

Regulation of Pharmaceutical Prices: Evidence from a Reference Price Reform in Denmark*

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Abstract

Reference price systems for prescription drugs constitute widely adopted cost containment tools. In these systems, patients co-pay a fraction of the difference between a drug's pharmacy retail price and a reference price that is set by the government. Reference prices are either determined externally (based on drug prices in other countries) or internally (based on domestic drug prices). We study the effects of a change from external to internal reference pricing in Denmark in 2005. The reform led to substantial reductions in retail prices, reference prices and consumer co-payments as well as to sizable decreases in overall producer revenues and health care expenditures. The reform induced consumers to substitute away from branded drugs for which we estimate strong preferences. Therefore, as long as we include the perceived differences between branded and generic drugs in our consumer welfare estimation, the increase in consumer welfare due to the reform is relatively small.

Keywords: pharmaceutical markets, regulation, co-payments, reference pricing

JEL Classification: I18, C23.

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1 Introduction

A steadily growing life expectancy, aging populations, and increasing cost of medical treatments have induced policy makers to introduce various cost containment tools. A particularly widely embraced approach is to base patients' reimbursements on drug-specific "reference prices" (Berndt and Dubois 2012; Espín et al. 2011; López-Casasnovas and Puig-Junoy 2000). Reference prices induce consumers to be cost conscious because their out-of-pocket payments increase in the retail price of a drug.

In reference price systems, a patients' drug expense, her "co-payment", is determined as the pharmacy retail price ("list" price hereafter) minus the reimbursement. A patient's reimbursement is a fraction of the respective drug's "reference price". The reference price is either a function (often the average or minimum) of prices of substitute products in other countries or a function of prices of domestic substitutes. The former is referred to as an "external" reference price while the latter is an "internal" reference price. In this paper we investigate the effects of a switch from an external to an internal reference price system that took place in Denmark in 2005. Before the reform, the reference price was determined as the European average price of substitute products (or the domestic price if that was lower). Since the reform, the reference price has been defined as the lowest domestic price of a substitute product.

After its first introduction in Germany in 1989, reference pricing spread. In 2010, 24 out of 32 EU countries used reference pricing alone or in combination with other price regulation policies to control expenditures on pharmaceutical products.¹ Among those EU countries, most employ external reference pricing with exceptions being Denmark, Sweden, and the United Kingdom (Carone et al. 2012). Moreover, the US states of Delaware (Medicaid), Massachusetts (Medicaid), some provinces of Canada, and New Zealand also adopted reference pricing (Berndt and Newhouse 2010).

While existing studies show that reference pricing effectively curtails prices of prescription drugs (Aronsson et al. 2001; Brekke et al. 2009, 2011; Kanavos et al. 2008; Pavcnik 2002; Puig-Junoy 2007), a hitherto empirically unanswered issue is to what extent differences in the *design* of reference pricing systems affect market outcomes. We attempt to fill this gap by addressing a particularly relevant question: should reference prices be determined "externally" or "internally"? Our analysis also improves on existing studies, which have relied on reduced form estimations of prices or market shares, by estimating a general and flexible demand function. This allows us to

¹Source: https://phis.goeg.at/index.aspx?_nav0031, accessed July 3, 2013.

explicitly consider substitution patterns across (different types of) products and measure directly changes in consumer surplus due to the reform.

The existing literature suggests a number of reasons why the Danish reform should strengthen competition and reduce prices. First, prior to the reform, firms faced demand that was more price elastic above the external reference price than below it. This introduced a tendency for prices to cluster at the reference price (Danzon and Liu 1998). Second, after the reform, Danish patients are paying the full price difference out-of-pocket when buying a product that is not the least expensive. Therefore, patients are as price sensitive as they would be without reimbursement from health insurance, leading to tougher competition (Brekke et al. 2011).

We confine our analysis to statins, drugs that treat high levels of cholesterol and that currently constitute the best-selling drugs in terms of sales both in Denmark and worldwide. To pin down the effects of the reform we conduct an empirical thought experiment where we consider what the market for statins would have looked like had the reform taken place before it actually did. We ask: (i) what would list prices have been had the reform taken place in a pre-reform period, the “base” period, and (ii) what would demand have looked like given these counter-factual prices? Our approach effectively filters out factors other than of the reform that may have affected post-reform market outcomes. To construct such a counter-factual world, we first estimate a demand model for statins. Second, we estimate the effect of the reform on list prices and predict counter-factual prices for statins in the hypothetical situation that the reform had been implemented in the base period. We subsequently use our predicted counter-factual prices in combination with the parameter estimates for our demand model to predict counter-factual demand for statins. Finally, we compare counter-factual and actual market outcomes to assess the reform effect on prices, demand, producer revenue, consumer expenditures and surplus as well as reimbursement expenditures.

The construction of valid counter-factual demand for statins requires a fully flexible model that generates realistic patterns of product substitution. We therefore adopt a structural logit-type demand model that accounts for consumer-specific heterogeneity as well as horizontal and vertical product differentiation, the random coefficients logit model due to Berry (1994) and Berry et al. (1995). This model is based on a consumer utility function that allows us to calculate a meaningful measure of reform-induced consumer welfare changes, consumer compensating variation. That is, the amount of money government would need to pay consumers for them to accept foregoing the reform.

We consider three different types of drugs: branded drugs (on- and off-patent), generic drugs,

and parallel imported drugs.² Existing studies show that the prices of branded and generic drugs react differently to changes in the competitive environment (Frank and Salkever 1997; Grabowski and Vernon 1992; Regan 2008; Scherer 1993), including a change from price cap to external reference pricing (Brekke et al. 2011). Few studies analyze parallel imports in the context of reference pricing, partly because parallel importing is prohibited in many countries.³

Our key finding is that the *design* of the reference price system matters substantially for prices and demand. In line with the theoretical arguments outlined above, the switch from external to internal reference pricing reduced list prices, reference prices, and consumer co-payments by around 20%. There are substantial differences between drug types: prices fall most for generics followed by parallel imports and branded drugs. We observe a strong price decrease for low-price generics paired with a weaker price decrease for high-price brands. This results in an increase in consumer co-payments for brands. Overall, producer revenues, reimbursements as well as consumer expenditures all decrease by around 10% as a consequence of the reform.

The calculation of consumer surplus raises the issue of how to treat perceived quality differences between the different types of drugs we consider. Our demand estimates suggest that consumers have strong preferences for branded drugs, followed by parallel imports and generics. The available scientific evidence does not, however, support the view that different types of bio-equivalent drugs have different therapeutic effects (Kesselheim et al. 2008). Following the literature on persuasive marketing, we calculate the compensating variation under two polar assumptions: (i) the additional utility from branded drugs is “real”, and (ii) the additional utility from branded drugs is “artificial” so that branded and generic drugs provide the same utility to the consumers. First, if we treat the perceived quality differences as real, the increase in consumer surplus is lower because consumers substitute from the preferred branded drugs to generic drugs. This explains why we estimate a modest increase in consumer surplus of 7% corresponding to an annual compensating variation of 6.3M Danish kroner (DKK), around 1M US dollars (USD). Second, if we treat the perceived quality differences as artificial by assuming that all drugs provide equal utility to consumers, we obtain a substantially larger increase in consumer surplus of 36%.⁴

²Branded drugs are produced and sold by the firm that holds the original patent for the drug. Generic drugs are bio-equivalent copies of branded drugs and may enter after patent expiration. Parallel importers are independent commercial agents that buy products in a low-price country, repackaging, relabeling, and redistribute them in a high-price country. Parallel imported drugs are usually branded drugs.

³Granlund and Köksal (2011) are a recent exception with their study on Sweden but they analyze only prices. Parallel importing is legal in the European Union and in the European Economic Area. In Denmark, similar to other EU countries such as the Netherlands, Norway, Sweden, and the UK, parallel imports accounted for around 15% of total sales of pharmaceutical products in 2005 (Enemark et al. 2006; Kanavos and Costa-Font 2005).

⁴Brand preferences may as well be explained by ill-informed consumers choosing what they already know (the branded product) over less well known parallel imports or generics. In the particular market we study, however, we

The existing literature consistently documents how the introduction of reference pricing reduced prices and increased demand for cheaper generic drugs (Brekke et al. 2009, 2011; Kanavos et al. 2008; Pavcnik 2002).⁵ A number of studies look either only at price or quantity effects (Pavcnik 2002; Puig-Junoy 2007) or at price and quantity separately (Ghislandi et al. 2012; Kanavos et al. 2008). This approach makes it difficult to draw strong conclusions regarding the welfare effects of reference pricing, which requires a joint analysis of prices and the quantities. Granlund (2010) and Brekke et al. (2011) take an important step forward by performing welfare analyses of reference pricing. Granlund studies a reform in Sweden in which mandatory generic substitution was accompanied by a reduction in the (internal) reference price, and Brekke and coauthors analyze a natural experiment in Norway in which price cap regulation was replaced by reference pricing for some (but not for all) drugs. Our study differs from these analyses in two important ways. First, we consider a different type of reform involving a change from external to internal reference pricing. Second, we estimate a much more general and flexible demand function, which allows us to explicitly consider substitution patterns across different types of products and to measure directly changes in consumer surplus taking into account preferences for branded and generic drugs.

The paper proceeds as follows: Section 2 describes the Danish pharmaceutical market and the reform of the reference price system, Section 3 describes our data set, Section 4 describes the empirical strategy, Section 5 summarizes our estimation results, and Section 6 concludes.

2 The Danish market for pharmaceutical products

As in other European countries, the market for pharmaceutical products in Denmark is regulated. Denmark follows EU regulations regarding product authorization. Product pricing, reimbursement rules, and the regulation of pharmacies are national matters. The pricing of pharmaceutical products in Denmark is free.⁶ Changes in pharmacy wholesale prices are notified to and evaluated

observe an institutional feature that is helpful in judging how informed consumers are. In Denmark, the points of sale, pharmacies, are required by regulation to dispense the cheapest substitute unless a customer (or her physician) explicitly asks for a different, more expensive product. This feature guarantees that every consumer is aware of at least one cheaper alternative at the time of purchase. In addition, statins are widely prescribed drugs and there are only six molecules in this market so that it seems reasonable that physicians are familiar with the molecules within this class of drugs.

⁵Other related studies analyze reference pricing in game-theoretic frameworks. A number of different issues are addressed, such as the effects of different types of reference pricing on equilibrium price levels (Mestre-Ferrándiz 2003; Merino-Castelló 2003), the choice between generic and therapeutic substitution groups (Brekke et al. 2007), and how the definition of the reference price affects firms' possibilities to coordinate prices (Ghislandi 2011; Miraldo 2009).

⁶There exists one fairly loose restriction, however: drugs for which an analogous product exists cannot be reimbursed if its price is more than 20 percent higher than the price of the analogous drug.

by the Danish Medicines Agency (DKMA). The agency updates prices every 14 days and makes them publicly available online. Prices are identical nationwide.

In Denmark, pharmacists must first offer the patient the cheapest product within a group of substitutes unless the prescription explicitly requires no substitution, which is the case for just five percent of all prescriptions. Such “mandatory substitution laws” are also known in the US where they are said to have contributed to the surge in the market shares of generics (Manchanda et al. 2005; Wosinska and Huckman 2004). The patient may then decide herself whether or not she buys the cheapest product or a substitute at a higher price and a higher co-payment. Other relevant market features are that (i) Denmark maintains a universal health care system that is financed through general tax revenues; (ii) advertising prescription drugs directly to patients is prohibited; and (iii) detailing, marketing to medical practitioners, is regulated. Detailing is mainly used for new products and not for established drugs which we focus on here.

Around the time of the reform there were other events happening that might have influenced the behavior of the market participants. We group these events and divide our data into six different periods, summarized in Appendix A. Our main relevant dates were set by the Danish government. In May 2004, the Danish parliament ratified the new reimbursement law making it public in June 2004. On April 1, 2005, the law was implemented. It is, however, likely that information regarding changes in reimbursement rules were available to market participants prior to these two legislatively determined dates. On September 17, 2003, the Danish Minister of Health announced the assembly of a group of experts with the aim of changing the existing reimbursement system to strengthen competition. Moreover, as a member of the working group, the Danish Association of the Pharmaceutical Industry (*Lægemiddel Industri Foreningen*; LIF) launched the idea of changing the way reference prices are calculated, in the way eventually adopted in April 2005. Between May 2001 and April 2003, LIF maintained a voluntary agreement on price ceilings, but not all members complied with the agreement. After its expiration in 2003, LIF announced a continuation of the price ceiling for another two years. This was a unilateral announcement on the side of LIF rather than an official agreement with the Danish Ministry of Health. Finally, the Danish Ministry of Health and LIF signed a new agreement on a price ceiling in October 2006.

Our analysis focuses on the base period (May 3, 2001, until April 14, 2003) and the implementation period (April 1, 2005, until September 25, 2006). Our base period is the time between the working group assembly and the ratification in parliament. It serves as a base period because no reliable information about prospective changes in the reimbursement system was publicly or pri-

vately available and because the number of firms as well as prices remained stable.⁷ Our treatment period covers the actual implementation of the reform. We discard the two LIF agreement periods as well as the adjustment period after the expiration of the first LIF agreement to avoid including effects other than the actual reform. We also discard the announcement period when firms were informed about the new legislation, thus allowing them to prepare for a new competitive setting.

3 Data

Our data set contains fortnightly prices and sales of statins for the February 2003 to June 2006 period. We downloaded our price data from <http://medicinpriser.dk>. The sales data are proprietary and were made available to us by LIF. They come with the same periodicity as the price data.

The site <http://medicinpriser.dk> contains a list of all authorized pharmaceutical products marketed in Denmark and is publicly available. Prices are updated every second Monday based on changes reported by producers. The data base is used by general practitioners when issuing prescriptions, by hospitals for their electronic patient records, and by pharmacies to ensure nationally uniform prices for prescription drugs.

A pharmaceutical product is characterized by its name, package size, form of administration, strength, 5-level anatomical therapeutic chemical classification code (ATC code), and producer name. The ATC-code is a combination of letters and digits that precisely describes a product's active substance. Appendix B contains a characterization of statins in terms of their ATC codes. Statins are divided into eight different ATC classes, of which six are marketed in Denmark. Three of them (Simvastatin, Lovastatin, and Pravastatin) lost patent protection before our data set starts; losing patent protection induces generic entry to the market. Fluvastatin lost patent protection by the end of 2003 and the remaining two molecules, Atorvastatin and Rosuvastatin, are on-patent during the whole period we analyze.

Medical practitioners in Denmark tend to regard all statins as close substitutes, at least with respect to their effects on cholesterol levels and slightly less so with respect to their resorption. When treating a patient, they follow the recommendations issued by the Institut for Rational

⁷Notwithstanding, we cannot exclude the possibility that the LIF announcement allowed producers in the market to agree upon higher price levels (Knittel and Stango 2003). However, uncertainty regarding the credibility of the LIF announcement, as well as the volatile market structure following the patent expiration of a popular product, Zocor, in 2001, suggest that price coordination was difficult to sustain. For these reasons, we interpret the price development as being the result of the announced reform, but we are not able to separate the effects of the reform from the possible effects of the LIF announcement.

Farmakoterapi (IRF, an institution under the Danish Medicines Agency that seeks to promote the most efficient use of medical products) and simultaneously choose the active ingredient and dosage. It is not clear, *a priori*, if and to what extent Danish medical doctors and patients are price sensitive. IRF does, however, issue recommendations to substitute one product by another if (i) it has been demonstrated in clinical studies that the effects are identical, and (ii) one of the products is substantially less expensive than the other.

Table 3 presents a descriptive overview of prices and sales of statins. To make the different strengths, package sizes, and active ingredients comparable we converted prices and quantities into Defined Daily Dosages (DDD). The table differentiates between the three different drug types we consider, branded drugs, generics and parallel imports. Prices are in Danish crowns (DKK), where $1 \text{ DKK} = .165 \text{ USD}$, and are deflated using the consumer price index with the year 2005 as the basis. The average list price of statins is 7.8 DKK per DDD across all periods and products. Average reference prices are 6.1 DKK and consumer co-payments are 2.9 DKK. These prices differ substantially across the three different types of drugs. Branded drugs are most expensive with an average list price of 12.2 DKK. Generics are cheapest and cost 3.6 DKK on average, while parallel imported drugs cost an average of 11 DKK. All prices decreased from the base to the implementation period on average. This decrease was stronger for list prices than for co-payments. The decline in list prices from the base to the implementation period is smaller for branded drugs than for generics or parallel imports. Co-payments even increased for branded drugs as reference prices decreased substantially more than list prices, on average from 4.6 to 5.8 DKK per DDD. Sales are on average highest for generics, followed by branded and parallel imported drugs. From the base to implementation period, sales of generics and parallel imports increased on average and sales of branded drugs decreased.

Appendix C summarizes other market and product characteristics such as the number of products on the market, the number of active firms, average package size, and average strength. It shows that half of the products are generics and that there are more firms selling generics than brand drug producers or parallel importers. We observe an increase in the number of generic products from the base to implementation period (from 54.5 to 70.3 on average) and a decrease in the number of branded and parallel imported products. The products we consider are all pills, coated pills or capsules. The median package size is 98 pills, and the median strength is 20 milligram of active substance per pill. These characteristics do not vary much between the base and the implementation period.

Table 1: Prices and sales for statins

	All			Brand			Parallel Imports			Generics		
	Mean	Median	Std. Dev.	Mean	Median	Std. Dev.	Mean	Median	Std. Dev.	Mean	Median	Std. Dev.
<i>All periods</i>												
List price	7.79	5.18	6.78	12.15	11.28	5.98	11	9.76	7.81	3.61	2.52	3.28
Reference price	6.09	3.43	6.16	8.91	7.38	6.2	9.11	6.90	7.51	2.91	1.9	3
Consumer co-payment	2.92	1.47	4.17	5.02	2.78	5.37	3.71	2.67	4.68	1.28	.72	1.7
Quantities (in 1000 DDD)	24.44	2.19	114.3	20.06	5.73	36.46	9.53	.63	55.59	34.48	1.44	157.31
Obs.	13861			3907			3321			6633		
<i>Base period</i>												
List price	9.37	7.57	6.51	12.56	11.57	5.38	12.69	13.05	6.87	5.1	3.64	4.06
Reference price	7.19	4.33	5.93	9.95	9.21	5.46	9.51	10.07	6.70	3.84	2.45	3.59
Consumer co-payment	3.62	2.09	4.82	4.6	2.75	5.38	5.08	3.40	6.00	2.02	1.15	2.61
Quantities (in 1000 DDD)	18.77	2.41	61.01	18.98	6.47	31.4	8.57	0.74	27.67	25.09	1.36	85.8
Obs.	2524			744			690			1090		
<i>Implementation period</i>												
List price	5.81	3.41	6.11	11.57	9.57	6.23	7.32	4.09	7.23	2.58	1.95	2.25
Reference price	4.21	2.03	5.39	7.26	6.75	6.58	6.63	3.73	7.19	2.01	1.38	2.07
Consumer co-payment	2.44	1.06	3.67	5.75	2.92	5.42	2.02	1.30	2.14	.97	.6	1.02
Quantities (in 1000 DDD)	26.54	1.6	125.8	18.18	4.83	34.17	9.52	.44	32.38	35.72	1.05	164.81
Obs.	4963			1340			842			2781		

Table 3 displays fortnightly mean and median as well as standard deviations of prices depicted in Danish kroner per DDD. All prices are deflated using consumer prices index with June 2005 as basis. Exchange rates in June 2005: 1 DKK = .165 USD. Quantities denote fortnightly 1000 DDDs.

4 Empirical strategy

Our empirical strategy to identify the effects of the reference price reform on prices and demand proceeds in four steps. We first estimate a model of the demand for statins over all periods in our data. Second, we estimate a pricing equation that explains prices in the base and treatment periods as a function of reform indicator variables, product characteristics, the number of competitors, and other variables that are likely to influence prices. Third, using the pricing equation and the observables in the base period, we predict counter-factual prices that would have been observed had the reform taken place in the base period. Finally, we combine our demand parameters with our counter-factual prices to predict what the market for statins had looked like had it taken place in the base period already. The differences between the counter-factual and the observed market outcomes in the base period represent the effects of the reform.

4.1 Demand

We estimate the demand for statins by a random coefficients logit (RC logit). It links observed and unobserved product as well as consumer characteristics to demand, thereby generating fully flexible and realistic patterns of demand (market shares). It has by now become a widely applied workhorse in industrial organization, and our implementation of the model follows the literature. An advantage of the model is that it accommodates vertical and horizontal product differentiation, which is important in the market for statins. Statins are vertically differentiated since original brand-name drugs are of higher perceived quality than their generic substitutes.⁸ They are also horizontally differentiated since consumers have idiosyncratic tastes, for example, for certain brand names due to their previous personal experience or for specific package sizes due to their individual treatment schedules. We will keep the presentation of the RC logit model relatively brief but refer to Nevo (2000) for a careful description of the model and to Akerberg et al. (2007) for a survey of its many applications.

Following Dunn (2012), our point of departure is consumer i , who is a patient/physician entity i ,⁹ that chooses product j that maximizes her utility. The model assumes that consumers are fully

⁸Brekke et al. (2011) and an extensive preceding literature provide strong empirical evidence for such vertical differentiation (Ching 2010a,b; Grabowski and Vernon 1992; Frank and Salkever 1997; Scott Morton 2000; Königbauer 2007).

⁹An argument in favor of this approximation is that, with chronic diseases, patients and physicians interact more frequently than, say, with acute diseases such as infections. Such repeated interaction should alleviate agency problems to some extent, for example due to physicians' reputation concerns. Skipper and Vejlin (2013) find evidence that physicians do not play an important role in the choice of expensive branded drugs in Denmark as they have no financial incentives to do so.

informed about products, product characteristics and prices. Omitting time index t for notational convenience:

$$U_{ij} = \delta_j + \sigma_p p_j^c \nu_{ij} + \varepsilon_{ij}, \quad (1)$$

where mean utility δ_j , common to all consumers, is defined as:

$$\delta_j = \mathbf{x}_j \boldsymbol{\beta} - \alpha p_j^c + \xi_j, \quad (2)$$

Consumer utility U_{ij} depends upon two components that are specific to each individual consumer: (i) $\sigma_p p_j^c \nu_{ij}$, which measures consumer i 's (dis-) taste for product j 's price, and (ii) an idiosyncratic utility component ε_{ij} , which is assumed to be i.i.d. Gumbel distributed. Utility U_{ij} decreases in p_j^c at the rate $\alpha - \sigma_p \nu_{ij}$, with a higher value of ν_{ij} corresponding to a greater willingness to pay for product j . The term ν_{ij} hence introduces consumer-specific heterogeneity in consumers' "taste" for the different products. We follow standard convention (Berry et al. 1995) and assume that ν_{ij} follows a normal distribution with mean 0 and standard deviation σ_p , a parameter that is to be estimated. The idiosyncratic random error term is denoted by ε_{ij} .

In the expression for the mean utility δ_j , \mathbf{x}_j denotes a vector of observed product characteristics and ξ_j denotes a product characteristic observed by both consumers and producers but not observed by the econometrician. We specify our vector of observed product characteristics \mathbf{x}_j as including a set of dummy variables for product names (product name fixed effects), the strength of the active ingredient, package size, as well as year, period, and monthly dummy variables to control for annual and seasonal variation.

As shown by Berry (1994), the assumption that consumers are utility-maximizers combined with the distributional assumption on ε_{ij} leads to the following expression for demand for product j , q_j , relative to total market size M :

$$\frac{q_j(\mathbf{x}_j, \mathbf{p}_j^c; \boldsymbol{\theta})}{M} = s_j(\mathbf{x}_j, \mathbf{p}_j^c; \boldsymbol{\theta}) = \int_{\nu} \frac{\exp(\delta_j + \sigma_p p_j^c \nu_i)}{1 + \sum_J \exp(\delta_j + \sigma_p p_j^c \nu_i)} dF_{\nu}(\nu), \quad (3)$$

where vector $\boldsymbol{\theta}$ consists of the parameters that are to be estimated, the coefficient vector $\boldsymbol{\beta}$, the mean utility term δ_j , and the consumer heterogeneity parameter σ_p .

To estimate our model, we need to define total market size, M , which implicitly defines the market share of the outside good $j = 0$, s_0 . Consumption of the outside good provides consumers with a mean utility that we normalize to 0 ($\delta_0 = 0$). In our setting, the composite outside good consists of products that are not statins and that may reduce cholesterol level including, for

example, a more healthy nutrition, homeopathic products, a bicycle, or a pair of running shoes. Importantly, we assume that the price of our outside good is not set in response to the prices of the inside goods, statins. If we did not consider an outside good, total demand for statins would be completely price-inelastic, an assumption that appears to be implausible and which is, as we shall show, clearly violated in our data. Subsection 4.2 describes how we define our market size.

If $\sigma_p = 0$, it follows immediately from Equation (1) and Equation (2) that consumers have homogeneous preferences regarding price which implies that they all have identical own-price and cross-price elasticities. In that case, the market share equation, Equation (3), collapses into the simple logit model of demand. The log relative market shares then take the following closed form (Berry 1994, p. 250):

$$\ln(s_j/s_0) = \delta_j = \mathbf{x}_j\boldsymbol{\beta} - \alpha p_{jt}^c + \xi_{jt}. \quad (4)$$

If prices were exogenous to demand, this equation could simply be estimated by OLS. We provide OLS estimation results for a logit demand model without heterogeneity as a first comparison to the full RC logit model. Since prices are likely to be endogenous to demand as discussed in Subsection 4.3, we provide an instrumental variables estimation of this model as a second comparison. If $\sigma_p > 0$, Equation (3) does not have an analytical solution and needs to be solved numerically. Appendix D outlines how we proceed.

The estimates for the price-related parameters α and σ_p do not directly translate into something quantitatively meaningful. For this reason, we also display median own-price and median cross-price elasticities in our results section. Notice here that for the simple logit model (i.e., $\sigma_p = 0$) the own price elasticity of product j is $\eta_{jj} = \partial q_j / \partial p_j p_j / q_j = \alpha p_j (1 - s_j)$ and the cross-price elasticity between product j and product k is $\eta_{jk} = -\alpha p_k s_k$. Own-price and cross-price elasticities are hence simple functions of observed market shares and the mean price parameter α . The logit demand model thus comes with two main strong and questionable implications: the own-price elasticity η_{jj} is linearly increasing in price and the cross-price elasticity η_{jk} does not depend on the actual similarity between products j and k . While computationally simple, it is hence likely to generate implausible substitution patterns. By contrast, the RC logit model generates fully flexible and considerably more realistic own-price and cross-price effects but it is computationally more burdensome.

4.2 Market size

We define total market size as the sum of DDDs consumed by patients in treatment and an estimate of DDDs consumed by potential patients, defined as individuals that have an elevated cholesterol level but do not receive treatment involving statins in our sample period.

The Danish Health Data and Disease Control Institute (www.medstat.dk) reports that 341,000 Danish residents are on statin treatment, consuming 4.8M DDD per 14 days.

To estimate DDD consumption of potential patients we use, similar to Ching et al. (2012), a combination of sources. We first infer the number of potential patients based on the share of the population with elevated levels of cholesterol. A potential patient is an adult with more than five millimole of total cholesterol per liter of blood (mmol/L) and more than three mmol/L of low-density lipoprotein cholesterol according to the official Danish guidelines in the time period considered.¹⁰ Statistics published jointly by the Danish Association of Heart Patients and the Danish National Institute of Public Health (Hjerteforeningen 2007) report that 60% of all Danish residents between the ages of 40 and 80 years exceed these thresholds. Given a population of about 2.5M in that age bracket, we estimate that a total of 1.5M individuals have an elevated blood cholesterol level.¹¹ We obtain the number of potential patients of 1.2M by subtracting the number of Danish residents on statins treatment from the total number of individuals with high cholesterol. Regarding the statins consumption of those 1.2M potential patients, the guidelines on how to treat high cholesterol levels were developing in the time period considered as the body of scientific evidence was still growing. In the guidelines to Danish general practitioners from 2002, the recommendation is a change of lifestyle for three months, followed by medical treatment if the desired levels of cholesterol are not reached. There was no recommendation regarding the initial dosage. In 2006, IRF issued guidelines recommending to start patients on Simvastatin 40mg daily, a treatment that had proven effective in large scale trials.¹² For our market size estimate we assume that as yet untreated patients with elevated cholesterol levels would consume 40mg of Simvastatin if they were to begin treatment. This assumption applied to the 1.2M potential

¹⁰The guidelines are issued by The Danish College of General Practitioners under the sponsorship of the Danish Ministry of Health. The guidelines can be found in “*Forebyggelse af iskaemisk hjertekarsygdom i almen praksis*”, 2. revideret udgave, 2002.

¹¹This share is in the upper-end of the interval reported by the World Health Organization (Roth et al. 2011). Here, it is estimated that the percentage of the total population in the same age bracket with elevated total cholesterol levels in countries similar to Denmark like England, Germany and Scotland is between 35% and 61%. However, the Danish Institute for Rational Pharmacotherapy (IRF 2006) reports that 2.1 million Danish residents above the age of 35 have total cholesterol levels of more than five mmol/L, a somewhat higher number than the one we use here.

¹²The guidelines are available at http://www.irf.dk/dk/publikationer/rationel_farmakoterapi/maanedssblad/2006/lipidsaenkende_behandling.htm.

patients leads to a potential market size of 21.3M DDD per 14 days and a total market size of 26.1M DDD per 14 days.¹³

4.3 Identification

As briefly discussed above, prices are likely to be endogenous to demand, which would deem our estimate for the mean price parameter α biased and inconsistent. The intuition here is that the product characteristic ξ is unobserved by us, as econometricians, but observed by consumers and producers. Consumers are willing to pay a higher price for a product with a high ξ and producers will take this into account in their pricing decision. This leads to a positive correlation between price and the unobserved product characteristic and hence to downward biased parameter estimates. Our inclusion of product name fixed effects already works as a remedy to this problem since physical product characteristics are time-invariant and hence absorbed by fixed effects (Nevo 2000). However, consumers (and producers) may encounter changes in their valuation of products. Consumer perception may for example change due to press coverage or population product experience (Ching et al. 2012; Coscelli 2000).

To address the endogeneity problem we use instrumental variables estimation techniques. The idea is to find a vector of variables \mathbf{Z} that are highly correlated with patient co-payment p^c but are uncorrelated with the unobserved product characteristic ξ . As suggested by Bresnahan (1987) and Berry et al. (1995) we use variables that affect production cost and variables that capture a product’s competitive environment. First, as cost shifters we use pulp and paper prices which enter the cost of packaging. These variables have a direct impact on production cost, and will hence be highly correlated with prices, but do not affect the unobserved product characteristic ξ . Second, we use the sums of other products’ characteristics (package size and active ingredient strength) in the relevant substitution groups. The idea behind these instruments is that if, e.g., the sum of all product strengths is high, there are likely to be many competing products in the market which should lead to a smaller markup and hence to lower prices for the product in question. Third, our more direct measure of the competitive situation is the number of competitors in product j ’s substitution group. If there are many competing products, markups and prices will be low. At the same time, the number of competing products is unlikely to be affected by unobserved product quality which deems a viable instrument. The latter two sets of competition-related instruments rest on the assumption that package size and strength are exogenous, which seems reasonable in

¹³The number of patients varies over time and in our estimations we use year-specific market sizes. For the sake of exposition we discuss average values here.

a market where the choice of these product characteristics is mainly determined by therapeutic needs. As a third set of instruments, we use observed product characteristics \mathbf{x} following Dubé et al. (2012). Specifically, we use polynomials of package size and strength. The intuition is that prices are assumed to be a possibly nonlinear function of product characteristics. The polynomial approximation allows for more flexible functional forms and increases the precision with which we estimate our demand parameters.

As suggested by Su and Judd (2012) as well as Dubé et al. (2012), we estimate the RC logit model by solving a mathematical program with equilibrium constraints (MPEC). To this end we adapt Matlab code provided by Dubé et al. (2012). Details of our approach are in Appendix D.

4.4 Pricing equation

The idea behind our pricing regression is to infer price changes due to the reform by regressing actual list prices on a large set of control variables, most importantly on a set of dummy variables for the reform. This allows us to calculate the prices that would have been observed had the reform taken place in the base period. We thereby follow Pavcnik’s (2002) approach to identify the effects of a switch from price cap to reference price regulation in Germany.

The reform effect on prices is identified only by price variation of products that existed both in the base and the reform periods, conditional on covariates. For prediction purposes we estimate the price equation for all products available (including their product name dummies) in the base or reform periods. We could in principle also compare prices in the base and the reform period to infer product prices in the hypothetical absence of the reform. That would, however, imply to discard products that were unavailable either in the base or in the reform period. By contrast, the regression approach we adopt allows us to predict prices for products that entered or exited in either period. A simple before-after comparison would also imply foregoing to control for confounding factors such as the competitive environment in the base period.

Our coefficient of main interest is the reform dummy, R , which is coded 1 in the reform period and 0 in the base period. We interact R with dummy variables for branded, generic and parallel imported drugs. Defining the interaction between the reform dummy and generics as the reference with an associated coefficient of 0 and using the exponential function to ensure strictly positive predicted prices, our estimating equation is:

$$p_{jt} = \exp(\gamma R + \gamma_B R_B + \gamma_{PI} R_{PI} + \mathbf{Z}_{jt}\boldsymbol{\kappa} + \mathbf{G}\boldsymbol{\lambda} + \varepsilon_{jt}), \quad (5)$$

where the dependent variable is the list price per DDD of product j at time t . The subscripts on R denote interactions of the reform dummy with dummy variables for each of the different product types we consider. Subscript B refers to an interaction with a dummy for branded drugs and PI to parallel imported drugs.¹⁴ Vector \mathbf{G} collects sets of dummy variables for (i) product names, (ii) substitution groups, (iii) time as well as the number of products on the entire statins market and the number of products in product j 's substitution group. We include these dummy variables to accurately describe each products characteristics as well as its competitive situation. Vector \mathbf{G} also contains pulp and paper prices as cost-drivers (and hence price-drivers). To increase flexibility, we interact these input prices with product name fixed effects. We finally include the sets of price instruments \mathbf{Z} used for our demand estimation discussed in Subsection 4.3.¹⁵ The term ε_{jt} denotes an idiosyncratic shock.

Our dependent variable, list price, is skewed and nonnegative. Log-linear regressions, which may appear as a natural model choice for estimating our pricing equation, Equation (5), is not advisable as it leads to inconsistent estimates in the presence of heteroskedasticity. The dependent variable needs to be transformed, and coefficients are not directly interpretable (see Manning and Mullahy 2001, for early concerns regarding log-linearization). Santos Silva and Tenreyro (2006) make a compelling case to use the Poisson pseudo-maximum-likelihood estimator instead. They build on the result in Gourieroux et al. (1984) to show that this estimator is consistent for continuous dependent variables even if the data-generating process is not Poisson. The coefficients in this model are semi-elasticities providing us with a direct interpretation: the γ coefficients are the percentage price effects of the reform. From our direct estimation of Equation (5), we calculate counter-factual product prices in the base period, period BP , as $\hat{p}_{jBP} = \exp(\gamma R + \gamma_B R_B + \gamma_{PI} R_{PI} + \mathbf{Z}_{jt}\hat{\boldsymbol{\kappa}} + \mathbf{G}\hat{\boldsymbol{\lambda}})$, setting R equal to one.

4.5 Consumer welfare

With a fully specified demand model and counter-factual prices at hand it is straightforward to compute a simple monetary measure of reform effects on consumer utility, the Hicksian compensating variation. Our assumption of linear utility implies the absence of income effects, which appears innocuous in our setting given that changes in consumer surplus are likely to be small

¹⁴The reform effects on each of the different products are to be calculated as follows: for generics the reform effect is given by γ , for branded drugs it is $\gamma + \gamma_B$, and for parallel imported drugs it is $\gamma + \gamma_{PI}$.

¹⁵The intuition behind them is that if they constitute valid instruments for co-payments (which they do, as we argue in Section 5), they are highly correlated with patient list prices (co-payments are mechanically derived from list prices post reform), the dependent variable in our pricing regression above. Leaving our set of instruments \mathbf{Z} out in our pricing regression would lead to an omitted variable bias.

relative to consumer household income (Train 2009). In the absence of income effects, compensating variation and Marshallian consumer surplus coincide. Formally, we obtain consumer compensating variation by solving the integral over the differences in maximum expected utilities via numerical simulation (Small and Rosen 1981):

$$CV = \int \frac{1}{\alpha + \nu_i} \left\{ \ln \sum_j \exp \left(\delta_j^{pre} + \sigma_p p_j^{c,pre} \nu_i \right) - \ln \sum_j \exp \left(\delta_j^{post} + \sigma_p p_j^{c,post} \nu_i \right) \right\} f(\boldsymbol{\nu} \mid \theta^{pre}) d(\boldsymbol{\nu}), \quad (6)$$

where the superscripts *pre* and *post* refer to pre-reform and post-reform prices and mean utilities.

5 Estimation results

Our estimation results fall in three parts: the demand model parameters with the associated own-price and cross-price elasticities, the pricing equation, as well as the reform effects on prices, demand, reimbursements, consumer expenditures, revenues, and consumer surplus.

5.1 Demand

Table 2 reports the estimated coefficients of our demand model. The left column shows simple OLS logit estimation results where we assume that consumers have homogeneous preferences with respect to patient co-payment ($\sigma_p = 0$) and that prices are exogenous to demand. The middle column shows IV logit results where we also assume homogeneity in price preferences but instrument prices as described in Subsection 4.3. The right column displays RC logit model results, our main and preferred specification.

The coefficients displayed in Table 2 do not directly translate into price elasticities. We therefore show median own-price elasticities at the bottom of the table. In addition, Table 3 reports median own-price and cross-price elasticities that are based on the full RC logit model for the three types of products we consider — brands, generics, and parallel imported drugs. We would like to stress that we estimate a *distribution* of price elasticities that depends both on each individual product and each individual consumer (the draw of ν_{ij} consumer i received). We take this heterogeneity into account when calculating the reform effects on demand and welfare and present the respective medians in Table 3 only to provide a more meaningful direct interpretation of our results.

Starting with the simple OLS logit model, we estimate a negative and significant co-payment

Table 2: Logit and random coefficient logit demand

	OLS logit	IV logit	RC logit	
			Mean	σ_p
Co-payment	-.18*** (.006)	-.39*** (.031)	-2.46*** (.390)	.85*** (.125)
Package Size	.02*** (.001)	.02*** (.001)	.02 (.001)	
Strength	.01*** (.001)	-.01*** (.003)	-.01*** (.003)	
Constant	-11.09*** (.137)	-8.66*** (.393)	-7.10*** (.678)	
η_{jj} (median)	-.39	-.85	-2.52	

Table 2 displays OLS logit, IV logit, and RC logit estimation results as discussed in Subsection 4.1. The specification also includes product name, month, and time period dummy variables. The number of observations is 13861. Robust standard errors in parentheses. The coefficient estimates do not have a direct quantitative interpretation which is why we additionally display the implied median own-price elasticities in the base period, denoted by η_{jj} . The asterisks ‘***’ denote marginal significance at the one percent level. *Reading example for “ η_{jj} (median)”*: a one percent increase in price leads to an average demand reduction of .39% in the OLS logit model.

coefficient, parameter α in Equation (2), and a median own-price elasticity of -.39. Once we instrument prices, identification as measured in terms of t -values, improves substantially and the coefficient more than doubles compared to the previous model. Correspondingly, the median own-price elasticity also more than doubles to -.85. We also use our IV logit estimation results, column (2) in Table 2, to assess how well our instruments are correlated with our endogenous variable consumer co-payment. Appendix E displays “first stage” estimation results of a regression of consumer co-payment on our exogenous variables and our instruments. The corresponding F -test for joint instrument significance is 168 and hence well above the critical threshold suggested by Stock et al. (2002).

The RC logit model drops the assumption that all consumers in Denmark are equally sensitive to price changes ($\sigma_p \neq 0$). The implied median own-price elasticity of -2.52 is almost three times as large as the one corresponding to the IV logit model. The mean price coefficients are all statistically highly significant and negative. In addition, the RC model finds that there indeed is substantial heterogeneity in consumer preferences for price since the estimated standard error of the heterogeneity term ν_{ij} , σ_p , is .85 and hence economically highly significant. It also is statistically significant given a t -value of 6.8. The RC logit model hence clearly rejects the computationally less burdensome but substantially more restrictive IV logit model — consumers differ significantly from one another with respect to price disutility and hence also in their price elasticities.

Table 3: Price elasticities

	Brands	Parallel imports	Generics
Brands	-1.12	.00006	.00009
Parallel imports	.00048	-.92	.00009
Generics	.00048	.00006	-1.79

Table 3 displays median own-price and cross-price semi-elasticities that correspond to our demand estimation results in Table 2. *Reading example:* a one unit (one DKK) change in brand prices is associated with a median decrease in demand by 1.12%.

Our estimates suggest that consumers are more price elastic compared to existing studies for the demand for pharmaceuticals surveyed by Gemmill et al. (2007). This appears unsurprising since an external reference price mechanism was already in place in Denmark prior to the reform. Even with external reference prices, consumers were faced with the choice between buying either cheaper generics and parallel imported drugs or the more expensive branded drugs and, hence,

they were more price-sensitive than in markets with little co-payment.

Other results of our demand estimations are that consumers appreciate larger package sizes and lower active ingredient strengths. We also find substantial differences in the coefficient estimates related to the 42 product name dummies we include in our demand specifications. We display these product name coefficients in Appendix F. The Appendix differentiates between the coefficients of the three types of drugs we consider. It shows that product name coefficients related to branded drugs are on average 54% times larger than for parallel imports and 117% larger than for generics. Consumers hence have a strong preference for branded drugs (given prices and other characteristics). This finding is consistent with existing evidence from self-reported survey data (Mott and Cline 2002).

5.2 Prices

Now that we have identified our demand model we turn to the estimation of the effects of the reform on product prices. We run a total of six alternative pricing regressions. Table 4 presents the coefficient estimates in the order of an increasing number of control variables. We use the full specification, depicted in column (6), to compute the reform effects on total demand, revenues, expenditures and consumer compensating variation. The estimation sample contains observations on all products on the market in the base period and the implementation period. To take into account potential serial correlation we compute standard errors that are robust to autocorrelation and heteroskedasticity, clustered at the product level.

Our base specification, which contains just the reform dummy and month dummies, generates a coefficient on the reform of -.48, which directly translates into an average price decrease by 48%. All further specifications including just the reform dummy, specifications (2)-(5), generate negative reform effects as well. Once substitution group and product name fixed effects are introduced in specifications (4) and (5), the reform effects do not change very much across the different specifications. This is to be expected given that time-invariant (perceived) quality differentiation should largely be explained by identical active ingredients within substitution groups and by product names. Specification (6) accounts for all control variables and additionally differentiates between our three types of products. It shows that the prices of generics statistically and economically significantly decrease as a consequence of the reform. There is no statistically significant difference between the price reactions of parallel imports and generics while the prices of branded drugs decrease statistically significantly less than generics and parallel imports. The

Table 4: Pricing regressions

	<i>retail price</i> ($N = 7487$)					
	(1)	(2)	(3)	(4)	(5)	(6)
Reform (γ)	-.48*** (.074)	-.51*** (.123)	-1.71*** (.218)	-.36*** (.081)	-.16*** (.047)	-.45*** (.097)
Reform \times Brand (γ_B)						.43*** (.109)
Reform \times Parallel Import (γ_{PI})						.12 (.127)
No. products in market			-.13*** (.028)	.0003 (.005)	.002 (.003)	.002 (.003)
No. products in subst. group			-.11*** (.018)	-.04* (.021)	.02 (.010)	.004 (.010)
Pulp & Paper \times Product name	No	No	No	No	Yes	Yes
BLP Instruments	No	Yes	Yes	Yes	Yes	Yes
Fixed effects						
Product name	No	No	No	No	Yes	Yes
Substitution group	No	No	No	Yes	Yes	Yes
Month	Yes	Yes	Yes	Yes	Yes	Yes
Constant	2.24*** (.063)	2.79*** (.484)	5.68*** (.526)	1.91*** (.344)	-7.66*** (1.536)	-7.78*** (1.484)
R^2	.07	.10	.24	.50	.92	.93

Table 4 displays poisson estimation results for our pricing equation, Equation (5). Coefficients are semi-elasticities so that the reform coefficients (γ) represent the percentage effects of the reform. Robust standard errors in parentheses and clustered at the product level. The asterisks ‘***’ and ‘*’ denote marginal significance at the one and ten percent level.

reform effect for branded drugs is, however, still statistically significantly negative.

Our finding of smaller price decreases for branded drugs than for generics contrasts with the results of studies that investigate switches from price cap to reference prices. Pavcnik (2002), Granlund (2010), and Brekke et al. (2009, 2011) find strongest price decreases for branded products. Our findings are related to the “generic competition paradox” where producers of branded drugs respond to the introduction of competition by raising prices (Frank and Salkever 1997; Grabowski and Vernon 1992; Regan 2008; Scherer 1993). In our case, tougher competition due to the change in the reference price system resulted in substantially smaller price decreases for branded drugs compared to generic and parallel imported drugs.

5.3 Reform Effects on Prices, Demand, and Consumer Surplus

The demand estimates and the estimates for counter-factual prices form the backbone of our calculation of counter-factual demand and consumer surplus. The flexibility of our demand model allows us to take into account consumers’ substitution behavior caused by our estimated list price changes from which we infer the induced reference price and patient co-payment changes.

Recall that the reference price is defined by the lowest price in a given substitution group after the reform. A strong price decrease for low-price generics paired with a weaker price decrease for high-price brands leads to an increase in consumer co-payments for brands. Hence, we expect the reform to be highly effective in pushing consumers to substitute away from brands towards generics and parallel imports.

Table 5 reports absolute and percentage differences between our observed market outcomes in the base period and our predicted counter-factual market outcomes had the reform been implemented in the base period already. It shows that both overall list prices, reference prices and co-payments decrease by around 22%. The largest list price decrease is found for generics where it is 36%. The list price reactions of parallel imported drugs are more similar to the price reactions of generics than brands.

Reference prices decrease for all types of products, most importantly for generics and parallel imported drugs. The change in reference prices is generally quite uniform across the different product types we consider which is due to the fact that most substitution groups include both branded and generic products even before the reform.

Consumer co-payments decrease for parallel imports and generics and increase for brands. The reason is that reference prices decrease relatively faster than brand list prices resulting in an

Table 5: Reform effects on market outcomes

	All		Brands		Parallel Imports		Generics	
	Δ	$\Delta\%$	Δ	$\Delta\%$	Δ	$\Delta\%$	Δ	$\Delta\%$
<i>Prices</i>								
List price	-1.84	-19.6	-.22	-1.8	-3.58	-28.2	-1.84	-36.0
Reference price	-1.61	-22.4	-1.66	-16.7	-2.22	-23.4	-1.19	-30.9
Consumer co-payment	-.55	-15.2	1.11	24.1	-1.80	-35.4	-.89	-43.8
<i>Aggregate outcomes</i>								
Quantities	8807	12.7	-4373	-21.4	5254	61.5	7926	19.7
Producer revenue	-41457	-10.3	-74956	-28.7	25769	41.8	12400	20.1
Government expenditures	-30835	-10.3	-48680	-25.4	18641	38.4	-796	-1.3
Consumer expenditures	-10622	-10.4	-26277	-37.8	7129	54.0	8527	44.3
Consumer surplus	6299	7.1						
Consumer surplus benchmark	15498	35.8						

Table 5 displays total effects of the reform on prices, quantities, revenues, as well as consumer and government expenditures. It also shows our estimate for consumer compensating variation. The results for price changes are based on our estimates for our pricing equation, Table 4. All other estimates are based on our results for our demand model, Table 2, combined with the estimates for our pricing equation. We provide a benchmark measure consumer compensating variation which we denote by “Consumer surplus benchmark” in the table. It refers to a situation where consumers appreciate branded drugs as much as they appreciate generics (while they in reality have strong preferences for branded drugs). All prices in June 2005 Danish Kroner per DDD, where 1 Danish Krone = .165 US dollars. Quantities in 1000 DDD per year. Revenue, expenditures, and consumer surplus in 1000 June 2005 Danish Kroner.

increase in co-payments for branded drugs. As the final purchase decision is with the consumer, these co-payment changes induce a substantial shift in demand away from branded drugs towards generics and parallel imports. This mechanism helps reducing expenditures even if brand list prices do not substantially decrease after the reform.

Indeed, we find that the demand for generics increases by 19.7% and for parallel imports by as much as 61.5% (starting, however, from a very low pre-reform market share). Branded drug sales encounter reform-induced losses of 21.4%, which highlights the power of a market-based competition-strengthening mechanism in inducing consumers to switch to cheaper substitutes.

The existing studies of Brekke et al. (2011) and Granlund (2010) use changes in consumer expenditures to approximate changes in consumer welfare due to reforms in medical pricing systems. We find that consumer expenditures decrease by 10% overall. Expenditures for branded drugs decrease most, by 37.8%, while expenditures for parallel imports and generics increase by 54% and 44.3%, respectively. These increases reflect that demand increased relatively much compared to the decrease in prices.

Calculating consumer surplus raises the issue of how to treat the perceived quality difference between different types of drugs. As discussed above, consumers have a preference for branded drugs. This could be due to switching costs where changes, e.g., in the design of the packaging might increase the risk of medication error. There also seems to be the widespread belief in the medical profession that branded drugs are of superior quality. Kesselheim et al. (2008) perform a meta-analysis of existing evidence regarding clinical equivalence of generic and branded drugs used in cardiovascular diseases, a class of drugs to which statins belong, and find no evidence of quality differences.¹⁶ Still, Kesselheim et al. (2008) report that more than half of the editorials in peer-reviewed medical and pharmaceutical journal discussing this issue express a negative view on generic substitution. While switching costs associated with the risk of medication error clearly should enter into an analysis of consumer welfare, it is less clear how to treat perceived quality differences unsupported by scientific evidence. A very similar problem appears in the welfare analysis of persuasive advertising that increases the perceived, but not the real, quality of a product (Dixit and Norman 1978). Two polar approaches have been proposed in this literature (Bagwell 2007). One view is that perceived quality differences between branded and generic drugs affect the (psychological) well-being of consumers and should enter into the consumer surplus. An alternative view is that the two types of drugs give rise to the same (physiological) well-being and

¹⁶Duerden and Hughes (2010) come to a similar conclusion in their survey on the available evidence regarding generic substitution.

that perceived quality differences for this reason should be ignored in the calculation of consumer surplus.

We exploit the fact that our approach is flexible enough to accommodate both views. First, if we were to consider the decrease in overall consumer expenditures as a welfare measure, we would conclude that the switch from external to internal reference pricing entailed a substantial increase in consumer welfare. Second, if we treat the perceived quality differences as real, the increase in consumer surplus is lower because consumers substitute away from the strongly preferred branded drugs to generic drugs. This explains why we estimate an annual compensating variation of 6.3M DKK, corresponding to a change in consumer surplus of 7.1%. Finally, we calculate consumer surplus under the condition that consumers obtain the same utility from branded and generic drug consumption. To this end, we set consumer preferences for branded drugs (the brand dummy variable in consumer utility, Equation (1), that are displayed in Appendix F) equal to our estimated average consumer preferences for generics. Proceeding this way generates an increase in consumer surplus of 35.8%, corresponding to a compensating variation of 15.5M DKK.

6 Conclusions

Reference pricing constitutes a widely adopted cost containment tool. While it is well documented that reference price systems drive down pharmaceutical prices, little is known about the design of such systems. A particularly important feature is the very definition of the reference price - should it be internally (as a function of the prices of domestic substitutes) or externally (as a function of the prices of foreign substitutes) determined? We used product-level data to study the effects of a switch from external to internal reference pricing on the market for statins in Denmark. The reference price was defined as the European average price of substitute products (or, as the domestic price if that was lower) before the reform and as the price of the cheapest substitute on the domestic market after the reform.

Our analysis shows that list prices, reference prices, and consumer co-payments all decreased by around 20% due to the switch to internal reference pricing. Prices decreased most substantially for generics where consumer co-payments declined by as much as 44%. Prices for parallel imported drugs also decreased significantly while prices for branded drugs changed comparatively little. While consumer co-payments generally decreased, they increased for branded drugs - the result of reference prices decreasing more than list prices. The changes in absolute and relative prices had large effects on the demand for statins. Overall demand increased by 13%. It increased most for

generic drugs where demand rose by 20%. Starting from a low pre-reform market share of 13%, parallel imported drugs witnessed a demand increase by 62%. Branded drugs demand decreased by 21% due to less favorable relative prices. Combining price and demand effects we estimated an overall average decrease in producer revenue, reimbursements and consumer expenditures by around 10%, respectively. Parallel importers benefited most from the reform. Their overall revenues increased by 42% while the revenues of firms selling generic and branded drugs increased by 20% and decreased by 29%, respectively.

We employ a structural logit-type demand estimation based on consumer utility maximization that allows us to calculate consumer compensating variation. If we treat the perceived quality differences between the different types of drugs as real (and as observed in the data), we obtain a compensating variation of 6.3 million DKK, an increase in consumer surplus by 7%. Then, our estimation results provide strong evidence for consumers strictly favoring branded drugs, followed by parallel imports and generics. The reform resulted in a relatively modest increase in consumer surplus, because the increase in the relative prices of branded drugs induced consumers to buy perceived inferior generic drugs. However, the available scientific evidence does not find differences in the therapeutic effects of branded and generic drugs. Hence, as an alternative benchmark for consumer surplus, we assume that all types of drugs provided the same utility to patients. This generates a consumer compensating variation of 15.5 million DKK corresponding to an increase in consumer surplus by 36%. The assessment of the reference pricing reform depends importantly on how consumer preferences for particular types of products are treated. Danish consumers take into account the additional utility that branded drugs provide to them relative to generics. Therefore, they are likely to have experienced lower gains from the reform than policy makers who tend to consider branded and generic drugs as equal based on clinical evidence.

An important question is to what extent our results generalize to other countries and to other types of drugs. There is no doubt that reference pricing must be complemented with other rules and regulations for generic competition to work well. Mandatory substitution and a formal application procedure when doctors prescribe a specific, more expensive product spurred generic competition and helped to realize gains from the Danish reform (Granlund 2010). Still, we believe that the Danish experience provides some general insights concerning the choice of reference prices. First, since consumers always pay the full price difference between their preferred drug and its cheapest substitute, they are sensitive to relative prices after the reform. Second, unlike an external reference pricing system where the reference price often becomes the market price, policy makers do not have to find ways to set reference prices close to the competitive level. Finally,

defining the reference prices as the lowest price in the substitution group provides strong incentive for firms to undercut the competitors' prices, making price coordination more difficult (Miraldo 2009; Ghislandi 2011).

Our analysis confines itself to a class of drugs targeting a chronic disease, albeit one that is consumed by a wide variety of patients throughout the world. We expect our results to carry over to other non-chronic diseases. However, the reform effects might be smaller since patients may be less informed about generic alternatives and total consumer expenditures typically are lower for acute diseases, reducing consumers' incentives to become better informed. We hope to address this issue in future research.

Finally, in our static framework, more competition and lower prices always result in higher welfare. This is a reasonable approach because the profits earned on the small Danish market have only a marginal effect on R&D incentives in the pharmaceutical industry. However, if more and larger countries were to introduce regulations such as internal reference pricing that would reduce the price levels of branded drugs, dynamic effects can no longer be ignored in the welfare analysis. While beyond the scope of this paper, investigating the trade-off between static and dynamic objectives in regulatory policies for research-intensive industries is an important research agenda.

Appendix A: Summary of events related to changes in the Danish reimbursement system

LIF Agreement	May 03 2001 Apr. 14 2003	After 2001, LIF members and the Danish Ministry of Health maintained an agreement on price ceilings that lasted until 2005. Not all LIF members complied with the agreement.
Adjustment	Apr. 28 2003 Sep. 01 2003	The Danish Medicine Agency starts updating pharmaceutical prices every 14 days. The update frequency was six months before that change.
Base: Working group	Sep. 15 2003 Jun. 07 2004	The Danish Ministry of Health announces the assembly of a working group that is asked to submit proposals regarding reimbursement rules with the aim to increase competition. The Association of Danish Pharmacies launches the idea that reimbursements should be based on the cheapest domestic product within substitute groups. The idea earns widespread support among leading politicians
Announcement	Jun. 21 2004 Mar. 28 2005	The Danish parliament passes the new law for internal reference price determination.
Treatment: Implementation New LIF agreement	Apr. 01 2005 Sep. 25 2006 since Oct. 29 2006	The new law is implemented. LIF and the government agree upon on a price ceiling corresponding to the price on 30 Aug. 2006.

Appendix B: characterization of statins in terms of their ATC code

2-Level	3-Level	4-Level	5 - Level
C10 Lipid Modifying Agents	C10A	C10AA HMG CoA reductase inhibitors (Statins)	C10AA01 simvastatin
			C10AA02 lovastatin
			C10AA03 pravastatin
			C10AA04 fluvastatin
			C10AA05 atorvastatin
			C10AA06 cerivastatin
			C10AA07 rosuvastatin
			C10AA08 pitavastatin
		C10AB Fibrates	C10AB01 clofibrate
			C10AB02 bezafibrate
			C10AB03 aluminium clofibrate
			C10AB04 gemfibrozil
			C10AB05 fenofibrate
			C10AB06 simfibrate
			C10AB07 ronifibrate
			C10AB08 ciprofibrate
			C10AB09 etofibrate
			C10AB10 clofibrade
		C10AC Bile acid sequestrants	C10AC01 colestyramine
			C10AC02 colestipol
			C10AC03 colextran
			C10AC04 colesevelam
		C10AD Nicotinic acid and derivatives	C10AD01 niceritrol
			C10AD02 nicotinic acid
			C10AD03 nicofuranose
			C10AD04 aluminium nicotinate
			C10AD05 nicotinyl alcohol (pyridylcarbinol)
			C10AD06 acipimox
			C10AD52 nicotinic acid, combinations
		C10AX Other lipid modifying agents	C10AX01 dextrothyroxine
			C10AX02 probucol
			C10AX03 tiadenol
			C10AX05 meglutol
			C10AX06 omega-3-triglycerides incl. other esters and acids
			C10AX07 magnesium pyridoxal 5-phosphate glutamate
			C10AX08 policosanol
			C10AX09 ezetimibe
			C10AX10 alipogene tiparvovec
	C10B	C10BA combinations	C10BA01 lovastatin and nicotinic acid
			C10BA02 simvastatin and ezetimibe
		C10BX combinations	C10BX01 simvastatin and acetylsalicylic acid
			C10BX02 pravastatin and acetylsalicylic acid
			C10BX03 atorvastatin and amlodipine

Notes: Table B displays a detailed classification of lipid modifying agents with their respective ATC codes. Only boldfaced chemical substances are marketed in Denmark. Source: WHO Collaborating Centre for Drug Statistics Methodology.

Appendix C: Other market and product characteristics

	All			Brand			Parallel Imports			Generics		
	Mean	Median	Std. Dev.	Mean	Median	Std. Dev.	Mean	Median	Std. Dev.	Mean	Median	Std. Dev.
<i>All periods</i>												
# products	122.27	127	14.16	34.42	35	3.79	32.08	29	9.41	60.81	60	11.73 *
# firms	20	19	3.12	4.92	5	0.27	5.64	5	1.75	9.95	10	1.71
Package size	67.75	98	35.79	67.84	98	34.77	67.93	84	34.17	67.61	98	37.16
Strength in mg.	28.62	20	18.56	33.92	20	23.67	24.09	20	14.6	27.77	20	15.99 *
Total quantities	2945.72	2758.39	1074.03	681.41	669.73	148.57	275.33	186.99	344.83	1988.98	1876.68	1055.15
Total market size	25356.72	25318.52	190.34									
<i>Base period</i>												
# products	126.39	127	4.85	37.23	38	0.97	35.28	35	5.24	54.59	55	2.24
# firms	19.01	19	0.44	5	5	0	5	5	0	10.01	10	0.44
Package size	65.97	98	34.96	64.62	98	35.06	66.98	84	34.72	66.24	98	35.04
Strength in mg.	26.7	20	16.55	34.35	20	22.85	22.93	20	10.7	23.85	20	12.2
Total quantities	2369.15	2347.12	410.81	706.05	677.2	111.93	295.57	276.53	114.47	1367.53	1305.22	474.8
Total market size	25216.47	25257.01	56.69									
<i>Implementation period</i>												
# firms	22.17	23	2.3	5	5	0	7.07	8	1.48	10.83	11	1.22
Package size	67.49	98	34.69	69.87	98	34.47	66.17	60	33.43	66.75	98	35.13
Strength in mg.	30.7	20	19.97	33.41	20	24.19	29.38	20	19.31	29.79	20	17.68
Total quantities	3292.82	3294.52	785.39	608.92	611.06	77.21	200.34	165.94	145.86	2483.56	2505.77	763.59
Total market size	25404.93	25483.11	83.24									

Mean and median for all figures for a 14-day period. Total quantities are mean and median total sales in 1000 DDD for a 14-day period. Market size is real and hypothetical sales in 1000 DDD for a 14-day period.

Appendix D: Identification and estimation of the demand model

Subsection 4.1 briefly sketches out our empirical approach. This Appendix provides further details and describes how we practically implement our estimator using optimal instruments.

As discussed in Subsection 4.1, identification of our model relies on the assumption of mean independence of unobserved product quality ξ_j and the vector of exogenous variables \mathbf{Z}_j discussed in Subsection 4.3: $E[\xi_j|\mathbf{Z}_j] = 0$. These conditional moment restrictions can be transformed into unconditional moment restrictions: $E[\xi_j \mathbf{H}(\mathbf{Z}_j)] = 0$, where $\mathbf{H}(\mathbf{Z}_j)$ denotes a set of functions of \mathbf{Z}_j .

Reynaert and Verboven (2012) show that Chamberlain’s (1987) optimal instruments work extremely well in RC logit models, most importantly in identifying the (nonlinear) parameter σ_p . The set of optimal instruments is defined as the set of derivatives of the unobserved product characteristic ξ_j with respect to the estimated model parameters:

$$\mathbf{H}(\mathbf{Z}_j) = E \left[\frac{\partial \xi_j(\theta)}{\partial \theta'} \middle| \mathbf{Z}_j = \left\{ \mathbf{X}, \sum_{k \neq j} \mathbf{X}_k, w_j \right\} \right], \quad (7)$$

where w_j denote the input cost shifters discussed in Subsection 4.1.¹⁷ The intuition behind these optimal instruments is equivalent to standard instruments with the difference being that the derivatives make use of the functional forms assumed in the model whereas standard instruments are simple linear projections (like two stage least squares). To see this, Reynaert and Verboven (2012) show that the set of derivatives with respect to the linear parameters β and α are simply the set of observed product characteristics and cost shifters. The derivative with respect to the nonlinear parameter σ_p is a nonlinear function of all competing products’ characteristics. The biggest gain from using optimal instruments is therefore achieved for the nonlinear parameter σ_p since the market share equation taking into account consumer heterogeneity can be exploited.

Note that in order to compute $\mathbf{H}(\mathbf{Z}_j)$ in Equation (7), we require initial estimates for θ , the parameter vector we ultimately aim to estimate. One option would be to estimate the computationally expensive heterogenous logit model using standard instruments and using the results obtain therein as initial estimates for the optimal instruments. Reynaert and Verboven (2012) propose a simpler approach and show that it performs equally well as running the more general model twice. The idea is to estimate a homogenous IV logit model first, our “IV Logit” results

¹⁷Berry et al. (1999) and Goeree (2008) are two applications using approximations to these optimal instruments.

from Table 2. This is a linear IV regression and, hence, very fast. This model does not obtain an estimate for σ_p so we must guess an initial value. We set this value equal to the absolute mean price coefficient $|\alpha|$. With these initial estimates at hand we compute the complete set of optimal instruments $\mathbf{H}(\mathbf{Z}_j)$ in Equation (7). Reynaert and Verboven (2012, p. 10) provide the exact algorithm we use. When constructing out optimal instruments $\mathbf{H}(\mathbf{Z}_j)$ we assume perfect competition in the prediction of prices for computational simplicity. Estimating the model assuming imperfect competition for the construction of $\mathbf{H}(\mathbf{Z}_j)$ yields very similar results.

The MPEC problem we solve to estimate our model uses data that includes all products marketed between February 2003 and June 2007. In this data, we observe 115 fortnightly time periods and about 100 products per period. Using our optimal instruments $\mathbf{H}(\mathbf{Z})$, we solve the GMM objective function following Dubé et al. (2012):

$$\begin{aligned} \min_{\theta, \xi} \quad & \mathbf{g}(\xi)' \mathbf{W} \mathbf{g}(\xi) \\ \text{subject to} \quad & \mathbf{s}(\xi; \theta) = \mathbf{S}, \end{aligned}$$

where $\mathbf{g}(\xi)$ is the sample analogue to $E(\mathbf{H}(\mathbf{Z})\xi)$, vector \mathbf{W} denotes a weighting matrix, and \mathbf{S} are the observed market shares. The main advantage of this approach as compared to the nested fixed point algorithm suggested by Berry et al. (1995) is that the first and second derivatives of this problem are highly sparse in our setting with many time periods (markets) and comparatively few products. This can be exploited by numerical solvers which substantially increase computational speed. It also avoids numerical error propagation by circumventing the nesting of loops for optimization.

To obtain the constraints $\mathbf{s}(\xi; \theta) = \mathbf{S}$, we solve the market share equation in Equation (3) numerically. We assume ν to follow a standard normal distribution and draw 5000 modified latin hypercube sampling draws for estimation, as proposed in Hess et al. (2006) since they constitute improvements over the more frequently used Halton draws.

We follow the proposition in Knittel and Metaxoglou (2012) to use 50 different starting values to increase confidence that the numerical solver stops at the true solution. The majority out of these 50 estimation runs converge, and those that do, converge to the same solution. The Knitro 8.0 solver's exit flag confirms convergence (as opposed to pre-mature stopping).

Appendix E: First stage regression results

Strength of other firms' products					.0003*** (.00007)
Strength of own products					-.0007*** (.0002)
Strength					-.067*** (.005)
Package size					-.017*** (.002)
Strength ²					-.0001* (.00006)
Package size ²					.0001*** (.00001)
Strength \times package size					.0001*** (.00004)
<i>Dummy variables</i>					
Atorvastatin Ranbaxy	-94.59 (88.66)	Pravastatin Recept	-8.58*** (3.254)	Zarator PI	-11.08*** (1.565)
Canef	-11.01*** (1.425)	Pravastatin Sandoz	-15.49*** (2.369)	Zocolip	-11.41*** (1.876)
Crestor	-8.73*** (1.023)	Pravastatin Stada	-46.68*** (16.31)	Zocor	9.55*** (2.734)
Crestor PI	-3.09*** (1.153)	Simvacop	-28.52*** (8.792)	January	.02 (.111)
Lescol	-5.42*** (1.011)	Simvastatin 1A Farma	8.63*** (2.923)	February	.13 (.124)
Lescol depot	-4.00*** (1.001)	Simvastatin Actavis	-4.82*** (1.622)	March	-.07 (.126)
Lipitor	-6.40*** (1.406)	Simvastatin Alpharma	-2.18 (1.408)	April	-.02 (.132)
Lovacodan	-4.45*** (1.577)	Simvastatin Alternova	-5.13*** (1.385)	May	-.20 (.130)
Lovastatin Actavis	-4.40*** (1.156)	Simvastatin Arrow	.19 (1.883)	June	-.13 (.128)
Lovastatin Alternova	-2.47* (1.293)	Simvastatin Genthon	-4.63 (10.69)	July	.05 (.138)
Lovastatin Universal Farma	-8.60*** (1.154)	Simvastatin Gevita	-4.19 (2.617)	August	.05 (.130)
Lovastatin ratiopharm	4.01 (4.224)	Simvastatin Hexal	-9.51*** (1.262)	September	-.06 (.130)
Mevacor	-4.29 (8.793)	Simvastatin Merck NM	-16.86** (7.177)	October	-.12 (.122)
Mevacor PI	-17.99** (8.442)	Simvastatin Orifarm	-22.78** (10.18)	November	-.11 (.117)
Perichol	-5.28** (2.141)	Simvastatin Paranova	-74.06*** (13.75)	LIF Agreement	-1.55*** (.236)
Pravachol	-34.43*** (2.562)	Simvastatin Ratiopharm	-24.42*** (3.516)	Adjustment	-.31 (.213)
Pravachol PI	-9.11*** (2.094)	Simvastatin Sandoz	-12.41*** (1.574)	Base	-.09 (.168)
Pravastatin 1A Farma	-13.58*** (2.433)	Sortis	.07 (2.951)	Announcement	-.56*** (.147)
Pravastatin Alternova	-3.50 (2.268)	Statinacop	-3.28 (2.789)	Implementation	-.11 (.134)
Pravastatin HEXAL	-18.02*** (2.408)	Tahor	-5.92*** (2.274)	P&P \times Name	Yes
Pravastatin Nycomed	-8.22*** (1.171)	Torvast	-10.83*** (2.492)	Constant	11.30*** (.446)
Pravastatin Ranbaxy	-14.37*** (2.921)	Zarator	-13.99*** (1.666)		
<i>F-test results</i>					
All instruments					166.76
BLP instruments					18.75
Pulp & Paper (P&P) instruments					14.21
Squares and interactions instruments					11.00
R ²					.61

Notes: Appendix E displays first stage OLS regression results of our endogenous variable price on all exogenous variables and our instruments. The abbreviation "PI" behind a product name indicates that the corresponding product is a parallel imported drug. The reference product name is Zocor PI. Other reference categories are the month December and the New LIF agreement period. The estimation involves 1361 observations. The asterisks '***', '**', and '*' denote marginal significance at the one, five, and ten percent level.

Appendix F: Product name dummies in random coefficient logit model

<i>Brands (Mean: 1.26)</i>					
Crestor	1.37*** (.249)	Mevacor	1.36*** (.113)	Zarator	3.69*** (.153)
Lescol	.60*** (.142)	Pravachol	2.80*** (.127)	Zocor	2.64*** (.126)
Lescol depot	.48*** (.140)	Simvastatin Merck NM	-1.61 (.962)		
<i>Parallel Imports (Mean: -.68)</i>					
Crestor	.70*** (.282)	Pravachol	1.22*** (.186)	Sortis	1.06*** (.254)
Lipitor	2.31*** (.184)	Pravastatin Recept	-2.34*** (.312)	Statinacop	-2.40*** (.513)
Lovacodan	-2.57*** (.246)	Pravastatin Stada	-1.90*** (.561)	Tahor	-.08 (.272)
Lovastatin Univ. Farma	-4.08*** (.429)	Simvacop	-.37 (.453)	Torvast	1.89*** (.385)
Mevacor	-.11 (.161)	Simvastatin Orifarm	-1.30*** (.339)	Zarator	1.68*** (.165)
Perichol	-2.44*** (.323)	Simvastatin Paranova	-2.74*** (.407)	Zocor (Reference)	
<i>Generics (Mean: -1.47)</i>					
Atorvastatin Ranbaxy	-2.10*** (.412)	Pravastatin Nycomed	-2.06*** (.425)	Simvastatin Genthon	.30*** (.275)
Canef	.88*** (.143)	Pravastatin Ranbaxy	-1.63*** (.433)	Simvastatin Gevita	-1.81*** (.369)
Lovastatin Actavis	-2.08*** (.314)	Pravastatin Sandoz	-2.44*** (.328)	Simvastatin Hexal	-.51 (.459)
Lovastatin Alternova	-2.44*** (.281)	Simvastatin 1A Farma	-.15 (.271)	Simvastatin Ratiopharm	-1.64*** (.285)
Lovastatin ratiopharm	-2.28*** (.317)	Simvastatin Actavis	-1.98*** (.315)	Simvastatin Sandoz	-2.69*** (.328)
Pravastatin 1A Farma	-1.98*** (.338)	Simvastatin Alparma	-.55 (.407)	Zocolip	-1.89*** (.436)
Pravastatin Alternova	-2.49*** (.342)	Simvastatin Alternova	-1.34*** (.415)		
Pravastatin HEXAL	-.78 (.337)	Simvastatin Arrow	-.69 (.306)		

Notes: Appendix F displays our coefficient estimates for our set of product name dummy variables that we omitted from Table 2 for brevity. The table additionally shows the mean values of these dummy variables for alternative product groups. The asterisks ‘***’ denote marginal significance at the one percent level.

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