Chapter 2
Reframing the Political Economy of New Drugs

Abstract The first rule of the new drug reimbursement game is to recognise it is a game and that the regulator makes the rules. The economic expression of this game is the Political Economy of New Drugs (PEND). The global PEND is driven and shaped primarily by the US: its pharmaceutical industry; its government via trade-negotiations with the Organisation for Economic Cooperation and Development (OECD); and US-based academic pharma-economists and the evidence they generate. In this chapter I use the PEND to illustrate the characteristics of this game. What is the political economy of new drugs? How does it influence the research agenda? Does it change over time? As the US starts to address issues such as whether it should use evidence of cost-effectiveness to make decisions about drug reimbursement, the global PEND must adapt to respond to the new forms of evidence and decision rules. I demonstrate how OECD regulators outside the US could use this time of change to reframe the global PEND. The reframed PEND would facilitate a strategic and economically meaningful choice in the decision threshold and allows regulators to respond optimally to the primary strategy of the pharmaceutical industry; the threat that lowering the price below a firm's preferred price is not in the best interests of the population.

2.1 The Political Economy of New Drugs

The term "Political Economy" is a former name of the discipline of economics. Today it is used in a number of senses, and its usage continues to evolve. Common to most of the modern interpretations is the economic analysis of tension in policy choices in a context that recognises both political and economic influences (Groenewegen 2008). In this book, the Political Economy of New Drugs (PEND) is defined following the precedent set by Comanor in his 1986 paper: "The Political Economy of the Pharmaceutical Industry". While Comanor did not explicitly define his use of this term, it can be inferred that the political economy of the pharmaceutical industry concerns the economics of the critical choices governments need to make about the pharmaceutical industry and its regulation. He identifies economics

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as a "practical science" the practitioners of which have always been interested in the "critical choices" by governments.[1]

Of particular interest to Comanor was the relationship between the economist's research agenda and the politics of pharmaceutical regulation. He found that the political economy framed the research, and as the political debate changed so too did the research.

In this book the focus is "the political economy of new drugs": the factors that influence how any surplus associated with a new drug or a future drug is allocated across stakeholders, including consumers, purchasers, budget holders and firms.[2] The relationship between the economic research agenda and the political process identified by Comanor is also a central issue in this book. This book's focus on the political economy of new drugs rather than the pharmaceutical industry itself reflects the increased role of CEA in informing pricing and the capacity for industry, researchers and institutions to quantify the innovation associated with individual new drugs.

One way that the pharmaceutical industry seeks a share of a new drug's surplus is through lobbying. Lobbying plays an important part in the allocation of surplus associated with patented innovation in any sector of the economy. In the case of new drugs, lobbying tends to focus on the question of an appropriate price for a new drug, given the health-generating potential of both that drug and of future innovation funded by sales of the drug. The associated policy choices include: (1) whether new drug price should be regulated; (2) the selection of a decision threshold price in a reimbursement process; and (3) whether bilateral Free Trade Agreements (FTAs) with the US should be used by the US to prevent partner countries from regulating the price US firms prefer for their new drugs.

In the broader economy, lobbying by patent-holding firms is characterised as rent seeking or rent protection.[3] In the prevailing PEND, lobbying for higher new drug prices is instead characterised as providing incentives for investment into further R&D. This way of framing the impetus for lobbying links increased price to both increased profits and increased future health outcomes, thus creating an apparent win-win situation for firms and consumers. These claims of the relationship between new drug price and future health are supported by peer reviewed research and government studies (Comanor 1986; Scherer 2000; International

[1] See page 1178 in Comanor (1986).

[2] A UK example of the political economy of new drugs and the appropriation of surplus appears in a commentary on proposed changes to the UK pricing scheme (Towse 2007). Towse refers to the positive relationship between surplus appropriation by the innovator and the incentive for future innovation. Towse also recognises that if a higher share of this surplus is available to the health budget, immediate health gains increase. Towse also refers to the "high societal gains" from pharmaceuticals and new technologies but does not consider whether they are the best option available for improved future health gains nor does he consider how increasing the share appropriated by innovators impacts on the return to consumers.

[3] The term "rent seeking" was coined by Kruger and her original paper remains a significant milestone in the economics of lobbying and the associated deadweight social loss (Krueger 1974).

Trade Administration 2004; Vernon et al. 2009). This evidence base supports the claim that the relationship between price and R&D investment is positive and that new drugs are a key driver of improved longevity (life expectancy) for consumers.[4] The claim that firms rely on non-capital market-funded R&D rather than capital market borrowings due to the riskiness of this investment is supported by the pharma-economic literature.[5] The claim of and evidence for a win-win outcome to the policy of higher prices for new drugs is critical to the success of lobbying by US Pharma.

2.2 The Rate of Return on Investment in Pharmaceutical R&D and the Political Economy

Comanor argued that the political economy of the pharmaceutical industry shaped the economic research agenda, most notably the premise that there is a trade-off between savings today and health tomorrow: society can have more of one and less of the other but not more of both. Hence the purpose of much of the research was to quantify this trade-off. Comanor noted that the literature did not question whether this trade-off exists. Instead the research agenda prioritised finding an estimate of this trade-off, in the form of the ratio of the return (future health) on the original investment. Comanor identified three potentially relevant rates of return: the return to the firm in terms of economic rent from their investments; the return to the industry overall; and the social return, where return is measured as the increase in social welfare (economic rent and consumer welfare) from the investment in higher prices.

Comanor found that the focus on evidence of these rates of return was the single issue common to the disparate economic literature on the pharmaceutical industry. He also found that, at the time of his review (1986), no reliable estimate of the social rate of return on R&D had been published in the peer reviewed literature.[6] Comanor concluded that it could be possible to increase competition (lower price)

[4] While improved quality of life is also an outcome of improved pharmaco-therapy, the US literature and lobbying is dominated by the evidence supporting the claims of improved longevity at the population level. This situation is probably a consequence of the preference in the US economic literature for population based analysis of the benefits of pharmaceutical innovation rather than CEAs of individual new drugs. The complexity of measuring quality of life at the population level, without a control group, is far greater than that of measuring quality of life in a controlled clinical trial.

[5] "Non-capital market funded R&D" is a term used in this book to refer to the strategy by pharmaceutical firms of funding their investments in R&D through "internal funds" (economic rent) and publically financed health research such as the NIH (Vernon 2003; Keyhani et al. 2005; Santerre and Vernon 2006). This term distinguishes this strategy from the strategy of funding R&D by borrowing from the capital market.

[6] Comanor identified one study that estimated this return for three drugs but he found that the author had inflated this return by estimating the total social welfare from a given drug rather than the incremental social welfare from the innovation of this drug.

without having a loss in future innovation, however the current political economy excluded this possibility from the research agenda. Consequently, the evidence that could test this hypothesis (the possibility that there is no trade-off) was not available.

2.3 Is the Political Economy of New Drugs Constant?

Comanor observed that during the period from 1959 to 1985, the political economy of the pharmaceutical industry was reframed at least twice in response to changes in the political debate. The focus shifted from questioning whether the industry did in fact experience monopoly rents, to accepting that they did and then considering the impact of regulation on these rents and the incentive for R&D. Comanor also noted that the adversarial nature of the political debate was reflected in the economic research. He notes that at the start of economists' engagement with this political economy the focus was not on identifying critical trade-offs. Instead each side of the debate had a different premise, specifically, that the key issue was that competition should be restricted in order to maximise innovation and hence social welfare and the second ignoring this relationship.[7]

In the 25 years since Comanor's 1986 review of the political economy of the US pharmaceutical industry, the following have continued to grow: the US pharmaceutical industry[8]; US expenditure on pharmaceuticals and health as a percentage of Gross Domestic Product (GDP)[9]; the number of new drugs in the US development pipeline[10]; and the average longevity of the US population.[11] Studies have provided further evidence that the following relationships are positive: new drug price and

[7] See page 1180 in Comanor 1986.

[8] To the extent that the almost 50 % increase in expenditure on pharmaceuticals as a percent of GDP reflects growth in the US sector (see following footnotes), it is reasonable to surmise that the role of the US pharmaceutical sector as a percent of GDP has also increased since 1986. But how big was it in 2009? In 2009 an input output analysis of the US pharmaceutical sector prepared by consultants (Battelle Technology Partnership Practice) for the PhRMA (an industry lobby group formed by manufacturers that also conduct research) found that the output of the US biopharmaceutical sector represented 917B annually, with $382B in direct contribution (a multiplier of 2.4). Given that the US GDP was estimated at $14,043B this suggests that the pharmaceutical sector contributes (directly and indirectly) around 6.7 % of the total GDP and around 2.3 % for its direct contribution. It is in the interests of lobby groups to overestimate the role of their sector to the economy. For example, the authors write that: "A $10 billion change in US biopharmaceutical revenues would have the following effect on the U.S. economy: $29.7 billion in total output; 130,000 total jobs; $9.2 billion in personal income" PhRMA (2011).

[9] Total pharmaceutical expenditure increased from 8.8 % in 1986 to 12 % in 2009 Total Health expenditure increased from 10.6 % in 1986 to 17.4 % in 2009 (OECD Health Statistics 2013).

[10] From around 1,300 in 1997 to 2,995 in 2010 (PhRMA 2010).

[11] Life expectancy increased from 74.7 years at birth in 1986 to 78.2 in 2009 (OECD Health Statistics 2013).

R&D investment by firms (Vernon 2005); R&D investments and new drugs, as summarised by the costs of bring a new drug to market (DiMasi 2001); and new drugs and longevity (Lichtenberg 2006). Furthermore, other evidence suggests that the costs of bringing a new drug to market continues to increase as does society's demand for new drugs, particularly in relation to chronic diseases for which obesity is a risk factor (Grabowski et al. 2002; DiMasi et al. 2003).[12] The evidence supporting the case for higher new drug price appears to have strengthened, but the focus of evidence development has not broadened; the landscape of this political economy appears to have intensified but not shifted.

Since 1986, there have also been three main developments in the global pharmaceutical economy. First, institutions throughout the OECD started using formal processes such as HTA/CEA[13] to assess the incremental costs and benefits of new drugs compared with the best existing therapy.[14] The results of HTA/CEA are then used in conjunction with a decision threshold and other information to assess whether the population will be better or worse off if the institution reimbursed the drug at the firm's offer price. Hence, the policy debate throughout much of the OECD is increasingly broader than that of the US debate. The latter is primarily concerned with policies around discounts to large purchasers, whether there should be universal access to drugs, and whether HTA/CEA should be used and prices regulated. The rest of the OECD is additionally concerned with the choice of decision threshold and the type of information that should be included in an assessment of costs and benefits of new drugs.[15] However, the imperative to maximise the benefits of pharmaceutical and biotechnology innovation remains a significant part of OECD-wide research on pharmaceutical policy.[16]

[12] The proportion of the population who are obese, in the US increased from 23.3 % in 1991 to 33.8 % in 2008. These proportions are based on measured height and weight, not self-report, which tends to be lower. Obesity is defined as a BMI > 30 kg/m^2 2009 (OECD Health Statistics 2013).

[13] Chandra et al. (2011) describe cost-effectiveness analysis as "the half sibling to comparative analysis". The latter term appears to be used in the US in the same sense that HTA is used throughout counties that use economic evaluation.

[14] A summary of the range of OECD institutions that used economic evaluation in the mid 2000s is presented in ITA (2004). All countries have offices or institutions that place their local conventions in the public domain.

[15] Research such as that presented in Lakdawalla et al. (2009) is a good example of how the pharmaceutical policy issues faced by the US are far removed from the methodological debates that occupy countries such as the UK and the associated institutions such as National Institute for Health and Clinical Excellence (NICE). The commentary on this piece by the eminent pharma-economist Scherer (2009) should be read in conjunction with that study; it summarises the technical reasons why their estimate of the health gains from new drugs are likely to be over-estimates. The opinion piece by Weinstein (2008) shows how the US is still struggling with the question of whether or not they should use a CEA *at all* in decision making. Weinstein was a co-author of one of the seminal papers that sought to formalise CEA (Weinstein and Stason 1977). More than thirty years later, Weinstein (2008) observed that Americans still have not come to terms with the resource constraint in health care.

[16] For example see the policy document on the bioeconomy (OECD 2009).

Second, there has been a significant increase in the quantity of evidence about the relationship between: (1) price and innovation; and (2) new drugs in general and health.[17] However, it was only comparatively recently that the US pharma-economic literature provided two estimates of the ratio of the social return on consumers' investment in higher drug prices in the US. Lichtenberg's 2004 estimate of the social return on additional investment in new drug R&D is in the order of 160:1. Santerre and Vernon's (2006) estimate of a return on consumer's investment via higher prices over the period 1960–2000, in terms of the value of the additional health benefits from additional drugs, is in the order of 28:1.

Third, the US pharmaceutical industry now has two additional avenues to take the PEND to the rest of the OECD: (1) the formal reimbursement process for individual new drugs (lobbying for choice of decision threshold) (Vernon et al. 2010); and (2) the bilateral FTAs between the US and OECD countries (lobbying to prevent trading partners from regulating new drug price) (Harvey et al. 2004).

US pharma-economists have sought to adapt the original US political economy and research agenda to accommodate some of these changes. For example, Vernon et al. (2009) chose to define the socially optimal threshold from the perspective of optimal innovation. The authors started with the premise that socially optimal decision investment in R&D occurs when the firm can appropriate 100 % of the associated social surplus. Vernon et al. argue that this result occurs when the incremental cost per quality-adjusted life year (QALY) of a new drug is the same as the incremental cost per QALY of the least cost-effective of currently funded services. The authors argue this reference is the provision of dialysis at a cost per QALY of $129,000. Other authors have argued that setting a price threshold of i[18] and comparing the results of CEA against this threshold of i is price control under another name and its result is the same: pricing below the free market price will lead to a deadweight social loss.[19] Jena and Philipson have published a number of papers about the inclusion of dynamic welfare considerations in the decision threshold (Jena and Philipson 2007, 2008). Originally they argued that this threshold should be the maxWTP, just as Vernon et al. have claimed. Their rationale included that "technology adoption through cost-effectiveness is a price-control policy in disguise and might therefore have many of the properties of such policies." However, in the later paper they recognised a number of factors that supported the case for the threshold to be lower than the maxWTP. These factors include budget constraints and the contribution by public sector research funds to pharmaceutical R&D. Jena and Philipson did not specify exactly what this price should be, only that it should be higher than the threshold applied to non-pharmacological therapies.

[17] Sloan and Hsieh provide a comprehensive summary of this literature (Sloan and Hsieh 2007).

[18] For example, $75,000 per incremental QALY.

[19] For example, the report on OECD price controls prepared by the US International Trade Administration (2004).

One key aspect of the political economy has remained constant, despite these developments: the trade-off between savings today and health tomorrow remains the central premise.[20] The possibility that increased competition (lower prices) could lead to more health in the future as well as today is not part of the research agenda. Furthermore, it is a possibility that continues to be excluded from the prevailing political economy.

2.4 Reframing the Political Economy

- Is it possible to reframe rather than adapt the prevailing PEND to accommodate the developments in drug reimbursement and HTA/CEA?
- Could this reframed political economy include the possibility that each of the following can be simultaneously improved: competition; current health; and future health?

This reframed political economy would focus on the central policy decision by a reimbursing institution: which decision threshold will maximise the npvPH? The first step in this research was to develop a formal model to define the political economy of new drugs in the context of policy choice and research. The model was used to specify both the current and alternative frames for the political economy.

2.4.1 Architecture of Evidence Based Policy

The relationship between the PEND and the research agenda is characterised using an adaption of Grüne-Yanoff and Schweinzer's Architecture of Game Theory (Grüne-Yanoff and Schweinzer 2008) with additional elements derived from Roe (1991) and Comanor (1986). The adaption is described in Pekarsky (2012, Appendix 1) and illustrated in Fig. 2.1. Amongst other advantages, this framework identifies the line of reasoning that leads to certain possibilities being excluded from the prevailing research agenda. For example, by defining the key trade-off as being between more health tomorrow and more savings today, the possibility that both competition and population health can be improved is excluded. Consequently, this framework identifies that there is a requirement to redefine the evidence based policy framework that shapes the current research agenda and suggests some mechanisms by which this could be achieved.

The following two sections populate this framework, first with a characterisation of the prevailing political economy and the second with an alternative frame.

[20] This is also expressed as the trade-off between access today and health tomorrow (Scherer 2000) and decreased welfare of current patients due to higher prices and increased welfare of future patients due to more innovation from these higher prices (Jena and Philipson 2007).

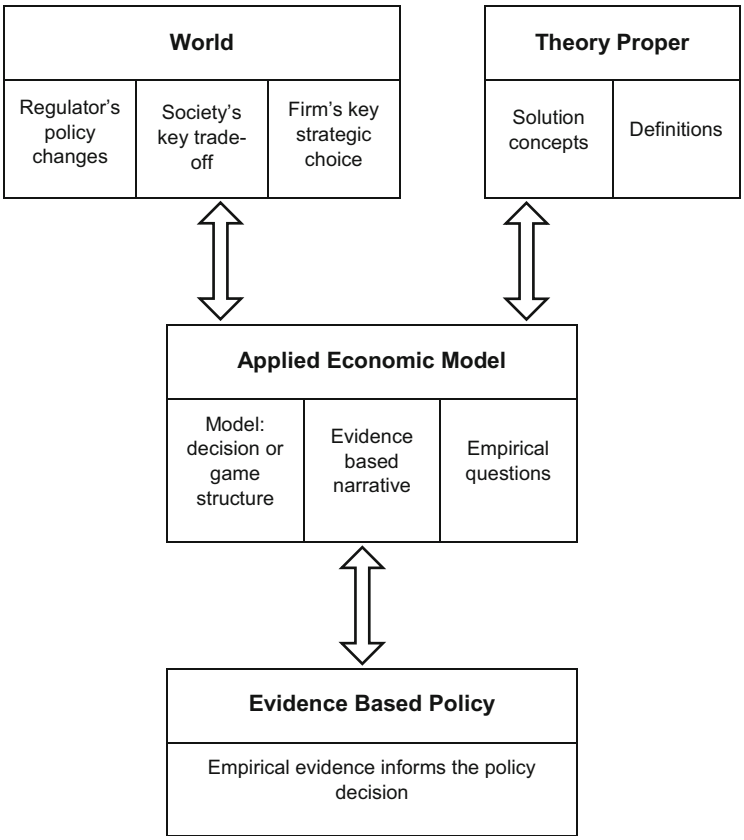

Fig. 2.1 An architecture of applied economics

2.4.2 Prevailing Political Economy

The key *trade-off* is between savings today and health tomorrow, for example:

- If the price of today's new drug is reduced below the FPP, there will be financial savings for *some* today but this is at the cost of access to more drugs for the *whole population* in the future.[21]

[21] An excerpt from the Joint Hearing of the Finance Committee of the US Senate in April 2004 is reproduced in Attachment 2 and contains a number of variations of this theme. This characterisation is a synthesis of the extensive literature on this topic, much of which is summarised in Comanor (1986) and Scherer (2000). Specific examples include: "Greater access to today's medicines… through drug price controls at a cost of fewer new drugs in the future" and "Understanding this tradeoff is imperative for sound public policy." (Vernon 2004). Another example is Vernon et al.'s (2006) analysis of a change in pricing policy in the US in which the authors state that the policy debate on lower prices should consider the "hidden potential costs" of lower prices (less innovation). They state that their analysis does not provide evidence of the "relative costs and benefits of pharmaceutical importation (or price regulation)." But then go on to infer that these "hidden potential costs" are so significant that they dominate policy choices.

The key *decision by the firm* is how much to invest in R&D and the key *policy choice* is whether or not to regulate or control the new drug price. This particular framing inspires *research questions* such as:

- What is the relationship between today's price of a new drug, pharmaceutical R&D and future innovation? (Vernon 2005; Abbott and Vernon 2007; Vernon et al. 2009); and
- What is the incentive for purchasers to maintain prices at the FPP? (Lichtenberg 2004; Santerre and Vernon 2006).

This frame excludes empirical questions about the direction of the relationship between: (1) new drug price, R&D, number of new drugs; and (2) future health of the population. This relationship is assumed to be positive under all conditions. The *critical piece of information* that will inform the regulator is the return on this investment in R&D (financed via higher prices and public investment), where this return is measured as the additional health gains possible from the availability of additional drugs in the future. If the health effects are monetised, for example using an estimate of the value of an additional year of life, then the return can be compared to the investment as a ratio. If this ratio is high then increased prices today represent a good evidence-based policy choice. If this ratio is less than one, then there is a net loss on the original investment.

The *evidence-based policy narrative* takes the following or a related form.

> New drugs have been shown to be the key driver of historic gains in life expectancy for the US population. In order to achieve sustained increases in life expectancy, more new drugs are needed in the future. Pharmaceutical innovation is driven by R&D investments by firms. R&D investments are driven by higher new drug prices, acting as both an incentive and a funding source for ongoing R&D. The value of the possible health gains far outweigh the financial costs of R&D, therefore higher—unregulated—prices represent good policy.

2.4.3 An Alternative Political Economy of New Drugs

This book explores the fresh paths for research and different critical research questions opened by reframing the prevailing PEND. There are many ways that the political economy could be reframed. The frame used in this book is summarised as follows.

The key *trade-off* is between savings for health purchasers today and firms' profits. The evidence for this trade-off is twofold. First, a firm would not lobby for a higher price unless this strategy increased its profits in the current period. Second,

an institution would not reject a higher price of new drugs if it also decreased costs of providing the same health benefits from today's budget. Therefore the existence of this trade-off is a reasonable premise.

The key *decision by the firm* is how to maximise profits today and tomorrow. One strategy available to the firm is to minimise the R&D costs borne by the firm by creating an incentive for institutions to subsidise these costs. One mechanism by which this is achieved is to increase the price of current drugs, without reducing quantity sold (for example, increase the decision threshold). The key *policy choices* for the institution are: (1) what should the decision threshold for the health effects for new drugs be; and (2) should this threshold be altered, given that there is a relationship between new drug price today and future population health. This particular framing inspires *research questions* such as:

- Given that budgets are constrained or fixed, under what conditions will increased pharmaceutical R&D today necessarily lead to increased population health in the future?;
- What about the impact on the population's future health due to less resources being allocated to health care today?; and
- How should institutions respond to Pharma's strategy of lobbying to increase the decision threshold?

The *critical pieces of information* for the institution are: (1) what is the maximum acceptable price for new drugs; and (2) how does this maximum price change if there is a relationship between price and the npvPH. The *evidence-based narrative* takes the following or a related form.

> Higher prices today mean increased economic rent for Pharma otherwise they would not lobby for them. It is in Pharma's interest to protect and seek these economic rents. Whether higher prices and more R&D today increase future health remains an empirical question. If higher prices also mean a higher net present value of the population's health, then it is in the institution's interest to increase prices. Given the institution's objectives, the most effective strategy a firm can use to protect these rents is "the Threat": lowering prices is against the interest of health funders because it will reduce a population's future health.

In this alternative framing, the market within which pharmaceuticals compete is expanded to include any health input, including unpatented programs and technologies. Competition for pharmaceutical R&D funds would include investments in other forms of medical and health innovation, including those that cannot be patented, and research on workforce and service delivery. The reframed political economy also recognises that there is a failure by markets to provide evidence of the cost-effectiveness of unpatented and unpatentable programmes. It recognises firms' rent-seeking motives, accepts these as rational, and explicates the increased

rent available to firms as a consequence of lobbying. Finally, it includes both of the following possible consequences of increased price of new drugs today, not just the first (as is the case with the prevailing political economy):

- New drug prices increase and the future health of the population improves; and
- New drug prices increase and the health of the current and future populations decreases.

Consequently, the following two central premises of the prevailing political economy become testable hypotheses under this alternative framing:

- Higher drug prices, more R&D and more new future drugs will always increase the future health of the population; and
- There is a trade-off between savings (and additional health from improved access) today[22] and health tomorrow.

2.4.4 Comparison of Prevailing and Proposed Frames

The prevailing and alternative frames of the political economy are compared Tables 2.1, 2.2, 2.3 and 2.4 in relation to each four components: World; Applied Economic Model; Theory; and Evidence Based Decisions. Only the alternative frame accommodates the possibility that the health of the future population might increase or decrease as a consequence of lower drug prices today. The alternative frame is designed to find the solution to the following policy problem: the choice of a decision threshold price for new drugs, where this threshold accommodates both characteristics of the health budget and the relationship between price today and innovation in the future. This intent is in contrast to the prevailing frame, which, as demonstrated in Chap. 3 and Pekarsky (2012, Appendix 7) is specified so as to fit a particular solution. This solution is that threshold prices below the firm's preferred price or the maxWTP are not in the interest of an institution seeking to maximise the population's health (1993).[23]

One issue that is raised by this alternative political economy is that it is not possible to calculate the critical ratio of costs to benefits of lower prices without evidence of the counterfactual. The counterfactual to higher drug prices becomes

[22] The reference to reduction in health today as a consequence of increased expenditure on more costly drugs was originally part of this trade-off. Typically this was expressed as the trade-off between access (lower priced drugs so that everyone, particularly the uninsured could afford them) and more health in the future. See for example Scherer (2000). However, increasingly the US literature expresses this as a trade-off between savings today and health in the future. For example, see Santerre and Vernon (2006). The critical question then is to compare the financial value of future health effects against these savings. For reasons discussed and demonstrated in Chap. 3, this particular framing results in a higher ratio of the gains in the future compared to the loss today.

[23] The contrast between framing a problem to "find" rather than "fit" the solution comes from Birch and Gafni (1993).

Table 2.1 Reframing the political economy of new drugs: World

	Framing the problem to FIT the solution	Framing the problem to FIND the solution
Trade-off	Savings today vs. more health in the future population	More economic rent today vs. more health (or more savings) today
Firm strategies	How much to invest in the R&D for new drugs?	How much to invest in lobbying for a higher price?
	What is the price at which R&D is optimised?	What is the most effective way to increase and protect economic rent?
Regulator policies	Should the new drug price be controlled?	What is the decision threshold (shadow price) for the additional health effect a new drug?
	How much should the public sector invest in R&D?	How much to invest in the development of evidence of counterfactuals?
	How should FTAs accommodate pharmaceutical pricing?	How to respond to the threat that lower prices are not in the population's interest?

Table 2.2 Reframing the political economy of new drugs: applied economic model

	Framing the problem to FIT the solution	Framing the problem to FIND the solution
Evidence based narrative	Improved longevity is driven by Pharma R&D. To continue to improve longevity we need to continue invest in R&D via higher prices and more public research funds	Less than 30 % of the economic rent from higher prices is allocated to NME R&D. Firms have an incentive to generate and protect these rents. The most effective threat is to claim that the higher prices are in the interest of the population's health
Model structure	Decision theoretic, uncertainty but no private information and new drug price is exogenous to the reimbursement process	Game theoretic, assuming that there is strategic response, new drug price is endogenous to the reimbursement process and firms hold private information (information in their private domain)
Research questions	What is the health value of historic R&D decisions?	What is the economic value of the clinical innovation of new drugs?
	What is the response of R&D to new drug price?	How much to invest in developing evidence of counterfactuals to Pharma R&D?
	What is the health return on consumers' investment in R&D?	Under what conditions will a price above the shadow price increase the npvPH?

Table 2.3 Reframing the political economy of new drugs: theory

	Framing the problem to FIT the solution	Framing the problem to FIND the solution
Theory proper	Firms require the full surplus associated with the drug in order to achieve socially optimal levels of R&D. Price control leads to a deadweight social loss and pharmaceutical price control is no exception to this basic economic fact	Shadow price of new drugs should accommodate existing inefficiencies and all alternative investment opportunities by the public sector. Firms have private information. There is a failure of markets to develop evidence of unpatentable health innovation

Table 2.4 Reframing the political economy of new drugs: Evidence based decisions

	Framing the problem to FIT the solution	Framing the problem to FIND the solution
Evidence	New drugs have contributed significantly to improvements in US longevity that would not have occurred without this R&D	The improvements in longevity experienced in the US are below those experienced in other countries such as Canada, UK and Australia. [See Pekarsky (2012, Appendix 3)] These other countries have not corrected for the failure of the market to provide evidence of the counterfactual but they have provided incentives to develop evidence of the cost and effect of new drugs
	There is a return of 28-fold in health benefits from every dollar invested in R&D raised through higher new drug price	
Policy decisions	Do not regulate new drug price	It could be that there is a price above the shadow price that is better for the npvPH. If this is the case, this price should be adopted. Otherwise the shadow price should be applied. How much should be invested to correct for the markets failure to generate evidence of unpatented and unpatentable services, technologies and programs?
	Increase public subsidy of private Pharma R&D	
	Use FTAs to control regulation in other countries	

relevant when the budget is assumed to be either fixed or constrained (that is, not unconstrained). (See the discussion of these terms in Sect. 3.3.) However, without evidence of the alternative uses of these funds, it is not possible to determine whether or not a country such as the US could have done better by investing in alternative technologies (perhaps with a low ICER) or in unpatented programmes. This issue is also relevant to countries that use HTA/CEA to inform new drug adoption decisions. The pharma-economic literature is strongly supportive of the use of patents to generate a financial incentive for investing in the R&D for new

drugs. However, as Arrow (1962) and Tirole (1988) both conclude, the failure of the market to provide an incentive to invest in innovation where that innovation cannot be patented is an economic case for public sector investment. The failure of the market to provide an incentive to invest in developing evidence of unpatented programmes and technologies is not afforded the same attention by pharma-economists as the potential failure to protect the results of patentable, pharmaceutical R&D (Sloan and Hsieh 2007). The issue of absence of evidence of the counterfactual is a barrier to testing the key empirical question under the prevailing frame. In the alternative frame, the absence of this evidence is a characteristic of economic context; the failure of the market to provide evidence of the unpatented counterfactual to higher prices.

2.5 Conclusion

The global PEND shapes the pharma-economic research agenda. But how can we reframe the political economy and research agenda so as to accommodate the critical policy issues faced by institutions outside the US? There is more than one way this alternative political economy could be specified. The frame proposed in this chapter and used throughout this book has a number of features that distinguish it from the prevailing political economy. One of these features is that it recognises that there is that pharmaceuticals face competition in the market for health inputs, including competition from unpatented and unpatentable technologies and inputs. Consequently, a critical piece of evidence is a qualitative value (equation) of a health shadow price that reflects the competition in the market for health inputs.

In the alternative PEND the evidence of the historic rate of return on consumers' investment in pharmaceutical R&D via higher prices is no longer the key piece of evidence that informs policy. However, if the evidence provided by Santerre and Vernon (2006) and Lichtenberg (2004) that this return is very high (between 28 and 160 for each dollar of higher prices) is correct, then it would appear that the value of an alternative political economy that can also identify the possibility of an increase in current and future health from lower prices is limited; it will not change a policy decision.

In the following chapter, I show that despite the US evidence of a very high ratio of social return on pharmaceutical R&D, it is both possible and plausible that, had prices of new drugs in the US been lower over the past 50 years, that the health of the US population today could have been better. A high return, as calculated in the US literature, does not exclude the possibility that lower prices can improve current and future health.

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