

# Analytical Models for Designing Pharmaceutical Contracts

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We develop the first integrated analytical framework to study contract and pricing strategies in the pharmaceutical industry. We demonstrate how this framework can be used to analyze optimal contract and pricing decisions for insurers and manufacturers, including recent pricing practices such as manufacturer's coupons and risk-sharing contracts. We discuss the implications of these decisions for consumers, insurers, and manufacturers.

*Key words:* Cost analysis; Utility-preference: Application; Utility-preference: Choice functions; Industries :  
Pharmaceutical; Health care

*History:*

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## 1. Introduction

The pharmaceutical industry has been facing tremendous financial pressure in recent years, as the rate of pharmaceutical discovery slows. While research and development spending by U.S. companies more than doubled between 1998 and 2008, the number of new drugs introduced has remained flat between 20 and 30 per year (Comanor and Scherer 2011). At the same time, highly profitable blockbuster drugs have been losing their ability to drive growth in the current series of patent expirations (Behner et al. 2011). It has been estimated that “from 2010 to 2013, pharmaceutical companies . . . will lose a total of \$137 billion to patent expiration and generic competition” (Maddock and Viton 2011).

These financial pressures are forcing pharmaceutical companies to pursue all avenues for improving profits, including the adoption of more innovative pricing strategies and the improvement of their tender and contract-management capabilities. In 2011, “four of the top five pharmaceutical

firms have invested in developing tender and contract management capabilities,” with the rest of the industry expected to follow suit (Behner et al. 2011).

A recent pricing innovation is the offering of *manufacturers’ coupons*. These are coupons issued by manufacturers of brand-name drugs to help patients reduce their copayments on these drugs. When a brand-name drug’s patent expires, there is usually immediate competition from generic drugs. When there is only one generic drug maker, the generic drug’s price “is only about 25 percent lower than for the branded drug;” however, when there are multiple generic drugs, the price of the generics usually drop to about “90%” percent below that of the brand-name drug, causing most patients to switch to a generic (Associated Press 2012). Manufacturers’s coupons can reduce, or even eliminate the copayments for brand-name drugs. For example, Pfizer pays up to \$75 of patients’ copayments for Lipitor (Associated Press 2012). Under the company’s Lipitor-for-you coupon program, insured patients pay only \$4 out of a typical copayment of \$25 to \$50 a month without coupons. Uninsured patients get \$75 off of each \$175 per month prescription (Associated Press 2012). With manufacturers’ coupons, doctors and patients have little motivation to switch to generic drugs. The tactic enables manufacturers to compete with generic versions of the drugs and prevent the loss of billions of dollars of revenue to generic competitors.

It is estimated that drug manufacturers are spending “between \$3 billion and \$6 billion annually on coupon programs,” and will continue to expand their coupon programs by about “15 percent per year,” so that coupons will be applied to half of about “500 million” brand-name prescriptions by 2021 (Cahn 2012). In 2009, half of the top-selling 109 drugs had coupons. In 2010, coupons were applied to 100 to 125 million prescriptions, or “11 percent to 13 percent of all brand-name prescriptions” (Cahn 2012). Over these two years, the number of coupons programs quadrupled from “86 in July 2009 [] to 362 in November 2011” (Cahn 2012). As of May 2012, coupons are offered for “more than 370 drugs,” including “Abilify, Atripla, Celebrex, Crestor, Diovan, Effexor XR, Geodon, Nexium, Vytarin and Zetia” (Cahn 2012).

Coupon programs have been controversial for several reasons. It is not clear that coupons are always a good strategy. Some companies have chosen not to offer coupons because they believe

that the strategy would be ineffective against preventing low prices of generic drugs to drain their market share (Associated Press 2012). While coupons enable consumers to stay with brand-name drugs without bearing the cost, they interfere with insurers' copayment program, which has traditionally been used to direct patients to more cost-effective choices, for example generics drugs or drugs for which the insurer has negotiated discounts (Grande 2012). They can also increase health insurance premiums, or aggregate health spending by users and non-users (Grande 2012). Finally, they can increase direct cost for coupon users if copayments are still higher with coupons compared to copayments for other alternatives (Grande 2012). The Pharmaceutical Care Management Association estimates that coupons could “raise prescription drug spending by \$32 billion over the next decade” (Associated Press 2012).

Another pricing innovation is the use of *risk-sharing contracts* in the market for new and innovative drugs. This market is usually fraught with uncertainty in the initial years after the drug is first introduced into general usage. Clinical research on drugs is geared towards designing randomized control trials (RCT) “to produce evidence for regulatory approval by the FDA” (Mullins et al. 2010). This goal results in RCT study designs that achieve “high internal validity,” or high confidence in the causal relationship established within the study, but not necessarily “generalizability to diverse real-world patient populations” (Mullins et al. 2010). Consequently, “systematic reviews for the purposes of coverage and treatment decisions often find relevant and high-quality evidence to be limited or nonexistent” (Mullins et al. 2010). This trend is especially true in oncology, when there is inherently high uncertainty regarding the outcome of treatments (Mullins et al. 2010). Thus, the initial process of obtaining regulatory approval is “considered as a necessary but not sufficient condition to verify the value of a new product” (de Pouvourville 2006). *Coverage decisions* (decisions made by insurers of whether or not to pay for a drug) then, are often made when there is still considerable uncertainty regarding the true benefit of a drug. At a time when the costs of prescription drugs are escalating, with many new treatments for conditions ranging from cancer to rheumatoid arthritis to multiple sclerosis costing over \$100,000 a year (Kolata 2008), the stakes in these coverage decisions are especially high for insurers. Insurers must balance the demands of

patients and physicians for innovative and potentially life-saving treatments and their own need to pay for value. For most new treatments, “substantial uncertainty exists about their optimal use for many years after they are initially introduced” (Mullins et al. 2010). Risk-sharing contracts can mitigate manufacturers’ difficulties by tying compensation to performance. In such a contract, payments from insurers to a manufacturer for a drug depend on the drug’s actual performance. The contract allows both sides to “share in the risk.” Some of the financial risk of the insurer is now assumed by the manufacturer. By making the approval of a drug less risky for insurers, the contract can improve the chance for the manufacturer of obtaining reimbursement approval.

U.S. companies have already started to experiment with risk-sharing contracts. United Healthcare has a risk-sharing contract with Genomic Health, which sells the \$3,460 Oncotype DX test to determine the likelihood of success of chemotherapy in early-stage breast cancer. If too many women with negative test results still receive chemotherapy, the insurer receives a lower pre-negotiated price based on the lower-than-expected impact of the test on actual medical practice (Levitt 2009). In an other example, Merck and CIGNA have a risk-sharing contract for the diabetes drugs sitagliptin and sitagliptin+metformin. Based on the improvement in blood sugar levels and compliance of patients taking the drugs, Merck will offer CIGNA pre-agreed discounts in exchange for a lower co-payment and better placement of the drugs on CIGNA’s formulary (Levitt 2009).

There is great interest in risk-sharing contracts in practice, but their use is still limited by the fact that little is understood about how to design and analyze them. There is a general “lack of consensus on how to design and implement” risk-sharing schemes (Cromwell 2011) and a lack of methods to analyze their benefits (de Pouvourville 2006).

The challenge in analyzing these and other pharmaceutical contract and pricing agreements lies in modeling the interplay of decisions made at various levels by patients, physicians, insurers, and manufacturers, each of whom is motivated by a different set of objectives. Manufacturers’ pricing decisions do not have a direct impact on consumer demand, since these prices are moderated by the copayments set by insurers for their beneficiaries. The copayments are ultimately what consumers pay. In structuring their copayments, insurer are concerned not only with controlling cost, but also

with promoting the well-being of their beneficiaries, due to their commitment to provide long-term, comprehensive healthcare benefits for them, competition with other healthcare plans, and the need to win regulatory approvals. Finally, patients and physicians' drug purchases are influenced not only by the cost of the drugs, but also by the potential benefit of the drugs and the suitability of the drugs to the patients' individual dispositions.

In this paper, we develop the first analytical framework to study pharmaceutical contract and pricing strategies. We demonstrate how this framework can be used to analyze optimal contract and pricing decisions for insurers and manufacturers, including optimal coupon offering and risk-sharing decisions. We discuss the implications of these decisions for consumers, insurers, and manufacturers.

We will adopt the following terminology throughout. Patients with the same medical condition are said to be in the same *category*. Similarly, drugs that can treat the same medical condition are said to be in the same *category*. Note that a patient can belong to multiple categories, and so can a drug. Generally, we will focus on a single medical category.

A *formulary* is a list of drugs approved by the insurer for use in a particular health plan, together with their associated co-payments. The co-payment may be the same for all drugs, or may vary with the drug. We refer to a formulary-design decision regarding a particular drug as the *coverage* decision for that drug.

We will use the term *patient choice* to mean the choice that is made by a patient in consultation with his physician. Thus, a patient and his physicians act as one agent. Choice refers to the fact that a drug that is covered by the insurer is likely to be chosen by a patient based on its expected benefit to him relative to other drugs in the formulary, as well as on its co-payment. In particular, the drug that is chosen by a particular patient depends on what other drugs are being offered in the formulary and what the co-payments of those drugs are. Consequently, the demand for a drug may change with the formulary.

### 1.1. Summary of contributions

- We model individual patient choice of drugs using the Multinomial Logit Model of customer choice. The model captures statistical variations in patient utility for any given drug in a diverse

population. The model also captures patient sensitivity to copayments set by insurers.

- We model each insurer’s decision problem as a formulary-design problem. The insurer sets the copayment for each drug to minimize the total immediate cost of providing a formulary, less the total utility of the formulary to its beneficiaries. The latter objective is important because the beneficiaries’ long-term health ultimately affects the insurer’s cost, and the quality of the benefits provided by an insurer determines both the insurer’s competitiveness as well as its ability to satisfy regulatory requirements. We show that under this objective, the optimal copayment structure equalizes the insurer’s payment, which we call the *insurer’s subsidy*, for all drugs. The subsidy increases with the mean utility and decreases with the price of each drug.

- We model each manufacturer as the leader in a Stackelberg pricing game with identical insurers. The manufacturer’s objective is to maximize profits. We provide analytical solution for the manufacturer’s optimal pricing decision. We also derive numerical insights about the optimal price and the corresponding insurer’s subsidy.

- We show that manufacturers’ coupons can significantly increase manufacturers’ profit at the expense of insurers. The optimal coupon amount always equals the copayment for a drug. Insurers can effectively counteract the effect of these coupons by raising copayments for drugs that have coupons. However, this strategy is difficult to implement due to the impracticability of making constant changes to their copayment structure. Coupons can increase consumer utility through improved access to brand-name drugs, but also increase the cost of insurance premium. They can improve or lower overall consumer utility depending on the balance between these two effects.

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- We modify our basic model to capture uncertainty about the true effectiveness of a new drug.

We show that when insurers expect the effectiveness to be lower than has been demonstrated in clinical trials, the effect is equivalent to having the cost of manufacturing the drug increase. This additional expense lowers the manufacturer's profit. The effect is one-sided, in the sense that it is a function of only insurers' perception.

- We show that risk-sharing contracts are an effective way for a manufacturer to assert its knowledge about the performance of a drug and prevent insurers' one-sided perception from affecting its profit. A manufacturer will offer a risk-sharing contract if and only if it is strictly more optimistic than the insurer about the expected risk-sharing payment. Risk sharing is equivalent to having the manufacturing cost of the drug be adjusted. However, this adjustment is a function of both insurers' and the manufacturer' expectation about the eventual benefit of the drug. Risk sharing can significantly increase the manufacturer's profit at the expense of insurers. It can improve overall consumer utility through improved access to a new drug, but only if the compensation for an ineffective drug is not too large as to make the cost to the insurer, therefore, the cost of insurance premiums to consumers, excessive.

## 1.2. Related Literature

**1.2.1. Patient and physician decisions.** The Multinomial Logit model has been widely used to model customer choice behavior in retailing in the Operations Management literature. See, for example, Kök et al. (2009) and the references therein. Truong (2011) uses a similar model to study the optimal selection of medical formularies. However, this paper is restricted to closed formularies, where insurers only control whether drugs are to be included in the formulary or excluded from it, and all included drugs are subjected to a uniformly small co-payment.

**1.2.2. Insurer decisions.** Our model of insurers' decisions is similar to models of retailer pricing decisions that account for customer choice. This problem is well studied (see, for example, Aydin and Ryan (2000)). An important difference in our model is that insurers are not simply pricing a formulary to minimize cost. Rather, their objective function strongly accounts for the

expected utility of the formulary to their beneficiaries (see Section 2.2). Despite this difference, the optimal decision in our setting has an elegant structure that is similar to that of pure cost-minimization problems. The optimal copayment structure equalizes the insurer’s payment across all drugs.

**1.2.3. Manufacturer decisions.** Unlike the literature on retail pricing under customer choice, the focus of our work is not on insurers’ copayment decisions (which as we noted, are similar to retailers’ pricing decisions). Rather, we are ultimately interested in a higher level of decisions, which is manufacturers’ contracting and pricing practices. Our contribution is an integrated model accounting for the disparate objectives and behavior of patient and physicians, insurers and manufacturers. We are not aware of any existing model designed for this purpose.

**1.2.4. Manufacturers’ coupons.** King et al. (2012) study the impact and strategic nature of manufacturers coupons using a Stackelberg game involving insurers, manufacturers, and patients. The insurers in their model are purely cost-minimizing. Thus, the authors do not model the fact that low patient utility for a formulary can result in negative health consequences that ultimately raise insurers’ cost, nor the fact that insurers need to maintain certain standards of benefits in order to stay competitive and to win regulatory approvals. In addition, the authors focus exclusively on analyzing manufacturers’ coupons, whereas our intent in this paper is to build a general model that can be used to analyze many types of pharmaceutical contracts. We study manufacturers’ general pricing problem as well as specific strategies like manufacturers’ coupons and risk-sharing contracts.

**1.2.5. Risk-sharing contracts.** Risk sharing contracts have been proposed by numerous authors (see, for example, Adamski et al. 2010, Claxton et al. 2008, de Pouvourville 2006, and Cook et al. 2008). Carlson et al. (2010) provide a comprehensive taxonomy of performance-based health outcomes reimbursement schemes that have been used in practice.

Several authors (Zhang et al. 2011, Zaric and O’Brien 2005) have studied risk-sharing contracts, where the main risk is not the quality but the volume of drugs sold, which may be greater than

anticipated by an insurer. These risk-sharing contracts are similar to price-volume risk-sharing contracts that are common in the Operations Management literature.

There are several quantitative models of risk-sharing. Barros (2011) considers a simple model of risk-sharing in which the probability of treatment success varies in population and is known by doctors. Doctors select whether or not to provide the treatment. A price is paid to the manufacturer for each patient successfully treated. In this model, doctors do not merely provide clinical advice, but must make economic decisions of whether to provide treatment to individual patients. This policy would be illegal in the U.S., where an insurer cannot selectively offer a drug only to certain patient groups, for example, to those for whom the drug is cost-effective. This restriction would violate the Patients' Bill of Rights Act of 1998, which states that "patients should not be discriminated against in their access to covered health-care services" (Olmstead and Zeckhauser 1999). Capri and Levaggi (2011), Antonanzas et al. (2011) and Zaric and Xie (2009) study risk-sharing contracts in non-competitive markets, where there is only one insurer, who is also a regulator. These papers lack a mechanism for describing the relationship between the demand for the drug and existing evidence of effectiveness for the drug or for alternative drugs. In Capri and Levaggi (2011), demand is a decision variable set by the manufacturer along with the price. Although the manufacturer might be able to decrease consumption by restricting the quantity of drug sold, it is not clear how it can increase consumption directly. In Antonanzas et al. (2011), physicians will prescribe the drug to all patients unless prevented from doing so by the insurer. In Zaric and Xie (2009), demand is a function of only the marketing budget and the price of the drug, but not the anticipated effectiveness.

**1.2.6. Design of warranties.** Risk sharing is related to the extensive literature on the design of warranties, including money-back warranties. We refer the reader to Thomas and Rao (1999) for a recent survey of this literature. These warranties are usually offered by retailers or manufacturers directly to consumers. In our problem setting, the "warranty" is extended by a manufacturer to an insurer. The effect of these warranties depends on the insurer's formulary policy. Thus, there is

an additional layer of decisions and effects to our problem. Additionally, risk-sharing contracts for new drugs are not meant to be on-going arrangements, as warranties are. They are usually used to reduce uncertainty only in the interval that the market is learning about the effectiveness of the drugs. Lastly, classical warranties are made based on the individual experience of a product, whereas the warranties in risk sharing are often based on the collective experience of a product in a patient population.

**1.2.7. Flexibility contracts in supply chains.** Risk-sharing contracts are related to supply-chain contracts that are designed to add flexibility to systems. For example, quantity flexibility can be specified in a supply contract that allows the buyer to adjust its order quantities after the initial order is placed. Such flexibility enables the buyer (e.g., a retailer that directly supplies to customer demand) to reduce its risk in overstock or under stock, and naturally results in certain extra payment that the buyer is willing to transfer to the producer. This payment, in turn, compensates the producer for offering the flexibility while undertaking more risk.

Cheng, Ettl, Lin, Tonner, and Yao (2011) model widely used contracts and practices such as capacity reservation and buy-back/return policies as call and put options, and develop the corresponding pricing schemes using game-theoretical equilibrium models. In the supply chain context, the primary risk factor is demand uncertainty, along with the fact that production typically runs in batch quantities, requiring a substantial lead time way before demand can be accurately predicted; hence, overstock or under stock is unavoidable. In the context of drug manufacturing, the main risk factor is the effectiveness of the drug, which takes a long time to evaluate. Production, on the other hand, appears to be less of an issue in terms of both capacity and lead time, once the drug is approved. In this regard, a risk-sharing contract between the drug manufacturer and the insurer relates more closely to the practice of equipment producers offering warranties on their products so as to offset buyer's risks in quality problems. Chen, Yao, and Zheng (2001) study certain operational decisions of a manufacturer that supplies its products along with various types of warranties, including those that return part of the buyer's cost on a pro-rata basis if the total lifetime of the

batch of products purchased fails to reach a pre-specified threshold. In this type of warranty, what the manufacturer does is to effectively encourage demand via mitigating the cost of risk in quality. The performance-based risk-sharing contract proposed here shares the same idea.

## 2. Basic Model

We will start with a Basic Model in which we describe the decision problem for the patients, doctors, insurers, and manufactures individually. We will later incorporate into this Basic Model additional features that can be adapted to model various pharmaceutical pricing tactics.

### 2.1. Patients and physicians

Our model of patient and physician decisions is adapted from Truong (2011), the difference here being that there is a copayment for each drug. Our presentation below closely follows Truong (2011).

Let  $\mathcal{S} = \{1, \dots, N\}$  denote the set of all drugs in a category on the formulary. We will use a discrete-choice model to capture the probability that a drug  $i$  is chosen by a patient, given the set  $\mathcal{S}$  and given the characteristics of the patient. One of the most widely used models of choice is the Multinomial Logit (MNL) Model. The MNL model has several attractive properties. It is conceptually appealing, since it is rooted in economic utility theory. It is also analytically tractable and has been shown to provide excellent empirical fit (Jain et al. 1994).

Following the MNL model, every patient has an expected utility from using a drug  $i$  that is captured by a function of the form

$$U_i = \mu_i + \xi_i - bc_i, \tag{1}$$

where  $\mu_i$  is a constant capturing the *effectiveness* of drug  $i$  (which we will elaborate on shortly),  $c_i$  is the co-payment for drug  $i$ , which is set by the insurer, and  $\xi_i$  accounts for differences between different patients in the population with respect to drug  $i$ . In particular, a particular patient has utility that is a sample  $\hat{U}_i = \mu_i + \hat{\xi}_i - bc_i$ , which is known to him and his doctor. At the population level,  $\mu_i$ ,  $b$ , and  $p_i$  are known, and it is also known that  $\{\xi_i\}_i$  are independent and identically distributed random variables having a Gumbel distribution with location parameter 0 and scale

parameter 1. In particular, the cumulative distribution function of each of these random variables is  $P(\xi \leq x) = e^{-e^{-x}}$  for every  $x \in \mathbb{R}$ . The Gumbel distribution is used because it is a flexible distribution that is closed under maximization (Talluri and Van Ryzin 2005). The no-purchase option, which is the option of selecting no drug, has index 0 and utility of the form

$$U_0 = 0 + \xi_0, \quad (2)$$

where  $\xi_0$  is also Gumbel distributed with mean 0.

Utility is a commonly used quantity in healthcare analysis although it might be difficult to quantify. A widely accepted unit of measurement for utility is Quality-Adjusted Life Years (QALY). One QALY equals one year in perfect health. This unit of measure is widely used in cost-effectiveness analysis. These analysis typically compare the cost per QALY for different medical interventions, arguing for the use of a new intervention only when it has cost per QALY no more than that of current methods (Garber and Phelps 1997).

The *effectiveness*  $\mu_i$  captures the expected benefit of treatment of patient with drug  $i$ , averaged across all patients in the population. The actual success of treatment is known to have the form  $\mu_i + \epsilon_i$ , where  $\epsilon_i$  is a mean-zero random variable. We will make the somewhat idealized assumption that patients are advised by physicians who are perfectly informed about the relative effectiveness of drugs that are available, namely, the values  $\mu_1, \dots, \mu_N$ .

In the context of the MNL model, each patient selects a drug in the formulary to maximize his utility. By convention we assume that the no-purchase option, or drug 0, is always available, but to simplify notation we will not explicitly include it as part of any candidate set of drugs. We will see that utility maximization leads to simple expressions for the probability of each drug being chosen, and the expected utility of all patients for any formulary  $\mathcal{S}$ .

Let the *preference* for drug  $i$  be defined by  $\nu_i = e^{\mu_i - bc_i}$  for every  $i$ . Note that the preference is a function of the effectiveness. McFadden (1972) has shown that given the set  $\mathcal{S}$  of drugs on the market, the probability  $P_i(\mathcal{S})$  that a patient chooses drug  $i$  is given by:

$$P_i(\mathcal{S}) = \begin{cases} \frac{\nu_i}{1 + \sum_{j \in \mathcal{S}} \nu_j}, & \text{if } i \in \mathcal{S}, \\ 0, & \text{otherwise.} \end{cases}$$

The probability that a patient does not choose any drug is  $1 - \sum_{i=1}^I P_i(\mathcal{S}) = P_0(\mathcal{S})$ . It has also been shown that the expected utility of a patient given the formulary  $\mathcal{S}$  is given by

$$U(\mathcal{S} \cup \{0\}) = E[\max_{j \in \mathcal{S} \cup \{0\}} U_j] = \ln(1 + \sum_{j \in \mathcal{S}} \nu_j) + K,$$

where  $K \approx 0.577$  is Euler’s constant (McFadden 1978). Note that since we assume that  $E[\epsilon_p] = 0$  independently of the particular formulary, the expected utility is equal to the expected actual benefit of the drug chosen to the patient. That is,

$$E[\max_{j \in \mathcal{S} \cup \{0\}} (U_{pj}) + \epsilon_p] = E[\max_{j \in \mathcal{S} \cup \{0\}} (U_{pj})] = U_p(\mathcal{S} \cup \{0\}).$$

The MNL model is known to have shortcomings (e.g. the so-called *independence of irrelevant alternatives* property). Nevertheless, the MNL model has found widespread use in marketing and economics (Van Ryzin and Mahajan 1999) and presents a good starting point for understanding patient choice in the drug market.

## 2.2. Insurer

The role of insurers is to maximize the health outcomes for the population of insured patients while controlling healthcare expenditure. In our problem setting, insurers accomplish this goal through their formulary policies. Our model of insurer decisions is adapted from Truong (2011), the difference here being that the insurer’s formulary policy is to set copayments for all drugs on a formulary, rather than to choose the list of drugs to include in a formulary. The following explanation of the insurer’s perspective is taken from Truong (2011):

Traditionally, formularies serve to improve patient safety by reducing adverse interactions, allow for systematic quality control via periodic targeted reviews of clinical literature, and help to control provider costs by directing patients to drugs with lower prices (Tanielian et al. 2003, Olmstead and Zeckhauser 1999). Some drugs offer only a small improvement over others at a substantial additional cost (Walkom et al. 2006). Formulary policies can potentially reduce costs while maintaining a high standard of care.

At the same time, there is evidence that an “overly restrictive formulary may potentially reduce the quality of care” by limiting access to needed medication (Tanielian et al. 2003). For example, instituting a formulary resulted in a lower rate of medication compliance among patients who were initially taking non-formulary medications (Motheral and Henderson 2000). According to Soumerai et al. (1991), a “three-drug limit” imposed on each patient doubled the rates of nursing home admissions of older Medicaid patients in New Hampshire; however, “after the three-drug limit was rescinded, the higher rates of nursing home admissions fell back to the initially observed rates.” This study suggests that patients shifted their expenditures to other health services when their use of medication was restricted. Thus, reducing access to drugs might also discourage continuation of essential medications among patients, with adverse consequences to their health, and possibly on future costs to the provider (Tanielian et al. 2003).

The National Committee for Quality Assurance has developed (NCQA) “a number of standards for the management of drug benefits and formularies in its accreditation program,” covering member rights and satisfaction, quality, coverage, access, and others (Levy and Cocks 1996). NCQA accreditation is encouraged or required by many employers, states and federal programs (Levy and Cocks 1996). Thus, it is in the interest of a provider to furnish a sufficiently rich formulary that will maintain a high standard of care for its patients.

An insurer must make the appropriate trade-off between incurring a higher *provisioning cost* by offering a richer formulary, which provides a better selection to patients, versus dealing with the adverse effects of an overly restrictive one. In making this trade off, the insurer must quantify the potential loss of benefit, which we call the *loss of utility*, to a patient caused by denying a beneficial drug. A natural, albeit simple, way to quantify this loss is to model it as a financial cost. We will refer to any cost derived in this manner a *disutility cost*. In addition to the loss of patient welfare, multiple other factors can be lumped into the disutility cost, including the expected standards of treatment set by accreditation programs for each medical

condition, the quality of care provided by alternative insurers, and costs to the insurer due to people choosing under provisioned alternative services.

We define the insurer’s problem as the problem of selecting a co-payment structure to minimize the sum of provisioning and disutility costs. For simplicity, we assume that the insurer covers a fixed population of patients and offers the same insurance plan to everyone.

Let  $p_i$  be the cost of providing drug  $i$  to a patient. Let  $c_i$  denote the co-payment for drug  $i$  selected by the insurer. Then the expected provisioning cost can be expressed as  $\frac{\sum_1^N e^{\mu_i - bc_i} (p_i - c_i)}{\sum_1^N e^{\mu_i - bc_i} + 1}$ . Note that the provisioning cost is a constant cost per patient. In practice, it is possible for this cost to decrease as the volume of patients who use the drug  $i$  increases due to quantity discounts. However, we do not model this effect here.

Let  $u$  denote the *unit disutility cost*. As we have discussed, the unit disutility cost  $u$  captures the cost of a unit reduction in utility of a patient compared to the case that all drugs are fully paid for by the insurer. The unit disutility cost is selected based on standards set by accreditation programs, the quality of care provided by alternative providers, and future costs to the provider due to people using choosing under provisioned alternative services. The expected disutility cost for a patient can be written as  $u \ln(1 + \sum_1^N e^{\mu_i}) - u \ln(1 + \sum_1^N e^{\mu_i - bc_i})$ . We will disregard the first term in the difference because it is a constant.

Let

$$I(c, p) = \frac{\sum_1^N e^{\mu_i - bc_i} (p_i - c_i)}{\sum_1^N e^{\mu_i - bc_i} + 1} - u \ln(1 + \sum_1^N e^{\mu_i - bc_i}). \quad (3)$$

$I(c, p)$  gives the total expected cost of the insurer if he charges the co-payment vector  $c$ . The insurer tries to minimize the cost  $I(c, p)$  subject to the constraint that  $c$  be non-negative. In reality, the minimum co-payment required is usually positive in order to discourage *moral hazard*, or the tendency of people to overuse a health benefit that they receive at no cost. We will assume that there is a minimum payment that is always charged, and the variable  $c$  denotes the amount charged above this minimum.

The co-payments chosen by the insurer for a drug  $i$  expresses a wide range of control over drug  $i$ . If the co-payment is set very high, demand for the drug will be very low and the effect is similar to exclusion of drug  $i$  from its formulary. On the other hand, if it sets the co-payment very low, then the effect is to increase patient access to drug  $i$ . Thus, controlling patient consumption of drugs via co-payments is a more general and finer form of control than using a closed formulary. In the latter format, drugs are simply included or excluded, and the co-payments for drugs that are included are uniformly small.

**THEOREM 1.** *Let  $S = \sum_{i=1}^N e^{\mu_i - bp_i}$ . Suppose  $ub \leq 1$ . Then, it is optimal for the insurer to set  $c_i^* = 0$ ,  $i = 1, \dots, N$ . Suppose  $ub > 1$ . If the following equation*

$$f(x) := bx - (ub - 1)(1 + Se^{bx}) = 0 \quad (4)$$

*has a solution  $x \in (0, u]$ , then it is optimal to set  $c_i^* = p_i - x$  for all  $i$ , provided  $x \leq p_i$  for all  $i$  (refer to Remark 1 below). Otherwise, set  $c_i^* = p_i$  for all  $i$ .*

*Proof.* Let  $p$  be fixed and suppress it in notation. Write the above objective function as  $I(c) = -u \ln B + \frac{A}{B}$ , with  $A$  and  $B$  denoting the numerator and denominator of the second term, the net cost. Then, instead of solving the minimization problem in (3), we can solve the following equivalent problem:

$$\min_c \tilde{I}(c) := -uB \ln B + A - \eta B, \quad (5)$$

where  $\eta > 0$  is a parameter. Specifically, for each given  $\eta$ , we minimize  $\tilde{I}$  over  $c$ . Let  $\eta^*$  be such that the minimal  $\tilde{I}^* = 0$ , with  $c^*(\eta^*)$  being the minimizer, i.e.,

$$\tilde{I}^*(c^*(\eta^*)) := -uB^* \ln B^* + A^* - \eta^* B^* = 0, \quad (6)$$

Then,  $\eta^*$  is the minimal value of the original objective function  $I$  and  $c^*(\eta^*)$  is its minimizer. This is because, when  $\eta = \eta^*$ , any (feasible solution)  $c$  yields an objective value

$$\tilde{I} = -uB \ln B + A - \eta^* B \geq \tilde{I}^*(c^*(\eta^*)) = 0.$$

Since  $B > 0$ , the above inequality implies:

$$I(c) = -u \ln B + \frac{A}{B} \geq \eta^* = -u \ln B^* + \frac{A^*}{B^*},$$

where the second equality follows from (6), i.e., confirming the minimality of  $\eta^*$  and  $c^*(\eta^*)$ .

To solve the minimization problem in (5), taking partial derivative wrt  $c_j$ , and writing  $\nu_j := e^{\mu_j - bc_j}$ , we have

$$\begin{aligned} \frac{\partial A}{\partial c_j} &= -\nu_j [1 + b(p_j - c_j)], \\ \frac{\partial B}{\partial c_j} &= -b\nu_j, \\ \frac{\partial}{\partial c_j} (B \ln B) &= \frac{\partial B}{\partial c_j} (1 + \ln B) = -b\nu_j (1 + \ln B). \end{aligned}$$

Hence, the first-order optimality equation is

$$-ub(1 + \ln B) + 1 + b(p_j - c_j) + \eta b = 0, \quad j = 1, \dots, n. \quad (7)$$

The above implies that the optimal  $c_j^*$  should be such that  $p_j - c_j^*$  is equal to a constant, independent of  $j$ . This reduces the insurer's optimization problem in (3) to one with a single decision variable  $x (= p_j - c_j^*)$ :

$$\min_x \left[ -u \ln(1 + e^{bx} S) + \frac{x e^{bx} S}{1 + e^{bx} S} \right], \quad \text{where } S := \sum_{i=1}^n e^{\mu_i - bp_i}. \quad (8)$$

Taking derivative wrt  $x$ , we have

$$\frac{ub e^{bx} S}{1 + e^{bx} S} - \left[ 1 - \frac{1}{1 + e^{bx} S} + \frac{bx e^{bx} S}{(1 + e^{bx} S)^2} \right] = \frac{(ub - 1)e^{bx} S}{1 + e^{bx} S} - \frac{bx e^{bx} S}{(1 + e^{bx} S)^2}, \quad (9)$$

The corresponding optimality equation is:

$$\frac{bx}{1 + S e^{bx}} = ub - 1, \quad \text{for } 1 < ub < 1 + \frac{1}{S e}. \quad (10)$$

To understand the restrictions on  $ub$  above, reason as follows. First, note that we require  $x \geq 0$  (i.e.,  $c_j \leq p_j$  for all  $j$ ). If  $ub \leq 1$ , then from (9), we know the objective function in (8) is increasing in  $x$ ; hence, the optimal  $x$  must be as small as possible, which leads to the trivial solution that  $c_j^* = p_j$  for all  $j$ .

Hence, assume  $ub > 1$  below. Rewrite the equation in (10) as

$$f(x) := bx - (ub - 1)(1 + Se^{bx}) = 0. \quad (11)$$

Note that  $f(x)$  is strictly concave in  $x$ ,  $f(0) < 0$ ,  $\lim_{x \rightarrow \infty} f(x) = -\infty$ , and  $f'(0) = b - (ub - 1)Sb$ . There are two cases. If  $f'(0) < 0$  then there is no solution to  $f(x) = 0$ . In this case, the optimal decision for the insurer is to set  $x$  as large as possible, since the objective function is decreasing in  $x$ . On the other hand, if  $f'(0) \geq 0$  then  $f(x)$  reaches its maximum at

$$x_* := \frac{1}{b} \ln \frac{1}{(ub - 1)S}, \quad \text{and} \quad f(x_*) = b(x_* - u). \quad (12)$$

If  $x_* < u$ , then,  $f(x) \leq f(x_*) < 0$  for all  $x$ ; meaning, there is no solution to (11), and hence, no solution to (10). In fact, in this case, since the derivative in (9) is negative, the objective function in (8) is decreasing in  $x$ . Hence, the optimal solution is to set  $x$  as large as possible.

On the other hand, if  $x_* \geq u$ , then  $f(x_*) \geq 0$ ; hence, there must be a solution to  $f(x) = 0$  in  $[0, x_*]$ , since  $f(0) < 0$ . Note that  $x_* \geq u$  implies:

$$ub \leq 1 + \frac{1}{Se^{ub}} < 1 + \frac{1}{Se},$$

which is the upper bound on  $ub$  in (10). (Note in the case when  $x_* \geq u$  and hence,  $f(x_*) \leq 0$ , there will be another solution to  $f(x) = 0$ , for  $x > x_*$ ; but that will be a *maximizer* of the objective function in (10), as its derivative  $f(x)$  goes from positive to negative.)

In fact, the argument above can be sharpened. From (11), if  $f(u) = 1 - (ub - 1)Se^{ub} < 0$ , then there can be no solution to  $f(x) = 0$  for  $x > u$ , since

$$f'(x) = b - b(ub - 1)Se^{bx} \leq bf(u) < 0,$$

for all  $x > u$ . On the other hand, if  $f(u) = 1 - (ub - 1)Se^{ub} \geq 0$ , then there must be a solution to  $f(x) = 0$  for  $x \in (0, u]$ , since  $f(0) < 0$ . And, this will be the only solution — as a minimizer of the objective function in (8). Hence, either (11) — and equivalently, (10) — has no solution, or it must have a solution  $x \in (0, u]$  that is the minimizer.  $\square$

The structure of the optimal price is a variation of the structure commonly observed in pricing problems under the MNL model in Operations Management. In these problems, the objective function can be transformed into convex form (see, for example, Song and Xue (2007)). This transformation does not work in this case due to the logarithmic term in  $I(c, p)$ . However, we can still show that the optimal solution has a nice structure.

We call  $x$  the *insurer's subsidy*.

REMARK 1. 1. The case of  $ub \leq 1$ , or  $u \leq \frac{1}{b}$ , which makes the objective function in (3) increasing in  $x$ , can be viewed as the shadow price on patient utility being set too low. ( $\frac{1}{b}$  can be interpreted as the “unit price” for treatment effectiveness.)

2. The other extreme is  $ub \geq 1 + \frac{1}{S}$ , which makes the objective function decreasing in  $x$ . It implies that the insurer can minimize its objective by offering *negative* co-payment, i.e., at the price of increasing its own cost. This certainly points to the fact that the utility is priced too high.

3. When  $ub$  falls in the right range,  $ub \in (1, 1 + \frac{1}{S})$ , a solution  $x$  to the equation in (11) may or may not exist. (The existence is guaranteed if  $0 < (ub - 1)e^{ub} \leq \frac{1}{S}$ .) When the solution does exist, then it can be verified that the solution must satisfy  $x \leq u$ . However, we may still have  $x > p_j$  for some  $j$ . This implies, again, that the insurer can afford a negative co-payment on drug  $j$  while still minimizing its overall objective value. This suggests that drug  $j$  is priced too low, i.e., the manufacturer (of the drug) has left money on the table, which is not likely to happen in reality, in particular if the insurer is the price taker (as we assume here throughout). Hence, it will not be unreasonable to assume that  $p_j \geq x$  for all  $j$ ; and a sufficient condition for this is  $p_j \geq u$  for all  $j$ .

Finally, we can show the following monotonicity result:

PROPOSITION 1. *Suppose  $ub > 1$ . If the optimal insurer's subsidy  $x$  is the unique solution to (11) in the range  $(0, u]$ , then it must be increasing in  $\mu_i$  and decreasing in  $p_i$ , for any  $i = 1, \dots, N$ .*

*Proof* Denote  $x'_i := \frac{\partial x}{\partial p_i}$ . From (10), taking derivatives, we have

$$bx'_i = (ub - 1)be^{bx}(x'S - e^{\mu_i - bp_i}),$$

and hence,

$$x'_i = \frac{(ub-1)e^{\mu_i - bp_i + bx}}{(ub-1)e^{bx}S - 1}.$$

Substituting (10) into the denominator, we have

$$x'_i = \frac{(ub-1)e^{\mu_i - bp_i + bx}}{b(x-u)} < 0, \quad i = 1, \dots, n. \quad (13)$$

since  $x < u$ .  $\square$

### 2.3. Manufacturer

The manufacturer is concerned with setting prices to maximize profit. We will show how the manufacturer's profit depends on the insurer's decision and the prices set by manufacturers of existing alternatives.

We assume that the manufacturer sells its product to  $N$  insurers who cover similar patient populations. In particular, the insurers differ only in the size of their patient pools. We also assume that the cost of research, development and marketing of a drug are sunk costs for the manufacturer. Let drug  $j$  have a unit manufacturing cost of  $w_j$ . Let  $p_i$  denote the price set for drug  $i$  for a particular insurer,  $i = 1, \dots, N$ . The manufacturer's expected profit per patient for drug  $N$ , assuming the price vector is  $p$ , is given by

$$M(p) = \frac{e^{\mu_N - bc_N^*(p)}(p_N - w_N)}{\sum_{i=1}^N e^{\mu_i - bc_i^*(p)} + 1}, \quad (14)$$

where  $c^*(p)$  denote the vector of optimal co-payments selected by the insurer, given the prices  $p$ . In general, the profit and hence the optimal price depends on prices set for competitor drugs. To rule out trivial solutions, below we suppose (11) has a solution  $x \in (0, u]$ .

Given the insurer's decision  $x$ , the manufacturer's problem can be expressed as:

$$\max_{p_N} \frac{e^{\mu_N - bp_N + bx}(p_N - w_N)}{1 + e^{bx}S}. \quad (15)$$

**THEOREM 2.** Assume that  $ub > 1$ . Let  $S_- := S - e^{\mu_N - bp_N}$ . If there are  $p_N, x$  satisfying

$$p_N = w_N + \frac{1 + e^{bx}S}{b \left( 1 + e^{bx}S_- - \frac{(ub-1)e^{\mu_N - bp_N + bx}}{b(x-u)} \right)}, \quad (16)$$

$$0 = (ub - 1)(1 + Se^{bx}) - bx \quad (17)$$

$$S \leq \frac{e^{-ub}}{ub - 1} \quad (18)$$

$$x \leq \frac{1}{b} \ln \frac{1}{(ub - 1)S}, \quad (19)$$

then the manufacturer's optimal decision is to set the price to  $p_N$ . Otherwise, the manufacturer's optimal decision is to set the price to

$$\arg \min_{p_N \geq 0} \left\{ S \mid S \geq \frac{e^{-ub}}{ub - 1} \right\} = \begin{cases} \max\left\{0, \frac{\mu_N}{b} - \frac{1}{b} \ln \left( \frac{e^{-ub}}{ub - 1} - S_- \right)\right\}, & \text{if } S_- < \frac{e^{-ub}}{ub - 1}; \\ \infty, & \text{otherwise.} \end{cases} \quad (20)$$

*Proof.* Assume that the manufacturer makes a one-shot decision by directly taking into account the insurer's optimal decision. (The implicit assumption is that the insurer is the price taker — accepting whatever price  $p_N$  from the manufacturer, and maximizing its own objective accordingly.)

Assume that a solution  $x$  exists on  $[0, u]$ . Then (17) to (19) must hold as a consequence of (12),  $f'(0) \leq 0$ ,  $x^* \geq u$ , and  $x \leq x^*$  in Theorem 1. Further, the derivative of the objective function in (15) becomes

$$\begin{aligned} & \frac{\nu_N}{1 + e^{bx}S} - (p_N - w_N) \frac{bx'e^{bx}S_-}{1 + e^{bx}S} + (p_N - w_N) \frac{(1 + e^{bx}S_-)(-b\nu_N + bx'\nu_N + bx'e^{bx}S_-)}{(1 + e^{bx}S)^2} \\ &= \frac{\nu_N}{1 + e^{bx}S} - (p_N - w_N) \frac{b\nu_N(1 + e^{bx}S_- - x')}{(1 + e^{bx}S)^2}. \end{aligned}$$

This leads to the following optimality equation:

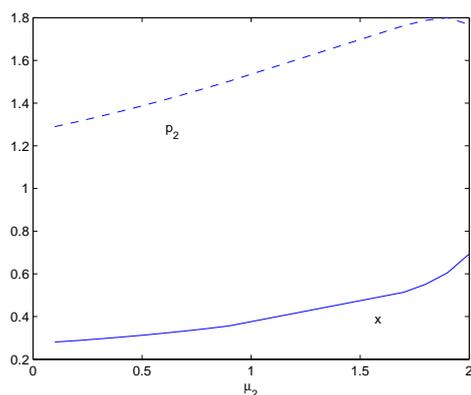
$$p_N = w_N + \frac{1 + e^{bx}S}{b(1 + e^{bx}S_- - x')}, \quad (21)$$

where  $x$  follows (10), and  $x' = x'_N$  in (13). Recall that  $x' < 0$ ; hence,  $p_N > w_N$  in (21).

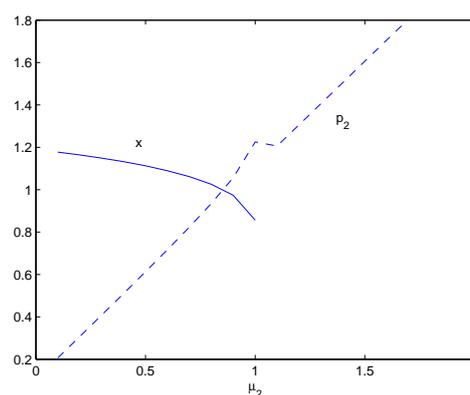
Now if a solution  $x$  does not exist on  $[0, u]$ , then the manufacturer's optimal decision is to set the price as high as possible, as long as  $S \geq \frac{e^{-ub}}{ub - 1}$ . Since  $S$  decreases with  $p_N$ , the optimal decision is to choose  $p_N$  that minimizes  $S$  subject to this constraint.  $\square$

#### 2.4. Numerical insights

When there is an existing alternative in the market (drug 1), which is priced high, the optimal price for drug 2 is higher. The insurer's subsidy  $x$  increases with the effectiveness of drug 2 to allow patients to benefit from drug 2. See Figure 1.



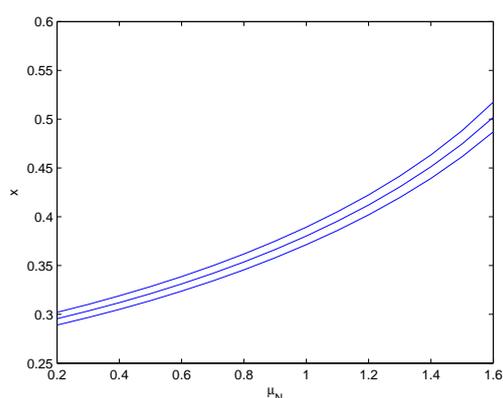
**Figure 1** Optimal decisions.  $N = 2$ ,  $\mu_1 = 1$ ,  $p_1 = 10$ ,  
 $u = 1.2$ ,  $w_2 = 0$ , and  $b = 1$ .



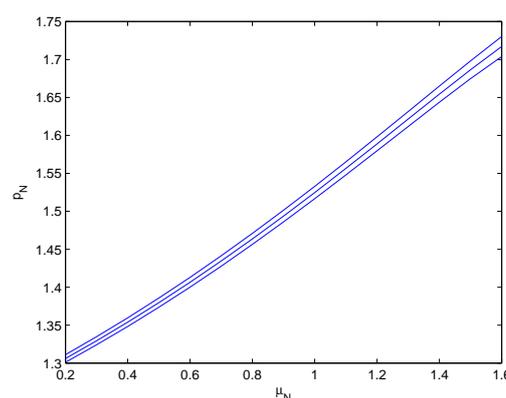
**Figure 2** Optimal decisions.  $N = 2$ ,  $\mu_1 = 1$ ,  $p_1 = 1.5$ ,  
 $u = 1.2$ ,  $w_2 = 0$ , and  $b = 1$ .

When the existing alternative in the market (drug 1), is priced low, the optimal price for drug 2 is lower due to price competition. When drug 2 is mildly effective relative to drug 1, the insurer's subsidy  $x$  decreases with the effectiveness of drug 2 because the increase in utility of drug 2 offsets the higher copayments. When drug 2 is sufficiently effective relative to drug 1, the subsidy covers all of the cost of drug 2 to allow patients to benefit from drug 2. See Figure 2.

When there are  $N - 1$  identical drugs on the market, the optimal price for drug  $N$  decreases slightly with  $N$  due to greater competition. On the other hand, the insurer's subsidy  $x$  increases slightly with  $N$  as the drugs become slightly more affordable. See Figures 3 to 4.

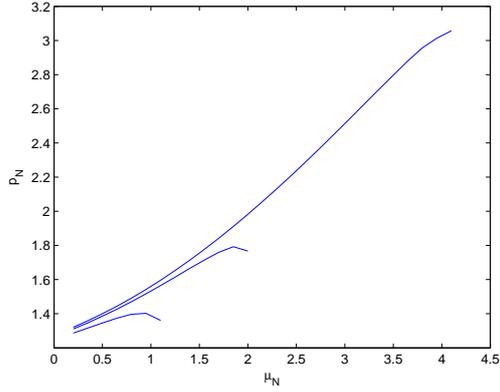


**Figure 3** Optimal price  $p_N$  decreases with  $N$ .  
 $N = 2, 7, 12$ ;  $\mu_i = 1$  and  $p_i = 6.5$  for all  $i = 1, \dots, N - 1$ ;  
 $u = 1.2$ ;  $w_N = 0$ ; and  $b = 1$ .



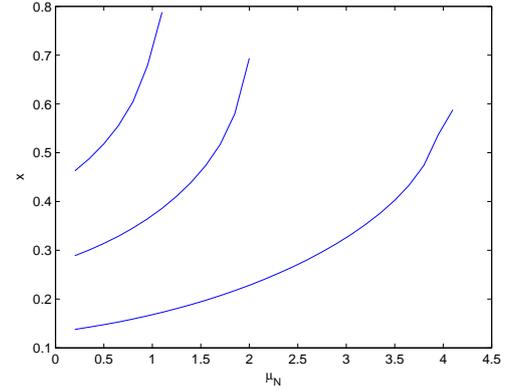
**Figure 4** Optimal insurer's subsidy  $x$  increases with  
 $N$ .  $N = 2, 7, 12$ ;  $\mu_i = 1$  and  $p_i = 6.5$  for all  $i = 1, \dots, N - 1$ ;  
 $u = 1.2$ ;  $w_N = 0$ ; and  $b = 1$ .

In a market with 2 drugs, the insurer’s subsidy increases significantly with  $u$ , as the insurer places greater value on patient utility. The optimal price for drug 2 decreases slightly with  $u$ , likely because the increased insurer’s subsidy enables the manufacturer to benefit from higher sales volumes. See Figures 5 to 6.



**Figure 5** Optimal price for drug  $N$  decreases with  $u$ .

$N = 2$ ;  $\mu_1 = 1$ ;  $p_1 = 6.5$ ;  $u = 1.1, 1.2, 1.3$ ;  $w_N = 0$ ; and  
 $b = 1$ .



**Figure 6** Optimal insurer’s subsidy  $x$  increases with  $u$ .

$N = 2$ ;  $\mu_1 = 1$ ;  $p_1 = 6.5$ ;  $u = 1.1, 1.2, 1.3$ ;  $w_N = 0$ ; and  
 $b = 1$ .

### 3. Manufacturers’ coupons

Assume that there are two manufacturers in the market, a manufacturer of a generic drug, indexed by 1, and a manufacturer of the corresponding brand-name drug, indexed by 2. The generic drug is a commodity whose price is exogenously determined. Thus, manufacturer 1 does not make active pricing decisions. Manufacturer 2 offers a coupon directly to consumer, valued at  $\kappa$ . The wholesale price that he sets for the insurer is  $p_2 + \kappa$ . When  $\kappa = 0$ , we have the basic contract of the previous section. For simplicity, we assume that all patients take advantage of the coupons whenever possible.

#### 3.1. Responsive insurer

Assume that the insurer anticipates the use of coupons by the brand-name manufacturer and adjusts its copayments accordingly. The insurer’s expected cost becomes

$$I(c, p, \kappa) = \frac{e^{\mu_1 - bc_1}(p_1 - c_1) + e^{\mu_2 - bc_2 + b\kappa}(p_2 - c_2 + \kappa)}{e^{\mu_1 - bc_1} + e^{\mu_2 - bc_2 + b\kappa} + 1} - u \ln(1 + e^{\mu_1 - bc_1} + e^{\mu_2 - bc_2 + b\kappa}). \quad (22)$$

The manufacturer's coupon has an effect equivalent to increasing the effectiveness of drug 2 from  $\mu_2$  to  $\mu_2 + b\kappa$  and at the same time, increasing the price of drug 2 from  $p$  to  $p + \kappa$ .

From Theorem 1 of Section 2, if  $ub > 1$ , and the equation (4) has a solution  $x \in (0, u]$ , then it is optimal for the insurer to set  $c_1^* = p_1 - x$ ,  $c_2^* = p_2 + \kappa - x$ , provided  $x \leq \min(p_1, p_2 + \kappa)$ . The copayment remains the same for the generic drug compared to the no-coupon case. The copayment, less coupon, paid by patients for the brand-name drug is the same as the copayment in the no-coupon case. Therefore, the market shares for both drugs remain the same.

Now consider the brand-name drug manufacturer's profit.

$$M(p, \kappa) = \frac{e^{\mu_2 - bc_2^*(p, \kappa)}(p_2 + \kappa - w_2)}{e^{\mu_1 - bc_1} + e^{\mu_2 - bc_2 + b\kappa} + 1}, \quad (23)$$

From Theorem 2, let  $S = e^{\mu_1 - bp_1} + e^{\mu_2 - bp_2}$  and  $S^- = S - e^{\mu_2 - bp_2}$ . The brand-name drug manufacturer's optimal decision is to set

$$p_2 + \kappa = w_2 + \frac{1 + e^{bx}S}{b(1 + e^{bx}S^- - x'_2)}. \quad (24)$$

Therefore, the effective wholesale price for the brand-name drug, namely  $p_2 + \kappa$ , is the same as in the no-coupon case.

We conclude that for both the generic and the brand-name drugs, the market shares as well as the wholesale prices are essentially the same as in the no-coupon case, assuming that the insurer is responsive in setting its copayments and offsets the effect of the coupons by a matching increase in copayment for the brand-name drug.

In fact, changing the copayments to “create a greater differential” among the drugs has been identified as a strategy whereby insurers can combat the effect of manufacturers' coupons (Cahn 2012). However, this strategy has the disadvantage of possibly introducing constant changes to copayments and “creating an unknown and unknowable plan structure for doctors, as well as plan beneficiaries” (Cahn 2012). Therefore, the strategy is difficult to implement in practice.

### 3.2. Unresponsive insurer

Assume that an insurer is unable to respond to coupons by planning ahead for their use. That is, the insurer's copayment decisions do not account for the use of the coupons. Assume that  $ub > 1$ . Since the insurer sees prices  $p_1$  and  $p_2 + \kappa$ , it would choose copayments  $\tilde{c}_1 = p_1 - \tilde{x}$ , and  $\tilde{c}_2 = p_2 + \kappa - \tilde{x}$ , if  $\tilde{x}$  exists in the interval  $[0, u]$  as the solution to

$$f(x) := (ub - 1)(1 + \tilde{S}e^{bx}) - bx = 0,$$

and  $\tilde{S} = e^{\mu_1 - bp_1} + e^{\mu_2 - bp_2 - b\kappa}$ . If such  $\tilde{x}$  does not exist, the insurer will set  $\tilde{c}_i = 0$  for  $i = 1, 2$ . In the former case, the brand-name drug manufacturer's profit is

$$M(p, \kappa) = \frac{e^{\mu_2 - b\tilde{c}_2 + b\kappa}(p_2 - w_2)}{e^{\mu_1 - b\tilde{c}_1} + e^{\mu_2 - b\tilde{c}_2 + b\kappa} + 1} = \frac{e^{\mu_2 - bp_2 + b\tilde{x}}(p_2 - w_2)}{e^{\mu_1 - bp_1 + b\tilde{x}} + e^{\mu_2 - bp_2 + b\tilde{x}} + 1}. \quad (25)$$

In the latter case, the profit is

$$M(p, \kappa = 0) = \frac{e^{\mu_2}(p_2 - w_2)}{e^{\mu_1} + e^{\mu_2} + 1}. \quad (26)$$

The manufacturer seeks to find  $(p_2, \kappa)$  to maximize its profit, subject to  $0 \leq \kappa \leq \tilde{c}_2$  and  $0 \leq p_2$ .

**THEOREM 3.** *Let  $ub > 1$ . Assume that the insurer is unresponsive and it is optimal for the brand-name manufacturer to offer coupons. Then the optimal price  $p_2$  and coupon amount  $\kappa$  must satisfy*

$$(ub - 1)(1 + e^{\mu_1 - bp_1 + bp_2} + e^{\mu_2 - b\kappa}) - bp_2 = 0,$$

$$e^{\mu_1 - bp_1 + bp_2}(1 - bp_2 + bw_2) + e^{\mu_2} + 1 = 0, \quad \text{and}$$

$$\kappa \geq 0.$$

Further, the coupon amount equals the copayment for the brand-name drug, i.e.,  $\tilde{\kappa} = \tilde{c}_2$ .

*Proof.* The constraints in the manufacturer's optimization problem simplify to  $0 \leq \kappa$  and  $\tilde{x} \leq p_2$ .

Note that  $\frac{\partial \tilde{x}}{\partial \kappa} = \frac{\partial \tilde{x}}{\partial p_2} = \tilde{x}'$ . We have

$$\frac{\partial}{\partial p_2} M(p, \kappa) = \frac{e^{\mu_2 - bp_2 + b\tilde{x}} b(\tilde{x}' - 1)(p_2 - w_2) + e^{\mu_2 - bp_2 + b\tilde{x}}}{e^{\mu_1 - bp_1 + b\tilde{x}} + e^{\mu_2 - bp_2 + b\tilde{x}} + 1}$$

$$\frac{\partial}{\partial \kappa} M(p, \kappa) = \frac{e^{\mu_2 - bp_2 + b\tilde{x}}(p_2 - w_2)b(e^{\mu_1 - bp_1 + b\tilde{x}}\tilde{x}' + e^{\mu_2 - bp_2 + b\tilde{x}}(\tilde{x}' - 1))}{(e^{\mu_1 - bp_1 + b\tilde{x}} + e^{\mu_2 - bp_2 + b\tilde{x}} + 1)^2},$$

$$\frac{\partial}{\partial \kappa} M(p, \kappa) = \frac{e^{\mu_2 - bp_2 + b\tilde{x}}b\tilde{x}'(p_2 - w_2)}{e^{\mu_1 - bp_1 + b\tilde{x}} + e^{\mu_2 - bp_2 + b\tilde{x}} + 1} - \frac{e^{\mu_2 - bp_2 + b\tilde{x}}(p_2 - w_2)b\tilde{x}'(e^{\mu_1 - bp_1 + b\tilde{x}} + e^{\mu_2 - bp_2 + b\tilde{x}})}{(e^{\mu_1 - bp_1 + b\tilde{x}} + e^{\mu_2 - bp_2 + b\tilde{x}} + 1)^2}.$$

The first-order conditions for an interior-point solution imply that  $\tilde{x}' = 0$ , which is impossible by (13).

For a boundary solution with positive coupon, we must have  $p_2 = \tilde{x}$ . That is,  $p_2 = p_2(\kappa)$  must solve

$$0 = (ub - 1)(1 + e^{\mu_1 - bp_1 + bp_2} + e^{\mu_2 - b\kappa}) - bp_2.$$

From this, we obtain

$$p_2' = \frac{\partial p_2}{\partial \kappa} = \frac{(ub - 1)e^{\mu_2 - b\kappa}}{(ub - 1)e^{\mu_1 - bp_1 + bp_2} - 1}.$$

It is clear that  $p_2' \neq 0$  if  $ub > 1$ .

The manufacturer's profit becomes

$$\frac{e^{\mu_2}(p_2 - w_2)}{e^{\mu_1 - bp_1 + bp_2} + e^{\mu_2} + 1}. \quad (27)$$

Setting the derivative with respect to  $\kappa$  to 0, we obtain

$$0 = e^{\mu_1 - bp_1 + bp_2}(1 - bp_2 + bw_2) + e^{\mu_2} + 1.$$

The function  $g(p_2) = e^{\mu_1 - bp_1 + bp_2}(1 - bp_2 + bw_2) + e^{\mu_2} + 1$  has at least one root on  $[w_2, \infty)$  because it is increasing on  $(-\infty, w_2]$ , decreasing on  $[w_2, \infty)$ , is positive valued at  $p_2 = w_2$ , and approaches  $-\infty$  as  $p_2 \rightarrow \infty$ .  $\square$

**PROPOSITION 2.** *There is a compact interval  $[a, b]$ ,  $a \geq \mu_1 + u - \ln(\frac{1}{ub-1})$  such that it is optimal for the brand-name manufacturer to offer coupons only if  $p_1 \in [a, b]$ .*

*Proof.* Fix  $\kappa \geq 0$  and let

$$f(x) = (ub - 1)(1 + e^{\mu_1 - bp_1 + bx} + e^{\mu_2 - b\kappa}) - bx,$$

$$g(x) = e^{\mu_1 - bp_1 + bx}(1 - bx + bw_2) + e^{\mu_2} + 1.$$

Then the optimal price  $p_2$  for the brand-name drug is a solution to  $f(x) = 0 = g(x)$ .

It is easy to check that  $f(x)$  is convex,  $f(0) > 0$ ,  $f(x)$  is minimized at  $x^*$  satisfying  $e^{\mu_1 - bp_1 + bx^*} = \frac{1}{ub-1}$ , and  $p_2 \leq x^*$ . Therefore,  $bp_2 \leq \ln(\frac{1}{ub-1}) - \mu_1 + bp_1$ .

On the other hand, since  $g(x)$  is decreasing,

$$g(p_2) \geq g\left(\frac{1}{b} \ln\left(\frac{1}{ub-1}\right) - \frac{\mu_1}{b} + p_1\right) = \frac{1}{ub-1} \left(1 + bw_2 - \ln\left(\frac{1}{ub-1}\right) - \mu_1 + bp_1\right) + e^{\mu_2} + 1.$$

As  $p_1 \rightarrow \infty$ , we cannot have  $g(p_2) = 0$  for any choice of  $\kappa$ .

In addition, for there to be a solution to  $f(x) = 0$ , we require that  $g(x^*) \leq 0$ , which implies that  $x^* \geq u$ . In other words,

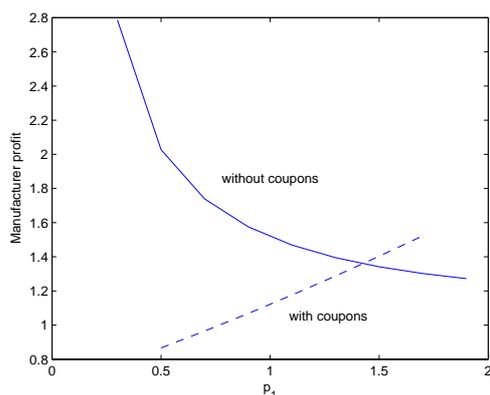
$$\frac{1}{ub-1} = e^{\mu_1 - bp_1 + bx^*} \geq e^{\mu_1 - bp_1 + bu}.$$

This inequality implies that  $bp_1 \geq \mu_1 + u - \ln(\frac{1}{ub-1})$ .

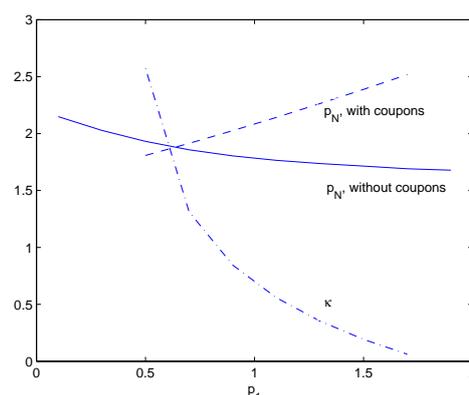
□

In Figures 7 to 10, coupons are optimal when the generic is priced between 1.4 and 1.7. When the generic drug is priced sufficiently low, it is better for the brand-name manufacturer not to compete on price. On the other hand, when the generic drug is priced sufficiently high, the brand-name manufacturer does not need to attract customers through price reduction (the alternative in this case is just as expensive). See Figures 7 to 8.

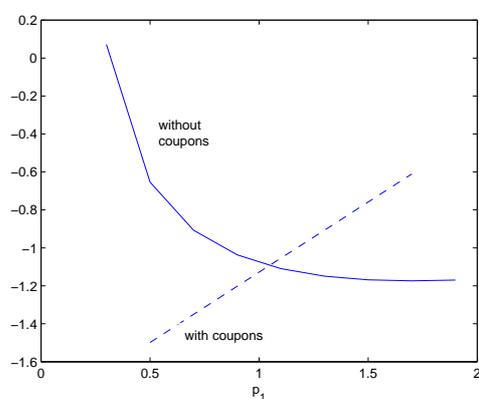
The insurer's cost is always higher with coupons because the brand-name manufacture is able to extract additional revenue at the expense of the insurer. Consumers pay a higher insurance premium as a result, but their access to the brand name drug is also improved. Therefore their total expected utility (which is the mean utility of the formulary, less the utility of the expected copayment and insurance premium), *can* be higher with coupons than without. See Figures 9 to 10.



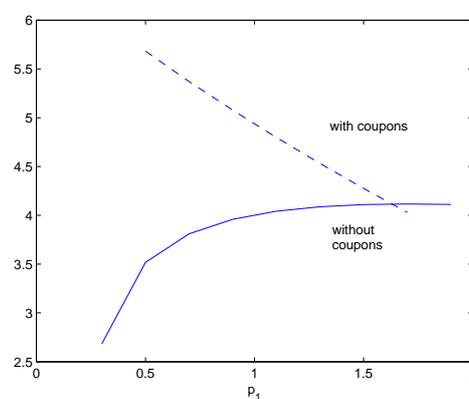
**Figure 7** Manufacturer profit for drug  $N$ .  $N = 2$ ;  $\mu_1 = 1$ ;  $\mu_2 = 2.5$ ,  $u = 1$ ;  $w_N = 0$ ; and  $b = 1.15$ .



**Figure 8** Pricing decisions.  $N = 2$ ;  $\mu_1 = 1$ ;  $\mu_2 = 2.5$ ,  $u = 1$ ;  $w_N = 0$ ; and  $b = 1.15$ .



**Figure 9** Insurer cost.  $N = 2$ ;  $\mu_1 = 1$ ;  $\mu_2 = 2.5$ ,  $u = 1$ ;  $w_N = 0$ ; and  $b = 1.15$ .



**Figure 10** Consumer utility.  $N = 2$ ;  $\mu_1 = 1$ ;  $\mu_2 = 2.5$ ,  $u = 1$ ;  $w_N = 0$ ; and  $b = 1.15$ .

#### 4. Risk-sharing contracts

We now modify our Basic Model in order to study risk-sharing contracts. We assume that there are currently  $N - 1$  drugs in a certain category on the market with prices  $p_1, \dots, p_{N-1}$  per treatment and no risk sharing. The manufacturer is seeking to introduce a new drug  $N$ . We assume that the manufacturer currently has no other drug in the category in the market.

Consider a horizon of two periods. In period 1, drug  $N$  has just been approved. The manufacturer sets a price  $p_N$  for the drug. The insurer follows by setting its co-payment  $c_N$  for the drug (which could be  $\infty$  if does not wish to cover the drug) and possibly adjusts the rest of the co-payments  $c_i$ ,  $i = 1, \dots, N - 1$ . Demand occurs for the drug and data is collected about treatment effectiveness.

In period 2, evidence about treatment is gathered and the actual effectiveness is learned by the manufacturers, the insurer, patients, and doctors. From period 2 onwards, the insurer will make its coverage decision and the manufacturer its pricing decision according to the Perfect-Information Model.

Since uncertainty over the drug prevails in period 1 and risk-sharing arrangements, if any, apply to period 1, we focus our attention on the decisions that take place in period 1. Our discussion below will concern period 1 unless otherwise indicated. Although period 1 is of finite length, it may last up to several years, and hence the costs and revenue, as well as the realized performance of the drug during this period are important to all participants in the system.

The effectiveness of the drug as indicated by initial evidence is  $\mu_N$ . We assume that in period 1,  $\mu_N$  is the best measure available of the effectiveness of the drug. Hence, patients and doctors make treatment decisions by using the value  $\mu_N$  in lieu of the actual effectiveness. Let the actual effectiveness of the drug  $N$  be  $\mu_N + \beta$ , where  $\beta$  is unknown in period 1. For both manufacturer and insurer,  $\beta$  is a random variable in period 1. The insurer may make its coverage decisions assuming a distribution of  $\beta$ , which reflects public information about the performance of the drug on clinical trials that have been conducted to obtain approval for the drug. The manufacturer may make its pricing decisions using a different distribution of  $\beta$  which incorporates not only information from some of the same sources that are available to the insurer, but also information obtained from its own experience in running clinical trials for the drug and manufacturing the drug in-house.

Our two-period model of learning is a simple model. However, it captures two essential periods in the lifetime of a drug, the initial highly uncertain period and the eventual resolution of that uncertainty. Since the outcomes of treatment are often manifested slowly over time and are highly variable at the patient level, it is unlikely that individual patients and doctors could learn and dynamically adjust their choices to reflect a gradual learning effect. Any conclusion about the effectiveness, therefore, would have to be drawn at the population level, at discrete review times.

#### 4.1. Uncertain-Drug Model

First, we will extend our Basic Model to capture the effect of uncertainty for a new drug when there is no risk sharing.

Assume that the prices of the drugs are given by  $p$  and the insurer selects a co-payment vector  $c$ . Since patients and doctors make choices assuming the co-payment  $c$  and the effectiveness values  $\mu_i$ ,  $i = 1, \dots, N$ , the insurer's purchase cost is  $\frac{\sum_1^N e^{\mu_i - bc_i} (p_i - c_i)}{\sum_1^N e^{\mu_i - bc_i} + 1}$ . The insurer's disutility cost, assuming drug  $N$  has utility  $\mu_N$ , is  $-u \ln(1 + \sum_1^N e^{\mu_i - bc_i})$ . Now, a fraction  $\frac{e^{\mu_N - bc_N}}{\sum_1^N e^{\mu_i - bc_i} + 1}$  of patients selects the drug  $N$ . For these patients, the utility they get from drug  $N$  must be adjusted by  $\beta$ . Hence, the insurer's expected cost is

$$I(c, p, \beta) = -u \ln(1 + \sum_1^n e^{\mu_i - bc_i}) - \frac{u E_\beta^I[\beta] e^{\mu_N - bc_N}}{\sum_1^n e^{\mu_i - bc_i} + 1} + \frac{\sum_1^n e^{\mu_i - bc_i} (p_i - c_i)}{\sum_1^n e^{\mu_i - bc_i} + 1}. \quad (28)$$

The superscript  $I$  in the expectation denotes the fact that the expectation is taken over the insurer's distribution of  $\beta$ . Note that  $I(c, p, \beta) = I(c, p(\beta))$ , which is the insurer's cost in the Basic Model with prices  $p(\beta) = (p_1, \dots, p_{N-1}, p_N - u E_\beta^I[\beta])$ . We call  $p(\beta)$  the *uncertainty-adjusted price*.

**PROPOSITION 3.** *For the insurer, uncertainty about drug  $N$  effectively changes the price vector from  $p$  to  $p(\beta)$  in the Basic Model.*

If  $E_\beta^I[\beta] > 0$ , that is, if the insurer expects the eventual effectiveness to be greater than initially indicated, then the uncertainty-adjusted price for drug  $N$  is smaller than the nominal price. Otherwise, if the insurer expects the eventual effectiveness to be smaller than initially indicated, then the uncertainty-adjusted price for drug  $N$  is greater than the nominal price.

Compared to the Basic Model, the uncertainty adjustment  $E_\beta^I[\beta]$ , when it is positive, has the effect of lowering the copayments for drug  $N$  and all other drugs. When it is negative, the uncertainty adjustment  $E_\beta^I[\beta]$ , increases the copayments for drug  $N$  and all other drugs. This is a consequence of Theorem 1.

The manufacturer  $N$ 's expected profit becomes

$$M(p, \beta) = \frac{e^{\mu_N - bc_N^*(p, \beta)} (p_N - w_N)}{\sum_1^n e^{\mu_i - bc_i^*(p, \beta)} + 1}. \quad (29)$$

where  $c^*(p, \beta) = c^*(p(\beta))$  is the insurer's optimal co-payment vector. We see that uncertainty affects the manufacturer through the co-payment function  $c^*(p, \beta)$ . Uncertainty might raise the effective price of drug  $n$  and possibly the co-payment for  $n$ , thus reducing the manufacturer's market share. Thus, one way in which the manufacturer can counteract this effect, especially if it is optimistic about the drug, is to enter into a risk-sharing contract with the insurer.

Using uncertainty-adjusted prices, we can write the expected profit for the manufacturer of  $N$  as

$$M(p, \beta) = M(p(\beta)) = \frac{e^{\mu_N - bc_N^*(p(\beta))} (p_N(\beta) - w_N + uE_\beta^I[\beta])}{\sum_1^n e^{\mu_i - bc_i^*(p(\beta))} + 1}. \quad (30)$$

We see that

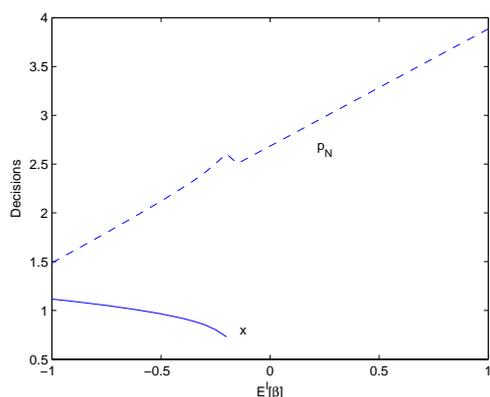
**THEOREM 4.** *For the manufacturer, uncertainty about drug  $N$  effectively changes the production price from  $w_N$  to  $w_N - uE_\beta^I[\beta]$  in the Basic Model.*

If the insurer expects  $\beta$  to be negative, then the adjustment is positive. In this case, since the manufacturer's profit decreases with its production cost, it experiences a net loss due to the uncertainty.

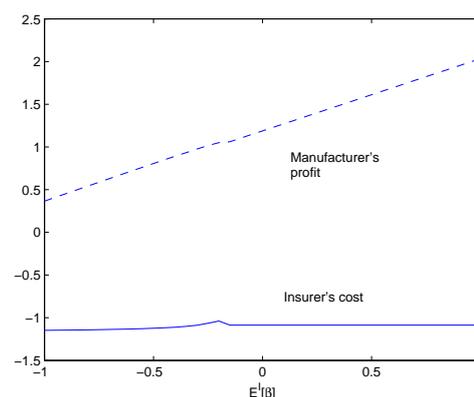
In Figure 11, manufacturer  $N$  sets a price that increases with the uncertainty adjustment  $E^I[\beta]$ . The insurer's subsidy initially decreases with the uncertainty adjustment because because the improved utility of the drug offsets its purchase cost for patients. When the uncertainty adjustment is sufficiently high, indicating that the drug is very effective, the insurer covers the entire cost of the drug because the drug is now under-priced for its effectiveness.

The manufacturer makes more profit as the expected uncertainty adjustment  $E^I[\beta]$  increases because it has produced a more effective drug. The insurer incurs higher cost initially because of higher prices, but eventually the cost stabilizes for the insurer as the increase in purchase cost of the insurer is balanced by an increase in utility of its formulary. See Figure 12.

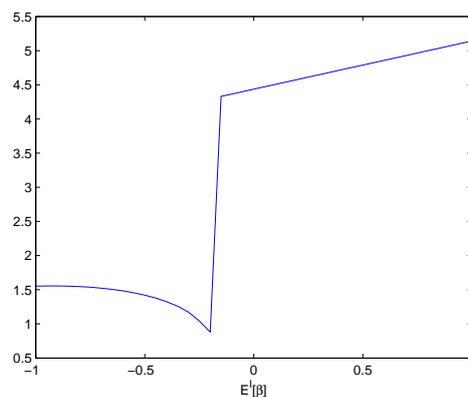
Consumers experience lower utility initially, as their copayment increases dominate the improvement in the effectiveness of drug  $N$ . Once the insurer covers the whole cost of drug  $N$ , consumers



**Figure 11** Optimal decisions.  $N = 2$ ,  $\mu_1 = 2$ ,  $\mu_2 = 3$ ,  
 $p_1 = 4$ ,  $u = 1.2$ ,  $w_2 = 1$ , and  $b = 1$ .



**Figure 12** Manufacturer's profit and insurer's cost.  
 $N = 2$ ,  $\mu_1 = 2$ ,  $\mu_2 = 3$ ,  $p_1 = 4$ ,  $u = 1.2$ ,  $w_2 = 1$ , and  $b = 1$ .



**Figure 13** Consumer utility.  $N = 2$ ,  $\mu_1 = 2$ ,  $\mu_2 = 3$ ,  $p_1 = 4$ ,  $u = 1.2$ ,  $w_2 = 1$ , and  $b = 1$ .

experience a major improvement in utility. Consumer's utility continues to improve once the premium stabilizes, the copayments go to 0, while the uncertainty adjustment continues to rise. See Figure 13.

Observe that the effect of uncertainty is entirely one-sided. It is a function of the insurer's expectation, and the insurer's alone. Next, we will see that with risk sharing, the manufacturer has an opportunity to assert its expectation about the uncertainty adjustment, thereby influencing the outcome of decisions.

## 4.2. Risk-Sharing Model

We will describe a general model of risk sharing, which can be specialized to capture different forms of risk sharing that occur in practice.

Let a risk-sharing contract be specified by a pair  $(p_N, r(\cdot))$ . In a risk-sharing contract, the interaction between insurer and manufacturer takes place in two periods as in the Uncertain-Drug Model. The only difference is that in the second period, the manufacturer makes a payment  $r(\beta)$  to the insurer for each patient treated with drug  $N$  in the first period. The payment is to compensate the insurer for the amount by which the actual effectiveness,  $\mu_N + \beta$ , falls short of  $\mu_N$ , thus possibly causing the insurer to incur additional medical costs.

Various forms for the function  $\beta$  can capture various forms of risk sharing. For example,  $r(\beta)$  could be fixed amount  $r$  whenever  $\beta$  falls short of a threshold  $T$ , i.e.,  $r(\beta) = r\mathbf{1}(\beta < T)$ . The payment  $r(\beta)$  could be a linear or convex function of the performance gap, i.e.,  $r(\beta) = r(T - \beta)^+$ , or  $r(\beta) = f((T - \beta)^+)$  for a convex function  $f$ .

**4.2.1. Insurer** The insurer's expected cost, assuming the co-payment  $c$  is

$$I(c, p, r, \beta) = -u \ln\left(1 + \sum_1^N e^{\mu_i - bc_i}\right) - E_\beta^I \left[ \frac{(r(\beta) + u\beta)e^{\mu_N - bc_N}}{\sum_1^N e^{\mu_i - bc_i} + 1} \right] + \frac{\sum_1^N e^{\mu_i - bc_i}(p_i - c_i)}{\sum_1^N e^{\mu_i - bc_i} + 1}. \quad (31)$$

Let  $p_N(\beta, r) = p_N - E_\beta^I[r(\beta) + u\beta]$  and  $p_i(\beta, r) = p_i$  for all  $i = 1, \dots, N - 1$ . We call  $p(\beta, r)$  the *risk-sharing adjusted prices*. Note that we can write

$$I(c, p, r, \beta) = I(c, p(\beta, r)). \quad (32)$$

More formally,

**PROPOSITION 4.** *For the insurer, the risk-sharing contract  $(p_N, r)$  has the same expected cost as a contract in the Basic Model with price vector  $p(\beta, r)$ .*

By Theorem 1 and Proposition 1, we can obtain analogous results for the structure of the optimal co-payments.

**4.2.2. Manufacturer** The  $N$ -th manufacturer's expected profit becomes

$$M(p, r, \beta) = E_{\beta}^M \left[ \frac{e^{\mu_N - bc_N^*(p, r, \beta)} (p_N - w_N - r(\beta))}{\sum_1^N e^{\mu_i - bc_i^*(p, r, \beta)} + 1} \right] = \frac{e^{\mu_N - bc_N^*(p, r, \beta)} (p_N - w_N - E_{\beta}^M[r(\beta)])}{\sum_1^N e^{\mu_i - bc_i^*(p, r, \beta)} + 1}, \quad (33)$$

where  $c^*(p, r, \beta)$  is the insurer's optimal co-payment vector, and the superscript  $M$  in the expectation denotes the fact that the expectation is taken over the manufacturer's distribution of  $\beta$ . Assume that the risk-sharing payment is never negative; that is,  $r(\beta) \geq 0$ . We see that the manufacturer would choose to share risk only if the decrease in expected drug revenue per patient is sufficiently compensated by a higher probability of having a patient choose the drug (due to its lower co-payment).

We can write the manufacturer's profit as a function of  $p(\beta, r)$  as follows:

$$\begin{aligned} M(p, r, \beta) &= \frac{e^{\mu_N - bc_N^*(p, r, \beta)} (p_N - w_N - E_{\beta}^M[r(\beta)])}{\sum_1^N e^{\mu_i - bc_i^*(p, r, \beta)} + 1} \\ &= \frac{e^{\mu_N - bc_N^*(p, r, \beta)} (p_N(\beta, r) - w_N + E_{\beta}^I[r(\beta) + u\beta] - E_{\beta}^M[r(\beta)])}{\sum_1^N e^{\mu_i - bc_i^*(p, r, \beta)} + 1}. \end{aligned} \quad (34)$$

Compare the above equation to (29). We obtain

**THEOREM 5.** *For a fixed function  $r(\cdot)$ , the risk-sharing contract  $(p_N, r)$  yields the same expected profit for the manufacturer as a contract in the Basic Model with manufacturing cost  $w_N - E_{\beta}^I[r(\beta) + u\beta] + E_{\beta}^M[r(\beta)]$ .*

From (29), it is clear that the manufacturer's profit decreases in  $w_N$ . Hence, by comparing the expected profit in the Risk-Sharing Model with that in the Uncertain-Drug Model (with no risk sharing), we obtain the following corollary:

**COROLLARY 1.** *The manufacturer would offer risk-sharing if and only if  $E_{\beta}^I[r(\beta)] > E_{\beta}^M[r(\beta)]$ .*

That is, the manufacturer would offer risk-sharing if it expects that the risk-sharing payment will be strictly less than that anticipated by the insurer. The difference  $E_{\beta}^I[r(\beta)] - E_{\beta}^M[r(\beta)]$  helps the manufacturer to mitigate some of the revenue loss due to the uncertainty over the effectiveness the drug.

Let  $r(\beta) = r\mathbf{1}(\beta < T)$  for some threshold  $T$ . ( $T$  would be chosen to maximize  $E_{\beta}^I[\beta < T] - E_{\beta}^M[\beta < T]$ ). Let  $B^I = E_{\beta}^I[\beta < T]$ ,  $B^M = E_{\beta}^M[\beta < T]$ , and  $E^I = E_{\beta}^I[\beta]$ .

**THEOREM 6.** *Assume that it is optimal for the insurer to set non-zero copayments and for manufacture  $N$  to share risk, then it is optimal for manufacturer  $N$  to set the drug price  $p_N$  as high as possible and to set the risk-sharing payment to  $r = \frac{p_N - uE^I}{B^I}$ .*

*Proof.* Assume that the manufacturer is the market leader. If  $B^I \leq B^M$  then the manufacturer will not offer to share risk and the solution to the manufacturer's problem is given by (17), with  $p_N$  replaced by  $p_N - uE^I$ . So assume that  $B^I > B^M$ .

Let  $c_j^*(p(\beta, r), \beta) = p_j - x$ ,  $j = 1, \dots, n - 1$ , and  $c_N^*(p(\beta, r), \beta) = p_N - brB^I - buE^I - x$ . Write  $S_- = \sum_1^{n-1} e^{\mu_i - bp_i}$  and let

$$S := S_- + \nu_N, \quad \text{where } \nu_N := e^{\mu_N - bp_N + brB^I + buE^I}.$$

Then  $x$  is the unique solution to

$$\frac{bx}{1 + Se^{bx}} = ub - 1.$$

The partial derivatives of  $x$  with respect to  $p_N$  and  $r$  are

$$\begin{aligned} 0 &= \frac{bx'}{1 + Se^{bx}} - \frac{bx(Se^{bx}bx' + e^{bx}S')}{(1 + Se^{bx})^2}, \\ 0 &= bx' - \frac{bx(Se^{bx}bx' + e^{bx}S')}{1 + Se^{bx}} = bx' - (ub - 1)(Se^{bx}bx' + e^{bx}S'), \\ x' &= \frac{(ub - 1)e^{bx}S'}{b - b(ub - 1)Se^{bx}} = \frac{(ub - 1)e^{bx}S'}{b(u - x)}, \\ \frac{\partial x}{\partial p_N} &= -\frac{(ub - 1)e^{bx}\nu_N}{(u - x)}, \\ \frac{\partial x}{\partial r} &= \frac{B^I(ub - 1)e^{bx}\nu_N}{(u - x)}. \end{aligned}$$

We can write the objective function of the manufacturer as

$$M(p, r, \beta) = \frac{\nu_N e^{bx}(p_N - w_N - rB^M)}{1 + Se^{bx}}. \quad (35)$$

The logarithm of the objective is

$$\ln(M(p, r, \beta)) = \mu_N - bp_N + brB^I + buE^I + bx + \ln(p_N - w_N - rB^M) - \ln(1 + Se^{bx}). \quad (36)$$

The first-order conditions for the manufacturer are

$$\begin{aligned}
0 &= -b + b \frac{\partial x}{\partial p_N} + \frac{1}{p_N - w_N - rB^M} - \frac{e^{bx} \frac{\partial S}{\partial p_N} + Sbe^{bx} \frac{\partial x}{\partial p_N}}{1 + Se^{bx}} \\
&= -b - \frac{b(ub-1)e^{bx}\nu_N}{(u-x)} + \frac{1}{p_N - w_N - rB^M} + \frac{e^{bx}b\nu_N - Sbe^{bx} \frac{(ub-1)e^{bx}\nu_N}{(u-x)}}{1 + Se^{bx}} \\
0 &= bB^I + b \frac{\partial x}{\partial r} - \frac{B^M}{p_N - w_N - rB^M} - \frac{e^{bx} \frac{\partial S}{\partial r} + Sbe^{bx} \frac{\partial x}{\partial r}}{1 + Se^{bx}} \\
&= bB^I + b \frac{B^I(ub-1)e^{bx}\nu_N}{(u-x)} - \frac{B^M}{p_N - w_N - rB^M} - \frac{e^{bx}\nu_N bB^I + Sbe^{bx} \frac{B^I(ub-1)e^{bx}\nu_N}{(u-x)}}{1 + Se^{bx}}.
\end{aligned}$$

These conditions imply that

$$0 = \frac{B^I - B^M}{p_N - w_N - rB^M},$$

which is impossible because we assumed that  $B^I > B^M$  and the margin of the manufacturer, namely,  $p_N - w_N - rB^M$  would be positive at optimality. Hence, there is no interior-point solution. We must have  $r = 0$  (no risk-sharing) or  $p_N - rB^I - uE^I = 0$ . In the latter case,  $S$  and  $x$  do not depend on  $p_N$ ,  $r = \frac{p_N - uE^I}{B^I}$ , and the logarithm of manufacturer's profit becomes

$$\ln(M(p, r, \beta)) = \mu_N + bx + \ln\left(p_N - w_N - \frac{B^M(p_N - uE^I)}{B^I}\right) - \ln(1 + Se^{bx}) \quad (37)$$

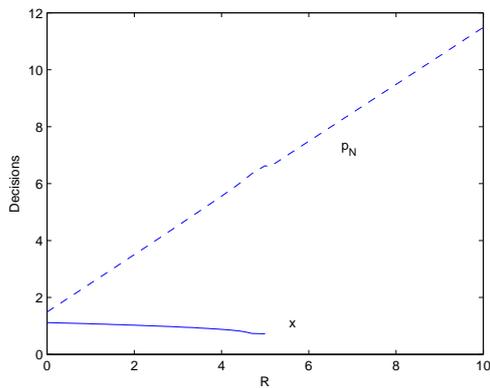
$$= \mu_N + bx + \ln\left(p_N\left(1 - \frac{B^M}{B^I}\right) - w_N + \frac{uB^ME^I}{B^I}\right) - \ln(1 + Se^{bx}). \quad (38)$$

Therefore, the manufacturer will set the price  $p_N$  to be as high as possible and will set  $r = \frac{p_N - uE^I}{B^I}$ .  
□

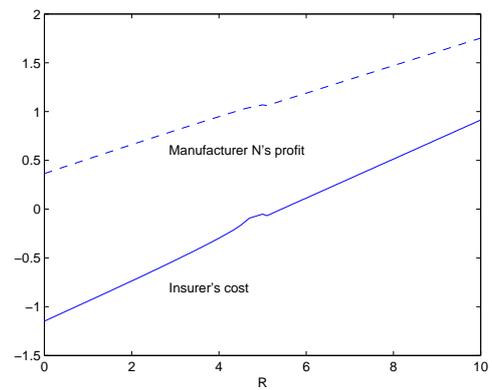
Assume that  $r(\beta) = -R\beta$ , and that manufacturer  $N$  knows the correct distribution of  $\beta$ . Assume also that consumers pay for the insurer's cost of risk sharing immediately in the form of increased premiums (In reality, this effect would be delayed). As  $R$  increases, the risk-sharing adjustment increases, and the insurer and manufacturer's decisions follow the same pattern as in Figure 11 in the Uncertain-Drug Model, when the uncertainty adjustment increases. A crucial difference is that the insurer is paying an additional cost as  $R$  increases, and its misestimate of the risk-sharing payment becomes magnified by  $R$  (The insurer's actual cost is (31), with  $E^I[r(\beta)]$  replaced by  $E^M[r(\beta)]$ ). Therefore, the insurer's cost increases significantly with  $R$ . The manufacturer's profit

also increases significantly with  $R$ , as it is able to manipulate the risk-sharing adjustment to its advantage. See Figure 15.

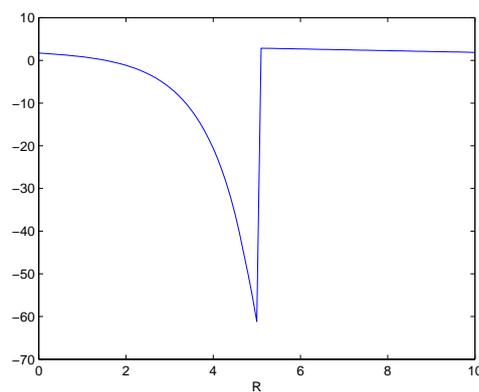
Consumer utility differs from the Uncertain-Drug model in a similar way. As  $R$  increases, consumer utility first decreases due to both higher copayments and higher premiums. Once the insurer covers the entire cost of the drug, the utility rises sharply. However, the utility eventually declines due to higher insurance premiums. See Figure 16 and compare it to Figure 13.



**Figure 14** Optimal decisions.  $N = 2$ ,  $\mu_1 = 2$ ,  $\mu_2 = 3$ ,  
 $p_1 = 4$ ,  $u = 1.2$ ,  $w_2 = 1$ ,  $b = 1$ ,  $E^I[\beta] = -1$ ,  $E^M[\beta] = -1.2$ ,  
 and  $r(\beta) = -R\beta$ .



**Figure 15** Manufacturer's profit and insurer's cost.  
 $N = 2$ ,  $\mu_1 = 2$ ,  $\mu_2 = 3$ ,  $p_1 = 4$ ,  $u = 1.2$ ,  $w_2 = 1$ ,  $b = 1$ ,  
 $E^I[\beta] = -1$ ,  $E^M[\beta] = -1.2$ , and  $r(\beta) = -R\beta$ .



**Figure 16** Consumer utility.  $N = 2$ ,  $\mu_1 = 2$ ,  $\mu_2 = 3$ ,  $p_1 = 4$ ,  $u = 1.2$ ,  $w_2 = 1$ ,  $b = 1$ ,  $E^I[\beta] = -1$ ,  $E^M[\beta] = -1.2$ , and  
 $r(\beta) = -R\beta$ .

**4.2.3. Implications for the manufacturer** We see in Section 4.1 that negative expectation by the insurer’s about the uncertainty adjustment effectively raises the cost of production, causing a loss of revenue for the manufacturer. Without risk sharing, the manufacturer has no opportunity to counter this effect; its knowledge about the adjustment  $\beta$  simply does not matter. With risk sharing, the manufacturer has an opportunity to assert its own knowledge of  $\beta$ , thereby circumventing the potential loss of revenue. More than that, risk sharing might even be an opportunity for the manufacturer to profit from the insurer’s lack of information.

The implication of Theorem 6 is as follows. When the manufacturer is less optimistic about the risk-sharing payment than the insurer, it will not offer to share risk. On the other hand, if it is strictly more optimistic, it will offer to share risk. The price of the drug will be set very high and the risk-sharing payment will be set similarly high, so as to make the insurer’s anticipated purchase cost for the drug (the risk-sharing-adjusted price) minimal. As a result, the insurer will set its copayment as low as possible for the drug, thereby maximizing market share of the drug for the manufacturer. The manufacturer makes money because it eventually makes a smaller risk-sharing payment to the insurer than the insurer believed.

Theoretically, there is no limit on  $r$ , the per-patient risk-sharing payment. However, in practice,  $r$  would be upper bounded by a natural limit, such as the maximum liability due to any decline in health that can be attributed to the inefficacy of a drug. When  $r$  is bounded,  $p_N$  will also be bounded via the relationship  $r = \frac{p_N - uE^I}{B^I}$ .

**4.2.4. Implications for the insurer** Risk-sharing is attractive to the manufacturer only when there is information asymmetry. Therefore, the insurer should be highly motivated to invest in methods to reduce its uncertainty about a new drug, for example, by conducting an independent evaluation. This conclusion is supported by an observed trend in public and private insurers’ conducting their own independent analysis of the health benefits of a drug, using either in-house capabilities (for example, WellPoint in the European Union), or using a semi-independent body (for example, the Centers for Medicare and Medicaid Services) (Eichler et al. 2010).

**4.2.5. Implications for consumers** Risk-sharing has the effect of lowering co-payments, therefore increasing access to the drug for consumers. But it also increases the expense of the insurer, eventually costing consumers higher insurance premiums. Overall, risk-sharing has the potential to improve consumer utility if the risk-sharing payment is not too large. See Figure 16. When the risk-sharing payment is very high, the rise in the cost of insurance premium dominates the gain in utility to consumers through improved market access.

**4.2.6. Transfer of risk.** As intended, risk sharing has the effect of transferring the risk associated with very low values of  $\beta$  from the insurer to the manufacturer. The former receives a compensating payment  $r(\beta)$  when  $\beta$  takes on sufficiently low values, whereas the latter sees its profit increase in variance under risk sharing.

*COROLLARY 2. The manufacturer's profit has higher variance with respect to  $\beta$  under risk sharing.*

*Proof.* Without risk sharing, the variance of  $\beta$  does not affect the manufacturer's profit (only the mean of  $\beta$  does). However, under risk-sharing, the manufacturer becomes exposed to the variability of  $\beta$  through the risk-sharing payment.  $\square$

**4.2.7. Magnitude of the information gap.** By Theorem 5, risk-sharing effectively reduces the cost of manufacturing the drug  $N$  from  $w_N$  to  $w_N - E_{\beta}^I[r(\beta)] + E_{\beta}^M[r(\beta)]$ . Therefore, the gain from risk-sharing for the manufacturer increases more than linearly with the size of the information gap. The greater the gap is, the more attractive the risk-sharing strategy becomes for the manufacturer.

When the manufacturer is concerned about the quality of its information (and the possibility of misinformation), it might be advisable not to proceed with risk sharing if the size of the information gap is small. This is because the gain in risk sharing is smaller and the advantage of the risk-sharing strategy is less certain.

**4.2.8. Information requirements of risk sharing.** An implication of Theorem 6 is that the manufacturer needs not have full information about the insurer’s cost structure (including the vector  $p$  of prices and  $\mu$  of effectiveness for all drugs) in order to negotiate a risk-sharing contract. Access to such information might be restricted, which hinders the manufacturer from accurately estimating the demand. Therefore, it is an extremely useful feature that the manufacturer’s optimal action can be oblivious to this information.

**COROLLARY 3.** *Assume that it is optimal to share risk. Then the terms of the optimal risk-sharing contract offered by the manufacturer are independent of the values  $p_i$  and  $\mu_i$ ,  $i = 1, \dots, N - 1$ .*

In contrast, in the case that there is no risk-sharing, the manufacturer requires knowledge of  $p_i$  and  $\mu_i$ ,  $i = 1, \dots, N - 1$ , in order to determine its pricing policy. This is because without risk-sharing, the manufacturer needs to control demand for its product, ultimately its profit, through price differentials with other product. In the risk-sharing case, the manufacturer can maximize the demand by making the effective payments by consumers for its drug minimal, and makes its profit through the smaller-than-expected risk-sharing payment.

**4.2.9. Information learning in risk-sharing negotiations.** Assuming that the manufacturer has knowledge of  $p_i$  and  $\mu_i$ ,  $i = 1, \dots, N - 1$ , the manufacturer has an opportunity to learn about the insurer’s valuation of  $\beta$  in contract negotiations. To each contract offered by the manufacturer, the insurer responds by setting a corresponding copayment for the drug. This price reveals information about the insurer’s expectation of  $\beta$ .

On the other hand, when the manufacturer tries to enforce risk sharing, the insurer has a very limited opportunity to learn about the manufacturer’s valuation of  $\beta$ . According to Theorem 6, in the manufacturer’s offered contract, the purchase price is as high as possible, which reveals no information about the manufacturer’s  $\beta$ . The risk sharing amount is  $r = \frac{p_{N-u}E^I}{B^I}$ , from which it is very difficult to infer the manufacturer’s expectation of  $\beta$ , namely  $E^I$ , without additional information, which the manufacturer is under no motivation to provide. Therefore, it would be

very difficult for the insurer to estimate what it can gain by investing in additional research in order to sharpen its estimate of  $\beta$ , i.e., its *value of information*.

However, the offering of a risk-sharing contract is an indicator to the insurer that it might be underestimating  $\beta$ . Assuming that the manufacturer has better information, the insurer can use this indicator to incrementally revise its estimate until it reaches a point where the manufacturer becomes indifferent between a regular and a risk-sharing contract.

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