less funding. While many factors could explain this pattern – in particular, scientific knowledge about such diseases may be lower, so funding is less productive – they do suggest the possibility that the political economy of funding decisions may be important.

Subsequent studies have indeed uncovered evidence of political influence at the NIH. Hegde (2009) examines how members of the US Congress may sway NIH grant allocations. While the main role of Congress is to decide the total NIH budget, representatives often "earmark" money for specific diseases. Hegde's analysis suggests that these earmarks favor potential grant re-

cipients in the representative's home district. For example, a representative whose district includes a university with a strong research program in infectious diseases is more likely to earmark NIH funds for infectious diseases, thus favoring the university. Hegde & Sampat (2015) study the role of lobbying by patient advocacy groups. They find that lobbying results in Congressional earmarks for diseases as well. It is possible that lobbying is related to the burden of disease, so that the most important diseases also have the highest levels of lobbying. It is also possible that earmarks favor the most productive universities. However, these two papers highlight the risk that governments do not always maximize social welfare in practice.

As noted above, the informational burden associated with push funding is quite high. Aside from the difficulty in determining the most deserving diseases, a funder must also select the most deserving recipients for performing the research. For the latter, the NIH uses expert committees to evaluate grant applications. These experts provide a numerical assessment of each application, and the NIH funds applications in order of this assessment up to its budget constraint. Several recent studies have closely examined this process. CITE Li:2015 considers the potential for biased experts. The grant reviewers may favor applications closely related to their own research; after all, they are more likely to find the questions interesting. Li:2015 shows that "proximity" of an expert reviewer to the application is as-

sociated with more positive assessments. However, she also finds that the informational advantage of experts outweighs this bias. Ginther & et al. (2011), who focus specifically on how race and ethnicity are related to the probability of receiving NIH funding, found large and statistically significant differences for non-white applicants, even after controlling for measures of applicant quality.

These results may not apply to other countries or to agencies' practices, of course. Indeed, there is much to learn from experiences in other countries in designing effective funding models. I merely want to illustrate that even in an environment where decisions are relatively transparent and data is widely available, the empirical reality may deviate in important ways from the theoretical ideal of government R&D support.

2) Effect of grants

While the papers described in the previous subsection analyze factors that affect the level of government support, another strand of the literature examines the effects of this support. Also for reasons of data availability, most studies on the effect of government R&D have also focused on biomedical research and on the US.

Survey evidence of firms points to a clear link between gov-

ernment funding, especially of basic research, and private sector investments (see CITE Mansfield 1998 and Cohen et al. (2002)). The relationship between the two was reported to be strongest for pharmaceuticals in both studies. CITE Cockburn1998, in an econometric study of pharmaceutical firm productivity, also identified the importance of public sector research: firms that were more connected to this research had better performance.

Many other academic papers have found a positive relationship between NIH funding of disease-specific research and private sector pharmaceutical R&D. Two examples are Toole (2007) and Blume-Kohout (2012). Both examine NIH spending by disease and its relationship to either the number of drug development projects entering clinical trials or the number of new drugs developed. The private sector increase is observed several years after public sector spending, which is consistent with the idea that public funding of basic research generates knowledge that takes some time to diffuse.

While these papers begin with data on R&D funding and look at outcomes, another approach to estimating the importance of public funding is to study whether successful outcomes are linked to public support. CITE Stevens2011 identify 153 drugs approved by the FDA that had origins in public sector research institutions. Similarly, Sampat & Lichtenberg (2011) find that

government funding at least indirectly contributed to about half of new drugs approved, and to an even greater share of those identified by the FDA as "priority" drugs.

The key challenge in identifying the effect of funding is the difficulty in finding an "experiment" to study. Funding is not randomly assigned, either to targets of research or to recipients. If governments generally fund the most promising science and the most capable researchers, we might over-estimate the effects of government support simply because of the high probability of useful results even in the absence of this funding. On the other hand, if governments instead try to fund science that poses the greatest challenges, or funds politically connected (but less productive) researchers, we might under-estimate the true effects of government support. The size and direction of the bias depends critically on how funding is allocated.

To address this bias, Jacob & Lefgren (2011) and Azoulay et al. (2015) link NIH grants to output measures using exogenous variation in grants that results from funding rules. Specifically, the NIH assigns scores to grant applications, and funds grants in order of these scores until the budget is exhausted. The "cutoff" for funding varies for reasons that are independent of the quality of grant applications, so the researchers can com-pare applications that were just above this cutoff to those just

below. Jacob & Lefgren (2011) focus on the research productivity of the researcher who was directly funded, and conclude that NIH funding results in no increase in scientific publications authored by that individual on average. They suggest that researchers can easily find alternative funding if rejected by the NIH, so the implication is not that funding makes no difference, but rather that the source of funding may be unimportant. In contrast, Azoulay et al. (2015) use private sectoring patenting as their output measure. They find an increase of 2.3 patents per $10 million of NIH funding.

Even if we can identify a causal positive relationship between NIH funding and private sector output, determining whether push funding is efficient remains difficult. To do so, we require a measure of benefits, such as years of life saved or improvements in the quality of life. While estimates of these exist, these must be linked to a specific treatment, and then the specific treatment must be linked to government-supported research. At the same time, it is necessary for all other factors that might be important. These include changes in pull policies as well as push policies in other countries, which are very rarely considered in academic studies.

3) Evidence of crowd-out and free-riding

As noted previously, government grants may risk crowding out private investment. If government budgets fund research that would have been financed by the private sector in any case, then it is less likely that the policy is addressing a market failure that leads to underinvestment, and the possibility of competing with government research may further deter private investors. A second potential issue is that of free-riding by foreign governments. Because the knowledge generated by research can be used across borders, it is tempting to let other countries finance the production of that knowledge and enjoy the benefits without paying.

Goolsbee (1998) studies the extent of crowding out in R&D funding. He argues that salaries of scientists and other R&D workers comprise the bulk of R&D spending, and that the supply of these scientists and engineers is inelastic because of the years of study required to achieve competency in these fields. This implies that when R&D spending increases, salaries of existing scientists are likely to rise. Since the private sector competes with universities and other public research institutions for scientific talent, this has the effect of raising R&D costs for firms. Even if private spending on R&D did not change as a result, the productivity of that spending would decrease. In this sense, Goolsbee (1998) finds that government crowding out is significant.

In the specific case of pharmaceuticals, most empirical evidence (cited in the previous section) suggests that public funding is associated with an increase in private investment, rather than crowding out. Perhaps the supply of medical researchers is more elastic, or government funding focuses on basic research or open science to a greater extent than in other fields. Certainly, a better understanding of specific policy features is needed.

The globalization of R&D may also have reduced the risk of crowding out. While the local supply of scientists may be inelastic, an increase in salaries driven by government R&D spending may induce firms to relocate some of their research activities to countries where there is a large, untapped supply. Of course, this is probably not the intention of R&D policy, and there may still be a loss in R&D productivity associated with this relocation.

If globalization has diminished crowding out, though, it has probably increased the temptation to free-ride on research funded by foreign governments. There are many studies on free-riding in strategic defense alliances, and this is an especially active area for policies concerning reduction of emissions and greenhouse gases. Trade agreements that include minimum requirements for intellectual property protection do so (at least in part) to restrict free-riding on the incentives cre-

ated by patent rights in foreign markets. However, few have examined whether free-riding occurs in R&D push policy.

In ongoing work, Kyle et al. (2015) study government (and non-profit foundation) support of infectious and parasitic disease research. We argue that these "neglected" diseases have minimal risk of crowding out, since they have historically been unsuccessful at attracting private investment. Countries where the burden is highest are generally poor, and their governments are unable to provide substantial support for R&D. Therefore, countries like the US, which provides more than half of the total R&D support, are providing a public good in financing this research. We find that when the US increases its total spending on these diseases, there is little response in the total spending by other governments. However, at the disease level, an increase by the US seems to induce a reallocation of other funders, who reduce their funding of that disease but increase funding of other infectious or parasitic diseases. These are merely preliminary findings, and much additional study – particularly of a larger set of diseases – is necessary.

Session 4 Conclusion

In my view, traditional R&D policies in pharmaceuticals should be reconsidered. Globalization and increased interna-

tional trade have made single country models inappropriate, particularly for the production of knowledge. The increased availability of venture capital and other financing, particularly the use of licensing and markets for technology, may have reduced the need for government support, as other solutions to potential market failures have appeared.

In addition, rather than focusing on overall R&D spending, we require a more nuanced understanding of policy details and implementation. How are grants allocated, for example, and can this process be improved? What is the appropriate balance of early-stage research and clinical development? Are public-private partnerships an efficient use of resources? Studies using data and policy efforts from outside the US would be especially valuable, as the optimal policy is different for smaller countries, those with different scientific resources on which to draw, and those with different systems of government.

Once again, however, it is worth considering how models or empirical results from eras in which national economies were far less globally integrated may apply going forward. Links between countries can result in policy spillovers (in which domestic policy choices have global consequences) as well as limit the impact of local policy (because most countries are only a small part of the global market). In the last several decades, international cooperation has led to a harmonization of patent rights.

While this remains controversial, particularly in light of the inefficiencies associated with patents as policy instruments, this is evidence that countries can agree to address problems of free-riding in the presence of externalities. Similar efforts should be considered for R&D funding.

3

The Lessons for Korea Arising from the General Regulation on Innovative Health Products

3 The Lessons for Korea Arising from the General Regulation of Innovative health products

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Session 1 Background

The Korean health care system has witnessed a remarkable expansion in health coverage over the past 30 years. Today Korea combines one of the highest life expectancies in the world with one of the lowest levels of health care expenditure amongst middle and high-income countries. Partly this has been achieved through a consolidation of a historically fragmented health insurance sector into an efficient social insurance funder of health care. This has allowed the prices of health care to be contained, helping to maintain overall expenditure.

However with increasing life expectancy comes an aging population and growing pressure on health care expenditure. As can be seen from [Figures 3-1] and [Figures 3-2] Korea has experienced high rates of growth in health care expenditure. Currently health expenditure is just under 7% of GDP, which is below the OECD average. Yet compared to other OECD countries, Korean health care spending per capita has grown twice as fast as the OECD average growth rate, almost trebling since 2000. This is clearly unsustainable.

〔Figure 3-1〕 Health Care Expenditure as % of GDP 2000-2012
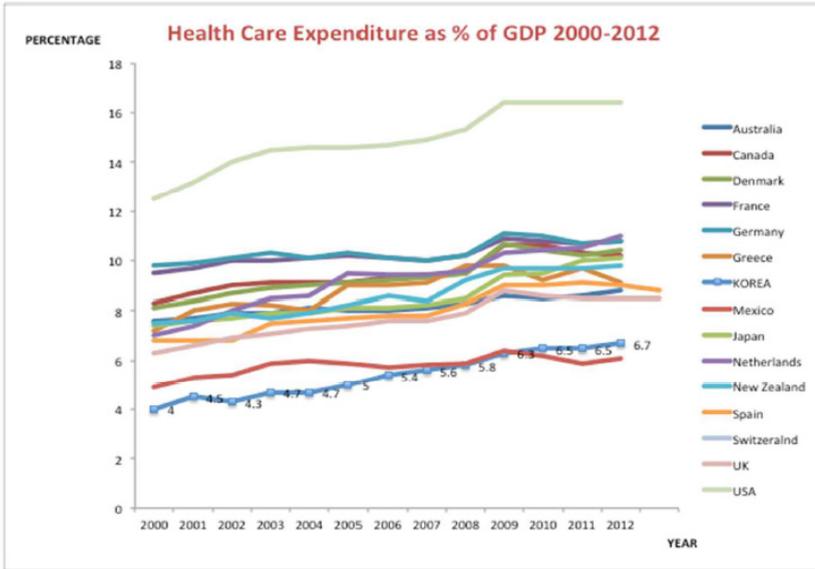
〔Figure 3-2〕 Health Care Expenditure per Capita($) 2000-2013
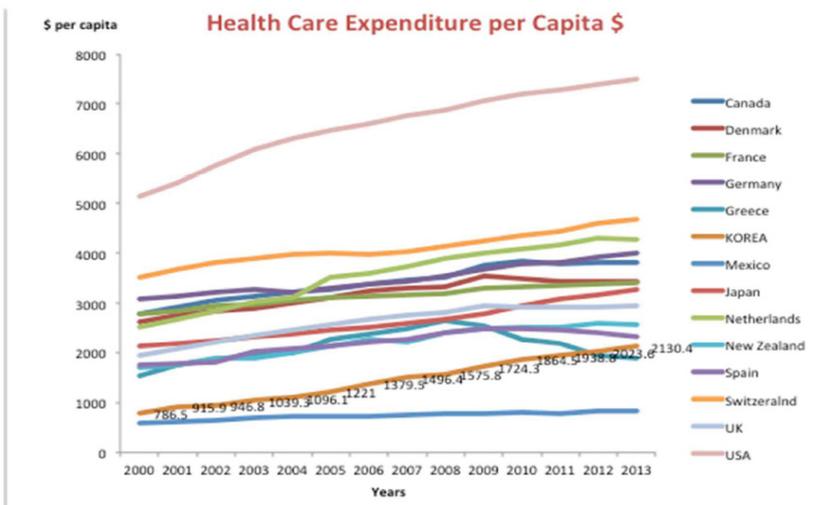
This rate of health expenditure growth has been a con-
sequence of the expansion in insurance coverage and the sub-
sequent increase in the access to health care and the resultant
utilisation growth. Expenditure pressures have largely been as-
sociated with increasing volume of health care use and increas-
ing preferences for high-quality medicine delivered largely
through the acute hospital sector.

〈Table 3-1〉 Health expenditure growth versus GDP Growth

GDP per capita	Average annual growth rate per capita, in real terms			
	1970-80	1980-90	1990-2000	2000-10
France	3.0	1.9	1.5	0.5
Germany [2,3]	2.8	2.1	1.3	1.0
United Kingdom	1.8	2.6	2.5	1.3
United States	2.2	2.3	2.2	0.6
Canada	2.8	1.6	1.9	0.8
Health Expenditure per capita	Annual growth rate per capita in real terms[1]			
	1970-80	1980-90	1990-2000	2000-10
France	7.51	4.29	4.02	2.12
Germany	8.52	2.16	2.56	2.31
United Kingdom	4.96	9.89	-0.11	5.56
United States	5.79	6.47	4.21	3.76
Canada	3.48	4.75	2.00	3.93

The aim of this paper is to put Korean health care ex-
penditure growth into some perspective. As 〈Table 3-1〉 illus-
trates many middle- and high-income countries have seen
health care expenditure, with some recent exceptions, out-
pacing the growth of national income per head in these coun-
tries for the past 40 years. In reaction there has been greater
understanding of the mechanisms of the growth in health care

expenditure, as well as increasingly efficient regulation of the sector itself.

Worldwide, health sector regulation has extended beyond traditional concerns with safety and efficacy, to evidence of performance and value. This is not surprising given that all OECD countries have seen their health care sectors grow faster than the general rate of growth in their economies. Put simply the health care sector, in all middle- and high-income countries throughout the world has expanded fasted (or declined less) than the competing sectors of each these economies. These widely prevalent regulatory reforms aimed at bench-marking performance and establishing value for money have targeting the curbing of such growth, and while not completely successful they have moved the balance of power back to the funders of health care and away from health care providers. The reforms are centred on three pillars.

First, prospective payment associated with pre-determined budgets and fixed prices,(Diagnostic Related Group pricing or DRG pricing), for services have commonly been introduced into the hospital sector. This helps to keep expenditure pressures down in what remains the largest component of any health care sector. As well as routinely accounting for 60% of the total health care budget, the hospital sector acts as the main conduit for new technology up-take and diffusion.

Second, as DRGs have been introduced they have been ac-
companied by the increasing use of Health Technology
Agencies, (HTAs), to introduce, regulate and monitor quality
standards within the health care sector. Importantly HTAs have
increasingly used the establishment of clinical guidelines, sup-
ported by the growth of evidence-based medicine, to comple-
ment (or even undermine) the self-regulating powers of the
medical profession. This has allowed managed care to evolve as
an international movement with clinical guidelines providing
explicit contracts as a complementary basis upon which DRG
pricing can be expanded.

Third, the establishment of HTAs have also increasingly been
used to establish value for money criteria against which to
judge whether new health care technologies, and in particular
pharmaceuticals, should be introduced into the health care
sector. This also complements the use of DRG pricing, as DRG
prices tend to based on historical treatment costs, introducing
a bias against the up-take of new technologies. HTA val-
ue-based pricing (VBP) approaches allow cost-effective new
treatments to be amalgamated into DRG fees and therefore in-
troduced in a more timely fashion.

Such changes directly impact on the ability of a health sector
to innovate, as DRGs tend to benchmark the average practice
and value based pricing attempts to restrict new technology
diffusion. Possibly, given the Weisbrod conundrum, where ex-

tending insurance coverage leads to more health care technology that in turn creates a demand for more insurance, this is warranted. It is also true that new health care technology appears to account for somewhere between 10 and 55% of the increase in health care expenditure growth (Smith et al, 2009). Although as such estimates are based on controlling for confounding factors and attributing the residual to the growth component of technology, little can be said of the mechanism through which this operates.

In line with this global revolution in health care regulation it is likely that the Korean health care system will also be subjected to higher levels of regulation as a response to Korean's fast growing expenditure levels. I consequently discuss these regulatory aspects in some detail below, beginning with a discussion of the general form of regulation that has captured the health care sector as based on Diagnostic Related Group (DRG) pricing in the hospital sector complemented by HTA evaluation of value based pricing, particularly as applied to the pharmaceutical sector. I then turn to consider how this has impacted on the timing of new drugs to market, before presenting some conclusions relating to the impact of such regulation on health care innovation generally. I then end with some general conclusions on regulation and innovation within the health care sector.

Session 2 DRG pricing

The hospital sector remains in a dominant position in most health care sectors, accounting for upwards of 60% of health care expenditure. Moreover the hospital plays a pivotal role in the up-take and diffusion of new health sector technology. It is little surprise that there has been increasing attention in seeking to control expenditure in this sector. The general trend in controlling hospital sector costs has focussed on the concept of yardstick competition as associated with Shliefer (1985) and builds on the introduction of Diagnostic Related Group (DRG) pricing introduced by Medicare in the late 1980s.

Medicare is the major insurer of the elderly in the USA, and provides coverage of hospital care for those over the age of 65. In the late 1980s, following a number of years of deficit funding, Medicare federal administrators moved from a low-powered incentive structure, based on retrospective payment and an implicit fee-for-service payment system to a prospective payment system where the volume of hospital patients would be reimbursed through a fixed fee for treating all patients within the same DRG. The fee itself is estimated through calculation of an average cost of treating patients within any given DRG at comparable hospitals.

The basic idea works as follows. If the total revenue is esti-

mated for each hospital based on the average cost for a set of comparable hospitals that are also producing the same DRG, this gives an incentive to each hospital to cut costs below the average, through inducing investment in cost-reducing technology to generate a surplus. When all hospitals do this the average cost falls and this incentive continues until price is set equal to the true average cost of treatment within each DRG.

Note two aspects of this equilibrium. First, the funder need not know the average cost of treatment within each hospital or each DRG. It is enough for the funder to collate information form each provider and then announce that the reimbursement level for each DRG is going to be set at the average level of the sample of average costs collected. This then provides hospitals that are above the sample average to reduce their treatment costs over time. Indeed the variation in treatment costs will also narrow over time, as the funder declares a reimbursement level that is nearer and nearer the true average cost of treatment. In other words, even with asymmetry of information the funder can establish incentives for all hospitals to move towards treatment at the true average cost of provision. Second, this pricing game establishes a regulated price that is compatible with the price that would be established if perfect market competition were in place and providers were just covering their costs of production; namely price set at average cost.

Shliefer (1985) shows the ideal conditions under which this efficient outcome will evolve, but also shows that under a fixed pricing rule based on yardstick competition and observable data can lead to efficient hospital production. As long as there is no collusion and the sample of hospitals providing each DRG is large enough there is little loss from simply setting price equal to average cost across all hospitals. Of course there must be no gaming of the system either. Hospitals should not attempt to re-classify low cost DRG treatments into high cost treatments to earn more revenue. They should also react rationally to the incentive mechanism, closing wards where the fail to compete with their yardstick providers.

While DRG pricing has been rolled out globally, it should be noted that not all countries have introduced DRGs for reimbursement purposes. A number of countries have introduced them merely to improve the information flow on hospital costs. Where they have been introduced for reimbursement purposes – and their introduction is truly global having extended from the USA through Europe to parts of Asia and South America – the effects have been predictable. In the USA, where the hospital sector has been characterised as one of excess supply and the DRG reimbursement of Medicare cases forms only part of the hospital sector reimbursement mechanism as large elements of hospital care remain in the privately insured sector, their introduction has led to a decrease in the typical length of stay for

any DRG, while activity has generally fallen. Across Europe, where the public funding of hospital care predominates, the introduction of DRG pricing has generally led to decreased length of stay and increased activity as hospitals compete for patients under budget constrained systems. (See Busse et al, 2011)

In the real world there are regulatory costs to ensure through monitoring that hospital providers are not gaming, operating cartels and are providing sufficient information for the system to operate effectively. Not surprisingly then the introduction of DRG, fixed fee pricing has lead to an increase in case-review and the establishment of guidelines on case management. This role is undertaken by the health care regulators, typically embedded within a Health Technology Assessment agency (HTA). It is this increasing use of standardised treatment protocols, to define the appropriate treatment for each DRG that has been termed "managed care".

This standardisation of the treatment protocols has two functions. It first introduces explicit specification of the (implicit) contract struck between the funders and providers of health care. This allows specification of the allowable treatment levels that are to be reimbursed. Second, it sets an average fixed reimbursement fee for each of these standardised, deliverable treatments. The average fee, the DRG price, established at the established true average treatment cost. Both

functions increase the degree of risk share by the hospital compared to the funder. The standardisation and fixing of the DRG reimbursement both promote the use of "average" care.

If the hospital product is truly a differential one, differentiated through quality and resulting in a monopolistic market, the crude imposition of yardstick-based competition may lead to a general underproduction of quality, especially if quality signals are difficult to observe and purchasers are cost-conscientious. If hospitals are grouped inappropriately, squeezing hospitals price-cost mark-ups may do nothing more than reduce the quality of care. Moreover, as the reimbursed price is based on historically observed cost-outputrelationships, and if the hospital does act as an important conduit for new, innovative medicine, then treatment quality may be further compromised.

For both of these reasons the health care regulatory system, worldwide, has tended to complement the introduction of DRG hospital payments with the assessment of new, innovative health care technologies, again through HTA regulation. Increasingly these HTA assessments rely on some form of value for money assessment, increasingly referred to as value based pricing for new technologies, in particular pharmaceuticals. I now turn to consider this aspect of the global revolution in health care regulation.

Session 3 Value based pricing

Value-based pricing, which increasingly underpins drug reimbursement within public-sector financed, budget de-limited health sectors, looks to estimate the value of a drug based on available evidence of performance. In this way drug payment is meant to vary in accordance with the clinical impact of the specific treatment in a particular patient population. The value-based pricing (VBP) approach can be widened to incorporate factors such as the burden of illness in society, the unmet need addressed, the budget impact of up-take, the degree of innovation judged to be associated with the drug and the wider social benefits derived from the drug.

The extension of regulation associated with VBP has increased the demand for evidence. Not only are head-to-head comparisons increasingly demanded, but evidence on the impact on existing treatment-pathways is also necessitated. However, evidence is not always complete at time of approval. Uncertainty may remain over long-term outcomes, treatment heterogeneity and the comparative value of interventions in clinical practice. This has lengthened the regulatory process, with a consequent impact on market access time, which subsequently affects the accrual of patient benefits and tends to erode the patent-protected market status that accompanies new innovation.

It has also led to increased opportunities to improve knowl-
edge on safety, effectiveness and value for actual practice.
Increasing data demands have led to improvements in data
sources, databases and analysis. There is increasing apprecia-
tion of clinical registries and research networks for example.
While simultaneously there has been increasing attention
drawn to population risk adjustment, the relationship between
short-term, surrogate markers and long-term outcomes and
improvements in methods generally.

As a result of these regulatory factors and the general in-
crease in the complexity and uncertainty associated with R&D
in the pharmaceutical sector, the cost of bringing new products
to market has increased rapidly, with some estimates being as
high as €2,600 million to bring a drug to market as only 1 in
10,000 compounds are successfully marketed. While debates
continue surrounding the degree of marketing versus develop-
ment expenditure across the pharmaceutical industry, drug de-
velopment costs have risen nearly 600% over the past 30 years,
as R&D addresses more intractable diseases such as cancer and
neurological disease. While there is some optimism to be
gained from the increase in New Molecular Entities (NMEs) be-
fore the FDA and EMA over the past year, success rates asso-
ciated with NMEs have fallen from 1 in 5 in the 1980s to 1 in 10
in the 2000s.

Others have recently documented falling pharmaceutical R&D productivity measured by expenditure to NMEs. Therefore, it is not surprising that increasing attention is being focused on the returns from such funding. In the area of health care the social benefit gained is difficult to quantify generally, and this also applies to the benefits derived from the R&D investments made by the pharmaceutical sector. While R&D productivity can be captured to an extent by the expenditure per new drug approved, although this undoubtedly under-estimates net worth. Drug approvals capture a heterogeneous mix of effect. Even focusing on the health return alone, they may alleviate symptoms or be life-saving; prevent disease or offer partial or complete cure.

At a wider level, at least three levels of returns to medical R&D can be distinguished: returns specified in terms of scientific knowledge; returns specified in terms of health benefits; and returns specified in terms of wider economic returns. All three levels have associated problems of measurement and evaluation. Although possibly the most inherently innovative part of medical R&D, returns to scientific knowledge are especially difficult to quantify. Spillover effects from knowledge gained in a specific area but used to generate innovations in other areas are difficult to trace, let alone quantify. The time span over which to measure R&D returns is hard to define. For these, and other reasons regulators have focused on the health

gain derived from pharmaceuticals as the primary measure of value. As discussed below even this is not without controversy. Even if the measurement of health is agreed upon there is a tendency to apply inconsistent health gain levels in the assessment of individual pharmaceuticals targeting different disease categories, even though there is a want of empirical support for doing so.

As reimbursement is increasingly tied to product value, some have argued that all dimensions of value must be taken account off, and that the highest levels of reimbursement should be given to the most innovative products. This calls for a definition of innovation. General agreement can be given to Aronson et al's (2012) definition of "rewardable innovation" as a product that provides "through a step change, something novel with the potential or proven ability to yield, for individuals and/or society a treatment not previously available or a clinically significant improvement, with large health gains and a favourable benefit to harm balance, at an acceptable cost". Such a statement requires further clarity of course, but as the authors state is not meant to rule out "evolutionary" or incremental change.

Some go further and argue that social benefit be defined and subsequently argue that attaching some form of societal willingness to pay thresholds to a treatment is required as a means of attaching further clarity to value. While there are difficulties

still to be resolved in attaching monetary thresholds to health gains, a number of public bodies in Europe support the implementation of such thresholds to help establish the reimbursement price of pharmaceutical products. The use of such valuations to help determine reimbursement levels has led to the value of the product being established in terms of health gain and society's willingness to pay for this gain is likewise established, the appropriate reimbursement price for each product can be established.

Moreover if proven, should high value products command high levels of reimbursement under a VBP system? Budget impact, as measured not only directly through value but also by volume of use, is sometimes also taken into account. Under budget constrained funding systems, the opportunity cost of high value products on de-limited drug budgets, given that it may be politically difficult to withdraw treatments, tends to result in a focus on the appropriate patient population in an attempt to limit budget impact by restricting use tohigh risk populations.

This of course moves pricing away from any direct production cost-based notion of reimbursement. Given the high R&D costs associated with establishing products in this sector this has been argued to lead to the creation of disincentives for investment in long-term R&D, especially as the costs of R&D

appear to be rising considerably. The use of patent protection
and the rights established to market exclusivity help to amelio-
rate these disincentives somewhat.

However as patents are associated with NMEs and not phar-
maceutical products, market exclusivity is undermined through
product competition. Moreover, to the extent that product
price is increasingly regulated through recourse to establishing
incremental (health-) value-added patent protection is weak-
ened and R&D incentives are distorted towards a focus on large
therapeutic markets. This has led to arguments that there
should be a de-coupling of product price from the mechanisms
used to incentivize R&D behaviour.

There is also increasing concern that as the length of devel-
opment time increases, at least partly because of greater regu-
lation, as associated with establishing incremental value and
then reimbursement, there is a further distortion in the phar-
maceutical market. Market access time is lengthened and
therefore patient benefit reduced. In an attempt to move prod-
ucts on to the market more swiftly interest has been growing in
a number of countries of quickening the regulatory review of
products. A number of suggestions have been implemented
based on different definitions of innovation, and leading to fur-
ther inconsistencies in the regulatory review process facing
pharmaceutical products.

The most direct returns relate to improvements in health care technology, which result in higher productivity within the health care sector and in improved population health. The return to R&D then becomes an issue of valuing health. Most European markets now appear to support some form of so-called value-based pricing VBP regulation.

In France and Germany many product reimbursements reflect innovative value, where innovative value is aligned with health benefit within a given therapeutic area (Bridges et al, 2009; Mossialos and Oliver, 2005). While England appears to be implementing a reimbursement system, like Canada and Sweden, based on health benefit as determined largely through implementation of cost-effectiveness thresholds. Here value, and the subsequent reimbursed price of the product is explicitly linked to the incremental health benefit produced, as specified by Quality Adjusted Life Year (QALY) gained. The definition of value is slightly different across jurisdictions, but always related to the health benefit attained.

From an economics perspective value is a measure of welfare. The objective is to maximize welfare. A return to R&D would then measure the improvement in the welfare gained by society from, for example new product development, assessed in terms of the value gained. Value gained may relate to improved welfare resulting from increased benefit or decreased

cost. An obvious characteristic of value gained specified in terms of increased benefit relates to health gain. Crucially a valuation has to be attached to the measured health gain for any return to measure improved benefit. Health gains may be the same for different treatments applied to different parts of society; but society may value these health gains differently as they apply to different members of society. The health gains received by children may have higher value than the same level of health gain received by middle-aged women and these may be valued higher than the same level of health gain received by middle-aged men. This is not a philosophical point; it is merely noting that health gain is not the same as valuation. The role of the regulator is to assign value. This tends to be done in two main ways: through consideration of the therapeutic value added or through some form of cost-effectiveness analysis based around an measure of health benefit, such as Quality Adjusted Life Years (QALYs) gained. I consider both in turn:

3.1 Health valued as Therapeutic Value Added

For a number of European Health Technology Agencies (HTAs) the standard assessment of value is defined through estimation of the therapeutic value added (TVA) derived from a product. Germany's IQWiG Methods Guidelines (2015), for example, assesses patient relevant outcomes such as improved

mortality, improved symptom, complication and side-effect profiles and improved quality of life. New health care technologies are assessed in terms of these outcomes against the existing standard therapy. Clinical trial evidence on TVA is considered to be the gold-standard. As such, from an economic perspective TVA is not concerned with value per se, but rather estimates of the differences in efficacy or effectiveness. The exception to this may be the definition of TVA assessed through changes in Quality of Life (QoL) measures, but such measures would have to relate to patient preferences in a logical manner to map these preferences against true value. It is most unlikely that such a mapping is straightforward or underpins these measures and QoL measures are most likely to be no more than an aggregation of symptom, complication and side-effect profiles.

TVA, if confined to health measurement is then most probably a measure of health benefit rather than be a valuation of that health benefit. This appears to be how it is used in a number of countries. France uses TVA within it's HAS technology assessment agency ASMR scaling. This six point definitional scale is an ordering, with innovative medicine awarded the highest reimbursement if innovative therapeutic benefit can be determined. Innovative drugs are then eligible for fast track pricing. Similarly, Italy rewards innovative products provisions for products through the Italian Medicines Agency

(AgenziaItaliana del Farmaco – AIFA) by considering the availability of treatments and the extent of the therapeutic effect these provide compared to existing treatments. Belgium's CRM agency also grants premium pricing to innovative products that demonstrate added therapeutic value. Austria operates perhaps the widest definition of innovation as based on a novel mechanism of action, a new formulation within a class or the ability to meet an unmet need, with innovative products commanding a premium price as based on cost-effectiveness calculations.

If TVA is used (directly or indirectly) as a basis for reimbursement, then under a fixed budget system, the price establishes the opportunity cost of the health benefit foregone in using each new technology within a therapeutic area. To the extent that the health gain is calibrated against standard therapy in any given therapeutic area TVA may differ in a relative sense; the value added may be different for any given treatment area, even though the absolute health gain is the same as produced by another intervention in another therapeutic area. Absolute effect may be of similar magnitude for different interventions in different therapeutic areas, but the comparative or relative effectiveness may differ across therapeutic area. If reimbursement is attached to relative effectiveness, under a fixed budget system, the opportunity cost of resource use will differ across different therapeutic areas, implying that some treatments are "valued" higher than others. Unless there is firm empirical evi-

dence to support this differential valuation of different therapeutic areas, such an approach will lead to inconsistency.

3.2 Health benefits as QALYs

The QALY is a widely recognized valuation instrument that attempts to combine dimensions of morbidity and mortality into a single commensurate measure of health state. The QALY has been used extensively for two main reasons: it arguably values health outcomes in a more acceptable metric than money does; and it feeds more easily into the wider medical decision-making process. Whether the QALY is reflective of health state preferences or health states per se, has given rise to a long rather fruitless literature (see Broome(1993) for a discussion of definition).

In most health care systems QALYs appear to be taken as measures of health states per se with an additional valuation on society's WTP for a given additional QALY taken as representing the societal value of a QALY.Even if agreement is reached over this normative approach, the actual calculation of a QALY relies on the measurement of preferences for different health states. In other words, the use of QALYs in health resource allocations moves us from the normative to the positive, where the decision rule based on QALY maximization under resource constraint necessitates some measure of the societal WTP for

additional QALY gains.

Some have argued that individuals may make systematic
biases in attempting to measure preferences associated with
their quality and length of life. Dolan and Khaneman (2008) ar-
gue that such preferences are liable to be distorted by an in-
dividual's own experiences and that, in any case, as health
states change individuals will adapt, so who to ask also be-
comes important. Others argue that the instruments used to
measure such preferences are not well understood and may
likewise impart biases. Broome (1993) has eloquently argued
that notwithstanding these problems, and that although addi-
tionally the QALY may not be conceptually clear and that the
QALY may reflect the 'goodness' of or benefit from a state of
health rather than a preference, it still represents the best ap-
proach to have been developed to date.[7]

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7) There are other contenders in terms of health state valuation. Other
   instruments such as Years of Healthy Life (HYL) and health-adjusted healthy
   life are QALYs in all but acronym (Berthelot et al., 1993; Erickson et al.,
   1995). Mehrez and Gafni (1981) proposed values based on health profiles,
   where various health states are considered in different sequences of event
   (profiles), and individuals trade off the number of years in perfect health
   against the years in profile that they deem equivalent; this seems an
   extension of the QALY concept to incorporate time in a health state into
   the value. Disability Adjusted Life Years (DALYs), which estimate life
   expectancy lost and weight this by the number of years lived in disability,
   are possibly the most commonly proposed alternative. Airoldi and Morton
   (2007) argue that once age weighting and differences in discounting into the
   DALY calculation have been made and adjustments made to allow a
   comparison between loss in quality of life and the disability weighting in
   the DALY, the two valuation concepts do not differ much. Both Airoldi
   (2007) and Sassi (2006) found, however, that the actual estimates of health

In a number of cases the WTP for a QALY, the so-called threshold value, appears to be similar. In England the threshold value is taken to be £20,000 - £30,000 per QALY, which is similar to the value of $50,000 per QALY given by the US cost-effectiveness panel (Gold et al, 1996), and the English value is used as an international benchmark by the Swedish HTA body. Devlin, Parkin and Appleby (Written Evidence for the House of Commons Select Committee Inquiry on NICE) provide evidence that NICE effectively operates a threshold somewhat above £30,000 per QALY, and that these were justified as based on a "special considerations" argument. Special considerations presumably relate to the mandate given to NICE to consider issues of innovation, patient preferences and political considerations as well as cost-effectiveness and therapeutic benefit when assessing health care technologies. Claxton et al (2015) have recently used NHS opportunity (treatment) cost calculations to estimate that the QALY value implicitly used in the NHS (in 2008/09) was £13,000 per QALY (estimated as £12,936 per QALY).

While the methodological debate over the estimation is on-going, the opportunity cost approach, unlike the WTP approach, does attempt to explicitly recognize the budget constraints. The argument is that the NHS budget is pre-determined by central government expenditure rounds, and once

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change based on the two approaches do differ systematically.

fixed the up-take of new treatments within this budget dis-
places other existing treatments. This displacement must take
account of the opportunity cost, defined by the cost-effective-
ness levels of these existing treatments.

That said, the current NICE cost per QALY estimates appear
to rest upon WTP calculations. Although end-of-life premiums,
and specifically cancer premiums have also been implemented
by health technology assessment agencies in a number of juris-
dictions, including NICE in England. In the UK, NICE appears
to accept an extra weight of approximately 2.5 applied to
end-of-life therapies giving a cost-per-QALY threshold for
these therapies of £50,000 per QALY.

The justification for these differential values presumably be-
ing that society attaches a different value to life at end of life.
This is the argument used in other UK government depart-
ments; for example the Health and Safety Executive apply a
value of twice the standard Value of Prevented Fatality (VPF) for
cancer when assessing their cost-benefit decisions. Dixon et al
(2009),however, in a review of the empirical evidence on social
valuations in health found little support for different valuation
of end of life treatments, although they suggest that severity of
illness rather than shortness of life expectancy may warrant a
premium given the empirical evidence.

Others, including Coast and Lavander (2009), have suggested

that the QALY is not useful in valuing end-of-life care as when there is little or no life expectancy gain as the QALY collapses in one dimension (the Life Year becomes redundant); that quality of life is much more important and the QALY is not sensitive enough to capture all quality of life dimensions at end of life; that patient preferences are unstable at end of life; that QALYs use a scale which anchors on a value of death (normally as = 0) and this is invalid if death is imminent; that time is valued differently at end of life compared to other stages of life. All such problems amalgamate to make the QALY a redundant measure for end of life care.

Round (2012) disputes these claims, arguing that most are empirical there is currently no empirical evidence to support them. Of the evidence that does exist Pinto-Prades et al (2014) finds some support for higher weighting at the end of life, although interestingly this does not appear to reflect higher valuation to reflect proximity to death per se, rather that quality of life improvement at end-of-life may be valued greater than small additions to life extension. It is not established how these premia are weighed, for example, with curative treatments.

If health sector R&D is supported primarily for product development that improves welfare, appropriate valuation of any associated health gain has to be made. This is particularly true in publicly funded health systems where, assuming the general

principle is that public sector expenditure be allocated con-
sistently across different sectors and within the health care sec-
tor different treatment areas, the valuation should rest on
sound, consistent empirical findings.

The threshold value of £20,000 to £30,000 per QALY is not
however strictly enforced within the UK, with some empirical
evidence suggesting that the applied threshold is over £30,000
per QALY. Others have argued for a more explicit opportunity
cost of NHS resource use, estimating this threshold to be
around £13,000 per QALY. There is also an implied threshold of
approximately £50,000 per QALY in place for end-of-life care,
but no empirical support relating to social valuations to sup-
port this end-of-life threshold.

There also seems to be some inconsistency associated with
the use of TVA relative effectiveness measures as used for ex-
ample by IQWiG in Germany, across therapeutic areas. To the
extent that both TVA and cost-per-QALY valuations inform
product reimbursement within the health care sector such in-
consistencies serve to distort the regulatory process.

There is some recognition that other characteristics of value
may be important. Value attached to increasing knowledge per
se is recognised, but in a policy context is not separable from
value defined in terms of health. The French ASMR system, The
German GMB and the Italian reimbursement authority all try to

give the highest reimbursement award to innovative medicine, for example, while measuring the return to innovation largely through TVA as defined above. Certainly across these authorities innovation definitions are applied differently. For example, within the therapeutic area of oncology the French system appears to be slightly more lenient than the German system, possibly reflecting the French acceptance of Progression Free Survival as a surrogate endpoint, while the German authorities place greater weight on Overall Survival.

Other commonly discussed aspects of value relate to the wider productivity returns associated with a healthier population or to savings in other public areas, for example social care, yet regulators may not explicitly incorporate such returns formally into their assessment of value arising from health care interventions. This may reflect the difficulties in overcoming governmental budget silos where, once public funds have been allocated to various government departments it becomes difficult to re-allocate or cross-subsidise funds that reflect the wider societal benefits arising from health improvements. While such wider benefits are real and in theory should be acknowledged the specific perspective adopted by any single department may rule out their consideration. Certainly this is the case for most European health departments, which tend to limit value to a pre-defined valuation of health and focus on their health budget alone.

Moreover, if the health benefit is judged to be high (close to curative, for example) then the cost-effectiveness ratio may be judged acceptable, within predetermined thresholds, but the budgetary impact may be exceptional. If the effectiveness is high, this might be associated with a "high value" and therefore high price, consistent with a cost-effectiveness ratio that is deemed "acceptable" within societal norms. At the same time, given treatment prevalence and the high price, budgetary impact may be extremely high, posing a major concern to publicly funded reimbursement bodies that may judge the budget impact excessive. Some have argued that this budget impact should be taken account off and the price/reimbursement decision adjusted to take account of this. This is clearly a further value impact that is directly associated with a definition of value based on health gain. The proponents of the opportunity cost valuation of health benefit, defined as a cost per QALY and based on displaced treatments, would argue that this, not the WTP approach, is the consistent method to be applied to budget constrained systems.

Session 4 Regulatory Impacts on R&D

Regulation is primarily applied within the health care sector to ensure product quality but also enforces product price and volume of care delivered. If regulation successfully contains

price and volume the return to innovation in the health care sector is reduced. As noted above DRG pricing in the hospital sector can be used to reduce hospital reimbursement prices to average costs which, if coupled with centralised control of health care budgets can have a subsequent dampening effect on innovation. This is in line with the findings by Beck et al (2009) that centralised budgetary health care systems appear to have lower levels of take-up and diffusion of new technology than decentralised, fee-for-service systems.

If this regulation of the hospital sector is accompanied by the use of HTA evaluations of new technologies, particularly drugs, and a single payment is used to cover both the production cost of new therapies and the cost of the R&D carried out by manufacturers to discover it, then innovation is further dampened. The regulation of product price may be justified in the pharmaceutical sectoras market access is accompanied by patent protection, which through protecting market entry creates monopoly rights to producers, and provides an incentive to invest in R&D given the problems of appropriating research returns.

If the regulated price is pushed down to manufacturing cost levels, regulation reduces the producers' ability to re-capture their substantial R&D investments. Patent protection will still ensure capture of some of the return to R&D, but does not guarantee a positive net return on R&D investment. Little is

known about the interaction between patent protection and
price regulation. The importance of this is that patent pro-
tection is coupled directly to price setting; the more protected
a market the higher the price can be. This coupling con-
sequently provides R&D incentives and reward. Patent pro-
tected price, one instrument, is attempting therefore to regu-
late two targets; static and dynamic efficiency; product mo-
nopoly power and R&D investments. Determination of optimal
patent coverage and optimal regulated product price is re-
quired to capture both static and dynamic efficiency.

The importance of patent protection is obvious for a system
of internal financing of R&D. Numerous studies identify a pos-
itive relationship between R&D investment and drug prices
(e.g. Grabowski and Vernon (1981);Vernon, 2005). While others
emphasize the related relationship between market size and
pharmaceutical innovation Dubois et al (2011).As price affects
cash flow and expected revenue, and these latter variables de-
termine future R&D levels, along with the intensity of R&D in-
vestment function, there is therefore a direct link between
price regulation and R&D. If price regulation distorts expected
revenues, then there will be an adverse influence on R&D
investments. If there is strong patent protection this may offset
these distortionary effects, but if patent protection is too strong
this provides incentives for over-investment in R&D. One form
of regulation thus influences the other.

Pharmaceutical products typically face a number of regulatory hurdles. Evidence on the quality, safety and efficacy of new molecules is estimated to take around ten years of pre-clinical and clinical research time. Following review of the new product dossier by a regulatory authority such as the Food and Drug Administration (FDA) in the USA or the European Medicines Agency (EMA) in Europe, marketing authorization is established, defining the relevant patient population and therapeutic use. In Europe this is followed by regulation of pricing and reimbursement. Such regulation is lengthy, delays market access and erodes patent protection. Of the literature explicitly addressing price and patent protection specifically a small number of articles empirically substantiate the claim that pharmaceutical pricing regulation lengthens the time to market, erodes patent protection and thus damages access to medicines.

The outcome of research, new knowledge is acknowledged to be a public good, with the accompanying difficulties of its return being fully appropriated by the owner. Once produced new knowledge, if not protected, is easily acquired by rivals. This, plus the fact that new (fundamental) knowledge is lumpy in production (tends to occur in jumps rather than smooth increments), and is subject to high levels of uncertainty leads to a well-recognised problem of under-production if it is not protected. Who would produce new knowledge if the returns

from the substantial investments required to produce it (because it is a highly uncertain and lumpy process) are not appropriable, in other words the knowledge can be freely acquired and used once it is produced?(Arrow, 1963).

Several studies have addressed delays attributable to drug review processes generally (Dranove and Meltzer 1994; Thomas et al. 1998; Carpenter et al. 2003; Carpenter and Turenne 2004; Bolten and Degregorio 2002), while more recent studies have emphasize price controls and variations in reimbursement schemes (see, for example, Danzon and Epstein 2008; Lanjouw 2005; Costa-Font, McGuire and Varol 2015).[8]

Increased regulation has a direct effect on access time and an indirect effect, mediated through price constraint, on time to market. This imposes welfare losses, particularly when the innovations that are delayed are cost-effective therapies from a societal perspective. These welfare losses may extend to other countries if the delays affect reference price setting in other countries. Delays in adoption also reduce the net present value of R&D investments by delaying cash flows and shortening the exclusivity period, which could reduce future R&D and in-

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8) Several studies have addressed delays attributable to drug review processes generally (Dranove and Meltzer 1994; Thomas et al. 1998; Carpenter et al. 2003; Carpenter and Turenne 2004; Bolten and Degregorio 2002), while more recent studies have emphasize price controls and variations in reimbursement schemes (see, for example, Danzon and Epstein 2008; Lanjouw 2005; Costa-Font, McGuire and Varol 2015).

novation (Giaccotto et al. 2005). Patent protection is therefore operating under increasing constraint from price regulation. Partly as a result of the erosion of true patent life through regulation the USA and Europe have both enacted patent restoration laws.

Without patent protection there will be under-investment in R&D, as appropriability is affected, and a subsequent loss of dynamic efficiency (Horowitz and Lai, 1996; Hugh, Moore and Snyder, 2002;Hughes et al, 2002).Optimal R&D is influenced by not only revenue appropriability as gained through patent protection however, but also expected product revenues, future cash flow, the level of uncertainty in the market, market size and structure, the degree of product competition, demographic factors, policies relating to governmental R&D subsidies and duration of R&D investment(Camejo, McGrath and Herings, 2011; Bardey, Bommier and Jullien, 2010;Isaac and Reynolds, 1988). There is simply no empirical evidence on the impact that price regulation has on any of these factors.

In the pursuit of static efficiency through price regulation all the major European markets now appear to support some form of value-based pricing (VBP) where value and subsequent product reimbursement price is explicitly linked to the incremental health benefit produced (OFT, 2007; Moise and Docteur, 2007). VBP approaches tend to confine value to health outcomes

through TVA or cost-effectiveness ratios. VBP, to the degree
that it helps identify unmeet health needs, may however in-
corporate a degree of dynamic incentive by directing research
activities into areas with high potential health gains. An imme-
diate problem is that VBP may not, in reality, have this desired
effect due to long lags between research and product launch.

Recognizing VBP requires larger data requirements and that
price regulation can lead to the erosion of patent time and
lengthening of time-to-market one response has been to en-
hance VBP, through enforcing risk-sharing agreements. Under
risk-share agreements payers and producers link payment to
observed health outcomes. The UK NHS has made use of such
arrangements with a number of performance based risk-shar-
ing agreements in place, for example in treatment areas for
multiple myeloma and multiple sclerosis. Such schemes may
have been helpful in addressing data requirements, but they
have been accompanied by a lack of transparency, high admin-
istrative cost and general difficulties in setting performance
targets. A major difficulty surrounds the collection and colla-
tion of patient data in these schemes. Such difficulties, accom-
panied with the detailed specification of the expected level of
performance over a given time period, has seen a loss in the
popularity of such schemes. Given these implementation diffi-
culties there is a trend towards patient access schemes, which
are essentially price discount and/or pay-back schemes, as ap-

pliedby the French reimbursement regulation.

It is clear that there is an on-going interaction between price and patent regulation in the pharmaceutical market. Internal financing of R&D emphasises revenue maximisation, which when coupled with VBP regulation this may distort the R&D process to address the greatest potential markets. Price regulation directly erodes patent protection and therefore the incentive to innovate. Yet strengthening patent protection can lead to duplication and over-investment in R&D investments. Unfortunately there is little empirical analysis of this interaction and it remains unclear how to define optimal patent depth and breadth and optimal VBP levels to ensure that static and dynamic efficiency are maintained.

At the same time, as noted earlier, the DRG pricing system operating through the hospital level shifts financial risk to the provider of care, as well as standardising care making it more difficult for the main player in the health care sector to innovate. Certainly if the new technology, and in particular pharmaceuticals, make it through the value for money criteria established by the regulator, there also has to be a means through which up-take can be eased within the hospital sector itself. This clearly entails integrating new innovative therapies into current pricing practices, but it also requires the ability of incentive structures to promote improved performance practices.

Session 5 Potential Regulatory Solutions to
Lengthening Time to Market

Recognizing the cost of longer market access times arising from regulation required to ensure safety and efficacy and then to establish reimbursement, a number of countries have recently attempted to counter this regulatory delay through the definition of a number of exceptions in establishing general efficacy. Largely this has been though designation of innovative capacity as based on innovative value as it relates to health benefit. For example, the FDA has considered:

1. Accelerated Approval where faster approval is based on surrogate or intermediate clinical endpoints and these are considered predictive of final clinical benefit. Such approval is applicable for drugs treating a serious condition that provide a "meaningful advantage over available therapies". Drugs approved on this indication are mandated to continue collection of clinical data in order to eventually substantiate their claim with a suitable endpoint, such as overall survival, post-marketing. First introduced in 1992.

2. Priority Review seeks to reduce the decision time for a given application from 10 months under a standard review to 6 months. This review is applied to drugs providing a "significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious con-

ditions when compared to standard applications."

3. Fast Track designation aims to provide increased collaboration between the manufacturer and the FDA to expedite the development and review processes. It is applied to drugs addressing an unmet medical need for a serious condition. The designation can be awarded on the basis of nonclinical or clinical data.

4. Breakthrough Therapy designation is a new, expedited pathway for the development of promising drugs, which receive intensive guidance and regulatory commitment. To be eligible the treatment has to apply to a serious condition and requires "preliminary clinical evidence…that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies."Unlike Fast Track designation preliminary clinical evidence should be submitted at the latest at the end of Phase II trials. In terms of defining the value of a substantial breakthrough, there is no single definition of "substantial improvement". Introduced in 2013.

Since their introduction there has been increasing use of these quicker routes to market. For example, since the introduction of Accelerated Approval approximately 10% of all drug approvals have taken this route. However, using cancer drugs as an example, only 33% have been successful. High fail-

ure rates have also been witnessed in the other quicker market
access routes. Using cancer drugs as examples Priority Review
has seen a 50% failure to be approved rate; and Fast Track a
54% failure rate .Indeed with all fast access policies there is a
potential adverse selection issue: the attraction of quicker ac-
cess may draw lower quality products into this route. A general
criticism is the lack of transparency in the matching of specific
drugs to the definitions used in the various expedited routes.
There has also been a lack of discussion of the implications
with respect to actual treatment given the lack of data asso-
ciated with some of these expedited routes of approval.

On top of these established quicker access pathways, the US
Congress is also considering 21st Century Cures legislation
where the proposal is for improved support for clinical trial re-
cruitment, clinical trial targeting and adaptive trial design;
greater data and methods sharing; and aid to identify sub-
populations through the development of biomarkers.

In Europe the EMA has proven effective in harmonising drug
approval across individual European countries. Although it has
not replaced individual countries' national medicines agencies,
drug approval sought through EMA can act as a substitute to
national approval. This has reduced regulatory costs for in-
dividual companies as well as widening access. Note however
that drug approval is based on safety and efficacy alone and

that individual EU countries still take responsibility for pricing and reimbursement.

The EMA initiated Conditional Marketing Authorisation with a goal to speed access to promising drug therapy, where limited information is available on efficacy. Limited 1-year market access will be provided if patient benefit, based on efficacy data, can be shown in populations who have early access, and where additional clinical data will be forthcoming. Additionally the EMA's Adaptive Pathways Pilot Programme, introduced in late 2014, is intended to improve access for narrow indications or well-defined populations. Early approval may be given contingent on follow-up real world data provision.

It is clear that both the FDA and the EMA are concerned with ensuring regulation does not inhibit market access. While both regulatory bodies are concern, rightly, with their own jurisdiction, note that there are important spillover effects at work here. The faster the market access gained by innovative drugs in one jurisdiction the greater the availability of data for other regulators. Furthermore, the faster is the up-take in the USA or Europe, the greater the potential for innovation to diffuse to other countries.

These various attempts to resolve lengthening market access times are a response to the erosion of patent protection, which itself affects R&D incentives. While these attempts are im-

portant responses, they are providing a range of different sig-
nals to producers. Not surprisingly there are definitional con-
sistency issues across the different designation routes and then
sorting problems in seeking the best route for a specific drug,
and possible adverse selection issues leading to relatively high
failure rates associated with any given route. The importance
of transparency in the definition of which regulatory route is
applicable under what circumstance cannot be un-
der-estimated.

Session 6 Conclusions

Economic regulation is a fact of life in the pharmaceutical
market. Market failure is ubiquitous in establishing efficient
levels of R&D, as the returns to R&D activity cannot be fully
appropriated unless protected. R&D is also inherently un-
certainty and investments in R&D activity are lumpy, involving
large up-front costs.[9] All such characteristics ensure that R&D
activity will be too low unless protection is offered. As a result
patents are in widespread use, establishing monopoly power
for producers, creating incentives to stimulate the R&D behav-
iour that is required to deliver pharmaceutical products of ben-
efit to society. Patent regulation is useful in determining R&D

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9) Uncertainty is different from risk which can be insured against.

appropriability and complementing pricing regulation through securing revenue returns, which provides a financial basis for further R&D.

Moreover, health is such a fundamental good that regulation is required to ensure that the delivered care is safe and efficacious.[10] Legislation cannot guarantee this is the case as contract and tort law would only offer compensation after harm. Regulation is therefore required here to ensure products do no harm. While incurring the cost of lengthening time to market, such regulation protects against product quality.

Reimbursement regulation is used to reward value, while simultaneously offsetting the monopoly created through patent protection. Such regulation, particularly in the predominately public funded European health care systems characterised either by tax-based or social insurance financing where the vast majority of health care expenditure is budget-delimited, has increasingly been applied to both the reimbursement of hospital treatments through the DRG fixed-fee process, and to the licensing and the pricing of drugs. Where there is an established rationale for pricing regulation it tends to be based on some form of value based pricing with incremental health benefit forming the main characterisation of value. Such price and reimbursement regulation does not efficiently incentivize R&D

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10) This argument applies to all health care.

and may distort R&D activity towards large markets as firms attempt to recover costs.

Europe has led the way in results-based payment structures centred on VBP. Even the DRG system is now being used to encourage improved performance. For example, Medicare only guarantees DRG reimbursement if patients are not re-admitted within 30-days of initial discharge. This encourages hospitals to improve outcome performance. Increasingly VBP is also being applied in considering the introduction of new technologies, particularly pharmaceuticals, into the health care systems.

Regulation has associated costs arising from monitoring, data acquisition, delayed access time to new innovative medicine, creation of monopoly rent through patent protection and the offsetting concern of static price efficiency as it affects dynamic R&D behaviour. Setting efficient levels of regulation in this sector is by no means straightforward. Static and dynamic efficiency are intertwined. The growth in regulation within the sector, and in particular the recent growth in attempts to secure quality as well as optimal quantity of care and the growth in explicit reimbursement regulation, is in part testimony to the high and possibly increasing degrees of complexity being experienced by the sector.

Efficient regulation should reward both innovative R&D and

products achieving high health benefits. This may encourage change in the current system. It is likely that this will include increasing use of priority channels for market access accompanied by increasing use of post-uptake evidence. Increasing use of individual risk data to identify high-risk populations to better target the use of innovative medicines with payment linked to quality and cost for a pre-specified population. Under a budget de-limited system greater use of standardised protocols, performance based pricing and restriction on the volumes of use of new innovative health care seems inevitable. Such measures will affect the return on innovation within this sector. It remains to be seen how this will play out.

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연구 2015-06	보건의료 공급체계 재설계를 통한 국민의료비 합리화 방안	정영호
연구 2015-07	호스피스·완화의료 활성화 방안 -노인장기요양서비스 이용자를 중심으로	최정수
연구 2015-08	주요 소득보장정책의 효과성 평가 연구	강신욱
연구 2015-09	돌봄·보건의료 연합서비스(Joned-up Services)공급 모형에 관한 전망과 과제	박세경
연구 2015-10	가족형태 다변화에 따른 부양체계 변화전망과 공사 간 부양분담방안	김유경
연구 2015-11	공공 사회복지 전달체계의 변화와 정책적 함의	이현주
연구 2015-12	각국 공공부조제도 비교 연구: 스웨덴&프랑스&미국 편	임완섭
연구 2015-13	사회보장 역할분담 구조 변화와 정책적 대응방안 연구	정해식
연구 2015-14	시간제 일자리 확산이 소득불평등과 빈곤에 미치는 영향	김현경
연구 2015-15	사회보장재정 재구조화를 위한 중장기 전략연구	고제이
연구 2015-16	사회보장재정과 경제 선순환 국제비교연구	유근춘
연구 2015-17	공·사적 연금 체계의 노후소득보장 효과 전망과 발전 방향	우해봉
연구 2015-18	사회보장 중장기 재정추계 모형 개발을 위한 연구: 장기재정전망과 재정평가	신화연
연구 2015-19	사회복지법인의 재정운용 실태와 제도개선 방안	고경환
연구 2015-20	지역단위 복지서비스 수요·공급 분석	정홍원
연구 2015-21-01	가족변화에 따른 결혼·출산행태 변화와 정책과제	이삼식
연구 2015-21-02	임신·출산 및 영아기 양육 인프라의 형평성과 정책과제	이소영
연구 2015-21-03	동아시아 국가의 가족정책 비교연구	신윤정
연구 2015-21-04	여성노동-출산 및 양육행태와 정책과제	박종서
연구 2015-21-05	저출산·고령사회 동태적 분석을 위한 지역추적조사(Ⅲ) -정릉3동·영등2동·소태면 사례를 중심으로	오영희

발간번호	보고서명	연구책임자
연구 2015-21-06	은퇴전환기 중고령자의 일·여가현황과 여가증진방안 연구	강은나
연구 2015-21-07	노인돌봄(케어)서비스의 제공주체간 역할정립과 연계체계 구축	선우덕
연구 2015-21-08	연령통합 지표 개발과 적용	정경희
연구 2015-21-09	인구구조 변화와 사회보장 재정의 사회경제적 파급 효과 연구	원종욱
연구 2015-21-10	저출산 극복을 위한 아동보호체계 국제비교 연구: 한중일 비교를 중심으로	류정희
연구 2015-21-11	소셜 빅데이터 기반 저출산 정책 수요 예측	송태민
연구 2015-22	한국사회의 사회·심리적 불안의 원인분석과 대응방안	이상영
연구 2015-23	건강영향평가 사업 운영	김정선
연구 2015-24	한국형 복지모형 구축: 생애주기별 소득·자산·소비 연계형 복지모형 구축	여유진
연구 2015-25	사회통합 실태진단 및 대응방안 Ⅱ: 사회통합과 사회이동	여유진/정해식
연구 2015-26	정책영향자의 사회통합 인식에 관한 연구	김미곤
연구 2015-27	아시아 각국의 복지제도 비교연구: 소득보장체계를 중심으로	노대명
연구 2015-28	2015년 지방자치단체 복지정책평가센터 운영 보고서 - 지역사회복지계획과 연차별 시행결과의 분석	강혜규
연구 2015-29	보건복지통계정보 통합 관리 및 운영	오미애
연구 2015-30-1	국민건강과 안전을 위한 아동안전전략 구축방안 -아동손상예방 전략을 중심으로	김미숙
연구 2015-30-2	국민건강과 안전을 위한 식품안전전략 구축방안	김정선
연구 2015-31	2015년 전국 출산력 및 가족보건·복지실태조사	이삼식
연구 2015-32	2015년 한국복지패널 기초분석 보고서	노대명
연구 2015-33	2013 한국의료패널 기초분석보고서(Ⅱ)-만성질환, 임신·출산, 보건의식행태-	이수형
연구 2015-34	2015년 빈곤통계연보	정은희
연구 2015-35	2015년 소셜 빅데이터 기반 보건복지 이슈 동향 분석	송태민
연구 2015-36	의료기술 혁신과 의료보장체계의 지속성을 위한 국제동향과 정책과제	박실비아
연구 2015-37	보건분야 국제공동연구사업: 주요국 보건의료산업 육성정책 변화와 동향연구	김대중