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ABSTRACT

We examine the issue of new goods and price indexes for the important and tractable case of generic and branded drugs. By treating generics as entirely distinct goods and "linking them in" to indexes with fixed weights, the standard price indexes fail to reflect the substantial welfare gains to those consumers who, like the FDA, regard generic and branded versions of a drug as being perfect substitutes. We discuss the treatment of heterogenous consumers in constructing aggregate price indexes, and then, using detailed data on wholesale prices of two anti-infective drugs, present calculations of various alternatives to the official indexes. These reflect both heterogeneity of tastes for brandedness, and also the empirically important phenomenon of diffusion of generic drugs into the market following patent expiration. We find very significant differences: for one of the drugs studied, the standard price index *rose* by 14% over the sample period, while our preferred alternative index fell by 48%.

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I. Introduction

This paper discusses the current treatment of the introduction of generic versions of previously patented (and branded) drugs into the official price indexes and suggests some alternative ways of proceeding. While generic pharmaceuticals are the substantive topic, the problem discussed is of much wider importance. It is a special and possibly "easy" case of the more general problem of new goods and quality change, where different quality versions are interpreted as new goods. In trying to solve the general quality change problem, official statistical agencies may unintentionally aggravate and overdo it, by defining commodities too narrowly and treating each new variety as a new good. Because new goods are usually "linked-in" rather than compared directly to the previous versions, the explicit and implicit price declines that consumers experience as the result of their appearance do not show up in the official indexes, ever. And generic pharmaceuticals are just the visible tip of a very large iceberg. A comparable problem exists, for example, in the treatment of the changing population of outlets in which various goods are sold. The whole supermarket revolution and the rise of various discount and self-service outlets has left almost no trace in the official statistics of prices and productivity (see, e.g., Reinsdorf (1993)).

Generic pharmaceuticals represent a particularly simple version of the "new goods problem". A generic drug is a variety of a previously existing commodity which a government agency, in this case the FDA, certifies as being "(bio-)equivalent" to the previously available version. It differs only in packaging, including the inert matter enclosing the active ingredients, in labelling, and provenance.[1] At this point two extreme approaches are possible. The first takes the FDA at its word and says that a pill, is a pill, is a pill, the relevant price being the average price of all pills sold for the same purpose. The other extreme, the current position of the statistical agencies, treats it as an entirely separate commodity, not to be compared to previously existing versions. The fact that not all consumers treat them as fully equivalent and switch immediately to the newly available cheaper variety provides some support for the second position. But the resulting exclusion of any gains from the appearance of such new versions of old (and also new) goods leaves the official measures potentially badly biased in a world where such changes are the rule rather than the exception.

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[1] Federal Drug Administration publishes a list of *Approved Drug Products with Therapeutic Equivalence Evaluations*, which provides definitive therapeutic equivalence evaluations of multisource prescription drug products. Equivalence between branded and generic drugs is a hotly debated topic. Products certified as "therapeutically equivalent" by the FDA are: (1) pharmaceutically equivalent, in that they contain the same active ingredient(s), are of the same dosage form, are identical in strength and route of administration, and meet applicable standards of purity, quality etc.; (2) bioequivalent, in that *in vivo* or *in vitro* tests show that a product meets statistical criteria for equivalence to the reference drug in the rate and extent of absorption of the active ingredient and its availability at the site of action; (3) adequately labelled; and (4) manufactured in compliance with Current Good Manufacturing Practice regulations. Therapeutically equivalent products may still vary in characteristics such as shape, color, flavor, scoring, packaging, labelling, and shelf life. These apparently trivial factors may still influence the clinical effectiveness of the drug insofar as they affect patients' ability to distinguish between different tablets and dosages, or their readiness to take the medicine at the times and in the amounts prescribed. Therapeutic equivalence ratings also do not take into account differences in stability under adverse storage conditions, or possible reactions by patients to coloring or preservative ingredients.

Let us start with a brief, stylized description of what has been happening with generic pharmaceuticals in recent years: When a patent expires, several generic versions, certified by the FDA to be "perfect" substitutes, appear very quickly, selling at much lower prices, about 30 to 50 percent cheaper than the original versions. The incumbents, the owners of the branded and previously patented version usually do not reduce their price, loosing much of their market share in quantities, but keeping a respectable share in market revenues. This response is probably optimal for them.[2] Often, there is additional entry of generic firms and the average generic price drops further within the first two years after entry, to something around 25 percent of the original price of the incumbent, or lower, which is presumably close to the long run marginal cost of production and distribution.

Tables 1 and 2 show these developments for cephalexin and cephradine, two systemic anti-infectives from the Cephalosporin family of antibiotics. These drugs are widely used for treating conditions such as ear infections and respiratory tract infections. In 1986, the year before these two drugs went off patent, the wholesale sales of cephalexin (Keflex) reported in our data were just under $280m, while wholesale sales of cephradine (Velosef) were just under $40m. By 1989, total annual wholesale revenues from the sale of cephalexin had fallen to $163m and cephradine sales were down to $17.4m (current dollars) with the revenue

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[2] See Caves et al. (1991). Obviously the above is an oversimplified version of a much more complex subject. For earlier analysis and richer detail see Masson and Steiner (1985), Grabowski and Vernon (1992), and Hurwitz and Caves (1988). The changes in market share and relative prices in our data are consistent with the results of these studies, which report on larger numbers of drugs.

shares of incumbent firms (Eli Lilly and Squibb respectively) at about 50%.

Figure 1 plots the numbers for a particular cephalexin "presentation": a specific formulation of the drug in a specific package. What is interesting for us in this figure is both the fact of rather large price differentials between the incumbent and entrants, and that not all consumers switch to the new cheaper variety, in spite of these differentials. For the latter to make sense, consumers must differ in their expectations about the efficacy and quality of such substitutes, despite what the FDA says, some of them preferring to pay much higher prices for the branded version.[3] It is the presence of heterogeneous consumers with different tastes which sustains the presence of many such varieties in the market, but standard consumer theory is rather uneasy with this fact. We invent the concept of the "representative" consumer, who consumes a bit of every variety, taking two generic and one branded pill a day. The more relevant notion of a population of heterogeneous consumers with different tastes requires some redefinition of the standard index number theory. We turn to this task and a brief discussion of new goods in price index theory next.

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[3] In this paper we are abstracting from the rather vexing problem of who is the "consumer" in the medical market. Who makes the decision: the patient or the doctor (or pharmacist) as his agent? And also who pays for it? Given insurance and reimbursements, it is not clear that standard consumer theory applies in this case. But the problem exists also outside the medical arena: we pay more for milk at the "convenience" store, and established names such as Leica can command significant premia over competing products whose quality differentials are rather hard to discern. Thus the treatment of such cases is of general interest even though the particular application of the theory to pharmaceuticals is somewhat ambiguous.

II. Aggregate Index Numbers

We start with the "Ideal" price index for individual h:

$$I_h^0 = \frac{E(p^1,u_h^0)}{E(p^0,u_h^0)}$$

where $E(p,u_h)$ is the minimum expenditure required by individual h to achieve the base utility level u^0 given prices p.[4] A comparable aggregate Ideal price index can be defined as the weighted average of such individual indexes:

$$J^0 = \frac{\sum_h E(p^1,u_h^0)}{\sum_h E(p^0,u_h^0)} = \sum_h w_h^0 I_h^0$$

where $w_h^0 = \frac{E(p^0,u_h^0)}{\sum_h E(p^0,u_h^0)} = \frac{p^0 q_h^0}{p^0 Q^0}$ is the relative share of individual h in total base period expenditures. The resulting Ideal aggregate price index J^0 gives the minimum amount (relative to base period 0) that a social planner would need to have so that he could keep every individual on his base utility level under the new price circumstances.[5] Define the operational Laspeyres price index at the individual level as $P_h^0 = \frac{p^1 q_h^0}{p^0 q_h^0}$, and the parallel aggregate Laspeyres price index as $P^0 = \sum_h w_h^0 P_h^0$, then

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[4] This section borrows heavily from Fisher and Griliches (1992).

[5] The resulting index is "plutocratic" rather than "democratic", with individuals getting unequal weights in the aggregate. See Diewert (1983) for discussion and references to the earlier literature.

$$P_h^0 \geq I_h^0 \text{ and } P^0 \geq J^0$$

The same argument also applies to the parallel Paasche computations and hence $J^1 \geq P^1$ where J^1 is a comparable Ideal index holding the utility level constant at u^1. This provides some justification for viewing the standard aggregate price index computations as approximating something of interest despite the underlying fact of consumer heterogeneity.

III. New Goods, New Varieties, and the Special Case of Generics

We now introduce the problem of new goods, commodities (or services) that were not available in period 0, for which we have no observations on p^0 and where $q^0=0$, presumably. The theoretical answer to this problem is well known (see Fisher and Shell (1971) and (1972)): estimate the reservation price of the new commodity in period zero, i.e., the price in period zero at which the demand for this particular commodity (or version) would be zero.[6] If such a reservation price could be estimated, or a reasonable assumption about it could be made, the rest would be "easy".

Note that the new goods problem does not affect the calculation of the Laspeyres price index, since the base period expenditure weight of the new good is zero. However, a better approximation to the J^0 Ideal index might still be possible. We shall come back to this point below.

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[6] We are discussing the problem of measuring a consumer price index. The problem of a producers (output) price index is similar. It is discussed in Section XII of the second essay in Fisher and Shell (1972). For more recent references on this range of issues see Feenstra (1992) and Zieschang (1989).

Having a reservation price does allow us to calculate a Paasche price index and also the associated Fisher's Ideal index, the square root of the product of the Laspeyres and Paasche indexes. One can also calculate the "superlative" (in Diewert's terminology) Divisia-Tornqvist index, where the percentage price decline from the reservation price will get a weight of half of the share of the new good in the comparison period. In general, however, if the new good is introduced into the price index early enough then, except in special cases, such as we will discuss below, its weight will be very small, and the whole argument is *de minimis*. Such a procedure assumes, however, that the market is in equilibrium and that everyone who would have liked to switch to the new commodity had the opportunity and the knowledge to do so in the first minute or month of its existence. If, in fact, the introduction and diffusion of new goods into a market takes some time, as does the learning of consumers about its actual and putative qualities, then the theoretical prescription "introduce it early and you will minimize the problem" may be all wrong, and so also the procedures outlined above. One cannot really escape the diffusion problem. In some form one has to face it head on and discuss what are the relevant points in time for which such computations are indeed sensible. We will, therefore, get back to this problem below. But first we shall deal with the related questions of estimating the reservation price and dealing with taste heterogeneity.

Assume, for the moment, that we know the reservation price p_k^r for every consumer. Then the aggregate Paasche price index is

$$P_a^1 = \frac{Q_b^1 p_b^1 + Q_g^1 p_g^1}{Q_b^1 p_b^0 + Q_g^1 \bar{p}^r}$$

where the subscripts b and g refer to brand and generic respectively, and

$\bar{p}^r = \frac{\sum_h q^1_{gh} p^r_h}{Q^1_g}$ is the average reservation price of those individuals who bought generics in period 1, weighted by the size of their purchases, with capital Q denoting aggregate quantities. Other price indexes can be defined in a similar fashion.

Assuming that a consumer buys either the branded version or the generic, we are in a two goods world and we can model the choice between them in a "linear utility" framework: generics are chosen by individual h if $p_b > p_g + b_h$, where b_h is the premium required by individual h when purchasing generics to compensate him for the putative loss in security or quality associated with this switch. The associated component of the utility function that is being maximized can be written as $q_b + (1-\delta_h)q_g$, where $\delta_h = b_h/p_b$ is the premium for "brandedness" relative to p_b and $p^r_h = p_b - b_h$ differs for each h. Individual h is then indifferent between buying the branded version or the generic if for her $p^r_h = p_g$. If she switches to a generic, it must be the case that a price decline of $p_g - p^r_h$ occurred.[7]

Given this interpretation, we can construct a better bound for the $J^1{}_a$ Ideal aggregate price index, even though the standard Laspeyres formula does not incorporate the presence of the generic since its weight in period zero is zero. Knowing that the consumer would have been indifferent between consuming the branded item at p_b or the generic at p^r_h

[7] The brand premium b_h need not be constant over time. It could change with the availability of other substitutes or with the passage of time as the uncertainty about the quality of generics dissipates.

in the base period, we choose the latter consumption point as our reference point, since it is on the same base-period indifference curve, and construct a Laspeyres-like index (assuming that total quantities did not change with only previous brand variety users switching to the generic):[8]

$$P_a^0 = \frac{Q_b^1 p_b^1 + Q_g^1 p_g^1}{Q_b^1 p_b^0 + Q_g^1 \bar{p}^r}$$

since for each individual the relevant price change is p_b^1/p_b^0 if he did not switch and p_g^1/p_g^r if he did. The first set of individuals are weighted by the value of their consumption in the base period, while the second, the shifters, are weighted by their potential consumption of generics evaluated at their reservation prices. Perhaps not surprisingly, the resulting Ideal aggregate Laspeyres index turns out to be exactly equal to the Paasche index. Given that the assumed utility function is linear, the two indexes are the same and the aggregate Paasche, in reservation prices, is "exact".[9]

IV. Reservation Prices

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[8] This is approximately correct for most of our examples, with the market expanding effect of the drop in average prices counterbalanced by the general decline in the overall market for the drug, since patent expiration comes usually relatively late in the life-cycle of a drug when it is already loosing market share to newer, more advanced drugs.

[9] This equivalence holds for the sub-index for the "nest" of these particular goods. It will not be necessarily true for the overall index, including other goods since u^0 and u^1 will differ.

The main problem, of course, is where are these reservation prices to come from? For versions that differ along some measured characteristics, one could estimate the potential supply price of the new variety given yesterday's technology, using the hedonic price indexes approach (see Griliches (1971) and (1990), Suslow (1992)).[10] But in the case of generics all the relevant measurable characteristics are presumably the same. In our case it is not that the goods differ but that consumers differ in their perceptions of their relative values, in their b_h. Since the probability of shifting to a generic depends on $p_b - p_g > b_h$, one can write the share of generic users in the total as $s_g = F(b_h)$, where $F(\,)$ is the cumulative distribution of reservation prices (for a fixed p_b). Assuming that $b_h \geq 0$, i.e., that b_h is a non-negative random variable, no consumer being willing to pay more for a generic version than for a branded one if the branded one is available, the average reservation price for the switchers is bounded between p_b and p_g and depends on the shape of $F(\,)$.[11] It is possible either to assume a reasonable shape for $F(\,)$ or try to infer it from the observed relationship between prices and market share.

Suppose that the distribution of brand preferences is constant and exogenous, and that equilibrium is reached instantly. As the price differential widens, the entrants' market share should just trace out the

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[10] The hedonic approach does not give, however, enough credit to the appearance of new varieties if their prices fall on the old hedonic price line. On this see Trajtenberg (1990).

[11] In this, the generics case differs from the more general "another variety" case in being hierarchical and asymmetric. In a sense, generics are perceived, at least to some extent, as lower quality versions. If we allowed b_h to take negative values, we would be in the more general but also less informative case.

shape of *F( )*.[12] If *F( )* is uniform the relationship will be exactly linear. Other possibilities are unimodal distributions such as the normal or logistic, implying the familiar S-shaped c.d.f. On the other hand, the distribution could be bimodal (u-shaped p.d.f.) such as the arcsin or other variations on the beta distribution, with most consumers having a very weak or very strong preference for the branded version, implying an "inverted S" shape for *F( )*. The simplest assumption for *F( )* is the uniform distribution: then the average reservation price for those that shifted is just halfway between p_b and p_g. To the extent that the uniform distribution over-estimates the tails of the normal or logistic, we will be over-adjusting the price indexes. On the other hand, if the true distribution is bimodal (u-shaped) we will be under-adjusting.

Unfortunately, our ability to distinguish between these alternatives is limited by several factors. There is the question of diffusion: in most of the cases examined so far the entrants rapidly gain significant market share in the first few months after patent expiration without a concomitant movement in the price differential. From a practical perspective, it is also clear that the curvature of the c.d.f.'s of

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[12] The size of the initial price differential and its evolution over time are presumably determined by the outcome of some game between the incumbent and the entrants. The standard vertical differentiation models (e.g. Shaked and Sutton (1982) are greatly simplified here: "quality" is either zero or one, and (at least for some drugs) it is not unreasonable to assume that all consumers have to buy either the brand or the generic, which makes moot the issues relating to "finiteness" and coverage of the market discussed in the theoretical literature. But the implications of alternative assumptions about the distribution of preferences for brandedness for the equilibrium in these models are difficult to draw out. Exact closed form solutions for even the simplest game are very difficult to obtain except for the uniform case. The most tractable alternative seems to be to simply segment the market into two distinct elastic and inelastic segments, see Frank and Salkever, (1991).

plausible distributions is very similar over the range of price differentials that we actually observe. The initial price differential is normally quite large, so that we rarely see the left hand tail of the distribution (which is in any case confounded with the diffusion effect) and entrants' prices rarely fall far enough for us to see the extreme right hand tail. The portion which is actually observed by us is approximately linear for most candidate distributions. In these circumstances we settle upon the uniform distribution as a "reasonable" assumption.

An alternative approach, which comes out of the recent literature on preferences for variety and differentiated product markets (see Dixit and Stiglitz (1977), Spence (1976), Grossman and Helpman (1991), and Feenstra (1992)), takes the reservation price as infinite but assumes a CES form for the utility function over varieties and produces a finite consumer surplus calculation arising from the introduction of a new one. It can be shown (see Anderson et al. (1992)) that the linear random utility model with varying tastes across individuals is observationally equivalent to a representative individual CES utility function, though the welfare implications can differ. In our case, and also in the case of the introduction of a new shirt or cereal variety, the assumption of an infinite reservation price seems both unreasonable and unnecessary. More generally, however, if the functional form of the demand structure over the various varieties can be estimated, then a reservation price could be computed, and the implicit utility function could be derived to produce the appropriate "exact" price indexes. (See also Berry (1991) for a more general approach to the estimation of the unobserved "quality" of a particular variety using the information contained in its market share.) We shall try to illustrate such approaches below, using both the CES and the addi-log demand structures.

V. Official Indexes and Alternatives

There are a number of problems with the treatment of generics in the official price indexes:

1. Generics belong to the more general class of "new goods" which are introduced relatively late in their life cycle into the official market "baskets". Even when baskets are changed more often, e.g. currently in the PPI and CPI on a four-five year rolling basis, this turns out to be too long a lag in many dynamic markets, especially because new goods tend to experience significant price declines in the earlier part of their life cycle.[13]
2. Because of the fixed weight aspect of the official indexes and the growing market share of generics, they are underweighted even when included.
3. Because they are linked-in, rather than compared directly with the previously existing versions, and treated as entirely "new" goods, none of the direct price decline experienced by those consumers who switch to generics is reflected in the official price indexes.

Problems one and two are "standard" and well known, though nonetheless very important. It is the last problem which forms the main topic of this paper.

In Figures 2 and 3, we plot a selection of possible price indexes for the drug cephalexin, which went off patent in April 1987. (Figures 4 and 5 plot the same indexes for cephradine. The basic data are given in

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[13] For additional evidence and discussion of this, see Berndt et al. (1992), and Triplett's discussion in Foss et al. (1993).

the top and bottom lines of this figure: the price series for the (average) brand and generic versions of this drug.[14] The "BLS" index attempts to approximate the outcome of the official PPI procedures. The official PPI was based on a basket of drugs chosen in 1981. It was rebased in January 1988, using information collected in 1987 (and earlier) on value shares to sample individual products (see Berndt et al. for details). Thus we "link-in" generics at 88.01 into a Laspeyres type index, with a relative weight of 0.27, their revenue share during the first quarter of their availability in mid-1987.[15]

The "BLS" index is to be compared to a "standard" Tornqvist-Divisia index given next, which maintains the spirit of the official approach, by treating generics as new commodities without making any direct price comparisons, but brings them in the second month after their entry and keeps shifting their weight as they gain market shares. Note that the "BLS" index departs from it both because it is late in including

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[14] These already represent a significant summary of the data. The incumbent's series are a Tornqvist-Divisia Price Index based on 28 distinct "presentations" of this drug at the monthly level. The generics price series is computed similarly, but with information from a changing number of manufacturers (3 in the month after the patent expired, rising to an average of about 30) selling between them 27 distinct presentations used in the calculation of the price index. This index is linked in at 87.05 using the average price differential between generic and branded versions at that date in the presentations where both were available, weighted by the total market shares of these presentations. The final numbers are not very sensitive to the fine details of this construction, as a look at the particular version of this drug, in Figure 1, indicates.

[15] This is probably already an overestimate of what BLS might have been able to do at the time, both because actual lags in the availability of information are likely to be longer, and because the establishments sampled were most likely based on lists collected in 1986 or earlier, and may not have contained generics producing plants, to the extent that they were new, rather than a re-direction of the output of an existing plant.

generics and because later on, when the incumbent raises its prices, it gets inordinate weight in the fixed weight version. (The specific numbers for these indexes for selected time periods after the entry of generics are given in Tables 3a and 3b.)

The average price index is a price index that takes the FDA at its word and treats all sources of the pill as equivalent. It is constructed by weighting the price series for the incumbent and entrants by their respective quantity shares. The distance between the Tornqvist-Divisia and this average price index provides, in a sense, a measure of the size of the "pure" generics problem: the problem raised by not comparing the new goods to some appropriate base period price. As can be seen, it is quite wide, with the average price index being about one-third to 45 percent lower one to three years after entry.

In making an adjustment for the introduction of generics, two decisions are crucial: (1) how is the reservation price to be computed, and (2), what is to be done about diffusion, about the fact that spread of the generic takes time and that today's switchers to the new versions are still reacting to the existence of the differential itself, that they would have switched even if prices had remained unchanged in the particular month.

As discussed above the uniform distribution is the simplest assumption that one can make about the unobserved tastes for "brandedness", and appears to be reasonably consistent with the data. It implies that average reservation price for "switchers" is the average of the generic and branded prices.[16] The Paasche index based on this calculation is denoted "Paasche (u)" in Table 3 and Figures 3 and 5. It turns out that this is roughly equivalent to using the branded price in *t-1*

[16] For logical consistency in the index number computations, we take the average between the brand price in *t-1* and the generic in *t*.

alone as a reservation price in a formula such as Fisher's Ideal or the Tornqvist-Divisia price index, where the base period share of generics is zero, and its effective weight is one-half of its comparison period share. That is, either taking the actual price-difference at one-half of its value, or giving generics one-half of their ultimate weight, gives essentially the same result. (See the relevant rows of Table 3, and Figures 3-5.)

That the diffusion problem is important can be seen from Figures 6 and 7, which plot the market share of generics (in quantity units) as a function of the price differential (relative to the branded prices) $\Delta p = \frac{p_b - p_g}{p_b}$. Since the price differential widens more or less monotonically with time, these figures can be thought both as describing diffusion and as an estimate of the cumulative distribution of the taste for "brandedness." Note the significant upward movement in the share of generics in the first six months to a year after entry, without much of a change in the price differential.

Tables 4a and 4b gives the results of a number of regressions relating the share of generics in cephalexin and cephradine to current and past price differentials and lagged shares and compares several functional forms. A number of things are worth noting about these results (and associated computations):

1. Lagged response is important. The average price differential during the previous six-months comes in significantly, as does the lagged share, indicating that diffusion is still going after six months.[17]

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[17] Similar results can be gleaned from the Hurwitz and Caves, and Grabowski and Vernon papers, where "time since introduction" is an important explanatory variable for the market share of generics.

2. The linear version, implying a uniform distribution for $F(\Delta p)$, fits marginally better than semi-log or the log-log (not shown) versions.

3. The logit version gives a direct estimate of the elasticity of substitution between the branded version and generics. It is about 2.1 for cephalexin and 3.4 for cephradine. This estimate, or the log price-ratio versions which are consistent with a separable addi-log demand structure (see Hausman et al. (1992)), can be used for an alternative construction of the reservation price, which is explored below.

4. Instrumenting the current price differential (and also the lagged share), using a time trend (linear and quadratic), the overall medical CPI and the number of generic entrants, does not change these results significantly.

Tables 3a and 3b show the main results of using the various possible approaches. In addition to using different index number formulae, one can also allow for diffusion in two different ways: either one can make the link later in the story, six months to a year later, allowing thereby much of the early diffusion to be completed before evaluating the direct contribution of generics (lines 9 - 12 in Table 3), or the index number formula can be adjusted to reflect the assumption that those shifting later on to generics, do so from the branded good, with an average reservation price which is half-way between the branded and generics prices (lines 6 and 7).[18] Both procedures drop the computed

[18] The Paasche formula becomes $P_a^1 = \dfrac{Q_b^1 p_b^1 + Q_g^1 p_g^1}{Q_b^1 p_b^0 + Q_g^1 p_g^0 + (Q_g^1 - Q_g^0)\bar{p}^r}$,

price indexes further, with the second procedure doing it somewhat more than the first. These indexes are also plotted in Figures 3 and 5, where (d) denotes "diffusion-adjusted". Either way it is clear that the diffusion question is of substantive importance, accounting for about one-third in our total adjustment of the "official" index.

These regression results also allow us to examine the implications of the remaining two approaches to the generics problem discussed above: a CES utility function assumption, and the imputation of reservation prices from an estimated demand equation. Feenstra's (1992) approach to the treatment of new goods assumes a CES utility or production function for the separable nest of differentiated goods, and a reservation price of infinity for goods not yet available. The CES functional form produces a finite gain in consumer surplus from the introduction of a new commodity (variety) despite the infinitely high reservation price. This approach requires knowledge of the elasticity of substitution between the old and new varieties. Applying this apparatus to our problem and using the estimated elasticities of substitution in Table 4 of 2.1 for cephalexin and 3.4 for cephradine, yields estimates (listed in line 13 of Tables 3a and 3b) which are *below* our average price index.[19] That is, the Feenstra index shows even more of a price decline than is implied by the assumption that

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where the assumption is made that total quantities are the same in both periods, and $\bar{p}_r^t = (p_g^t + p_b^{t-1})/2$. That is, "shifters" from the branded version to the generic version are assumed to have experienced a price decline of one half of the branded-generic differential also in periods subsequent to the initial appearance of generics.

[19] This computation is based on formula 4′ in Feenstra and Markusen 1992. Formula 4 leads to nonsensical results. The computations are quite sensitive to the particular assumption for σ and the date at which the value shares are evaluated.

generics are perfect substitutes for the branded versions.[20] Thus our approach is conservative relative to the CES functional form approach.

Finally, the estimated demand relationships in Tables 4a and 4b can be used to infer the reservation price, i.e. the price ratio that predicts a zero share for generics, by extrapolation. Since most of the estimates in Tables 4a and 4b are based on samples which include the initial point (generic share=0, relative price=1), it is not surprising that the linear versions of the equation yield an answer for the reservation price close to the brand price (a price ratio of 1). The equations using the log of price ratios yield reservation prices somewhat higher than that, e.g. 1.3 for the first estimate on the cephradine section of the table. Dropping the first observation and re-estimating without it does not change matters much: the estimated reservation prices are somewhat higher, i.e. above the brand price. This implies that our suggested procedure of taking the reservation price at the midpoint between the brand and the generics is conservative. Both our attempt to estimate the reservation price from the data by extrapolation of the share equations, or the use of the CES approximation yields price indexes that would decline by even more than our suggested compromise procedures.

We can summarize this section by noting that we effectively partition the distance between the consequences of the two "extreme" treatments of generics (the BLS assumption of generics being different goods and their belated introduction with fixed weights, and the alternative extreme assumption of complete equivalence) into roughly four parts. For cephalexin, the single largest part, slightly over 42 percent (by

[20] The CES function guarantees that utility will increase simply as the result of adding a new good.

the end of three years after entry) is due to "standard" index number problems -- late inclusion of generics with too low and too fixed a weight. The remaining 58 percent, the distance between linking in generics without giving the transition from branded items any weight (line 2) and the full weight treatment implicit in the average price formula (line 8) is divided roughly in half by the suggested treatment of generics, with the correct linking in of generics at the beginning accounting for about one-third, and the estimated role of subsequent diffusion for two-thirds (lines 2-3, and 3-7). The other half, the distance from our "best" and lowest index (line 7) and the average price is consistent with the assumption used in our calculations, that the "correct" reservation price is not the actual price of the branded good, but the mid-point between it and its generic rivals. The story for cephradine is similar but the magnitudes are somewhat smaller, reflecting a smaller original price differential and the lower market share of generics. The main point of this section is that the correct treatment of generics is empirically important, not just at the moment of their appearance but also through the later stages of their diffusion.

VI. Interim Conclusions

This is an interim report from an ongoing project. Only two episodes of patent expiration and entry by generics are examined in detail. We are currently assembling a significantly larger number of such episodes, which should provide us with more variability in the price differential at entry and thus give us a better chance to infer something more specific about the shape of the underlying distribution of tastes for "brandedness". Efforts are also underway to use some of the implications of theoretical models of incumbent and entrant interaction to infer the shape of the unobserved portion of this distribution. We are also planning to explore the question of entry and diffusion at the more detailed level of particular presentations of a drug. While incomplete, our analysis to date does indicate that the problems raised here may be both pervasive and important, and hence worthy of further attention. Consider cephalexin: the "BLS" approach gives an *increase* in the wholesale price index of about 14% over the 45 months observed in our data; the opposite extreme, assuming that branded and generic versions are perfect substitutes, gives a price decline of 53%; and our preferred "adjusted Paasche" index falls by 48%. These are very substantial differences.

Official agencies could improve the accuracy of their price measures by moving towards a more current sampling of new products, faster introduction, and more current weighting. As an alternative compromise to existing procedures, new "gaining" varieties and outlets could be introduced by comparing them directly to the incumbent ones, with at least half of the apparent price difference being taken as "real".

Appendix: Data Sources

The primary source of data for this study is audits of wholesale transactions conducted by IMS America Inc, a market research firm. Sales revenues and quantities are derived from two sources: invoices of a panel of purchasers, and information provided by wholesalers. We examine only "systemic anti-infective" drugs for which the incumbent firm's patent expired in the period of time covered by the machine-readable file.

Individual items in the file are identified by

(a) "manufacturer", which may be the actual producer of the drug, or a firm specializing in distribution
(b) "product name", either the brand name or the generic name of the drug
(c) "description", a brief summary of the dosage, formulation, and packaging of the item

Correspondences between brand names and generic names were checked using *Drug Facts and Comparisons*, a standard reference source used by pharmacists.

For each drug, all items were classified using this information into a "product" code, within which items are identical in terms of active ingredient, formulation, dosage, and packaging. For cephalexin, there were 38 distinct "products", for example "250mg Tablets, 100 count", or "Suspension, 125mg/5ml, 250ml, x 6". In a small number of cases, there appear to be errors and ambiguities in labelling, making it difficult to classify these items. For the two drugs examined here, this was not a serious problem, and we are confident that our classification is accurate. For other drugs, particularly those administered parenterally, there are serious problems in assigning items in the IMS file to homogeneous "product" codes.

Within each product manufacturers were classified as "incumbent" or "entrant", being careful to recognize that some "firms" are in fact subsidiaries or divisions of a parent company. The total amount of the active ingredient in each package was also computed, which when multiplied by the number of packages on the invoice gives an alternate measure of quantities.

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Figure 1: Notes

The figure plots monthly data for one of the most popular presentations of cephalexin, a bottle of 100 250mg capsules, for the period October 1984 to September 1990. The patent for cephalexin expired in April 1987. The data are broken down by incumbent, and two classes of entrants: "majors" i.e. large R&D-performing firms, and "other", which are firms specializing in the production of generics and performing little product-oriented R&D. (This 3-way classification is not used elsewhere in the paper. As the figure indicates, there is very little difference in the prices charged by the two kinds of entrants, and the two groups are combined into a single "entrants" class.)

The solid line represents the incumbent, the broken line represents the "majors", and the dotted line represents the "other" group.

Panel (a) plots the revenue shares of the three groups over time

Panel (b) plots the price per bottle for each group over time (in current dollars)

Panel (c) plots quantities for each group over time (in 100s of bottles)

Panel (d) plots the number of firms in each group over time

Figure 1

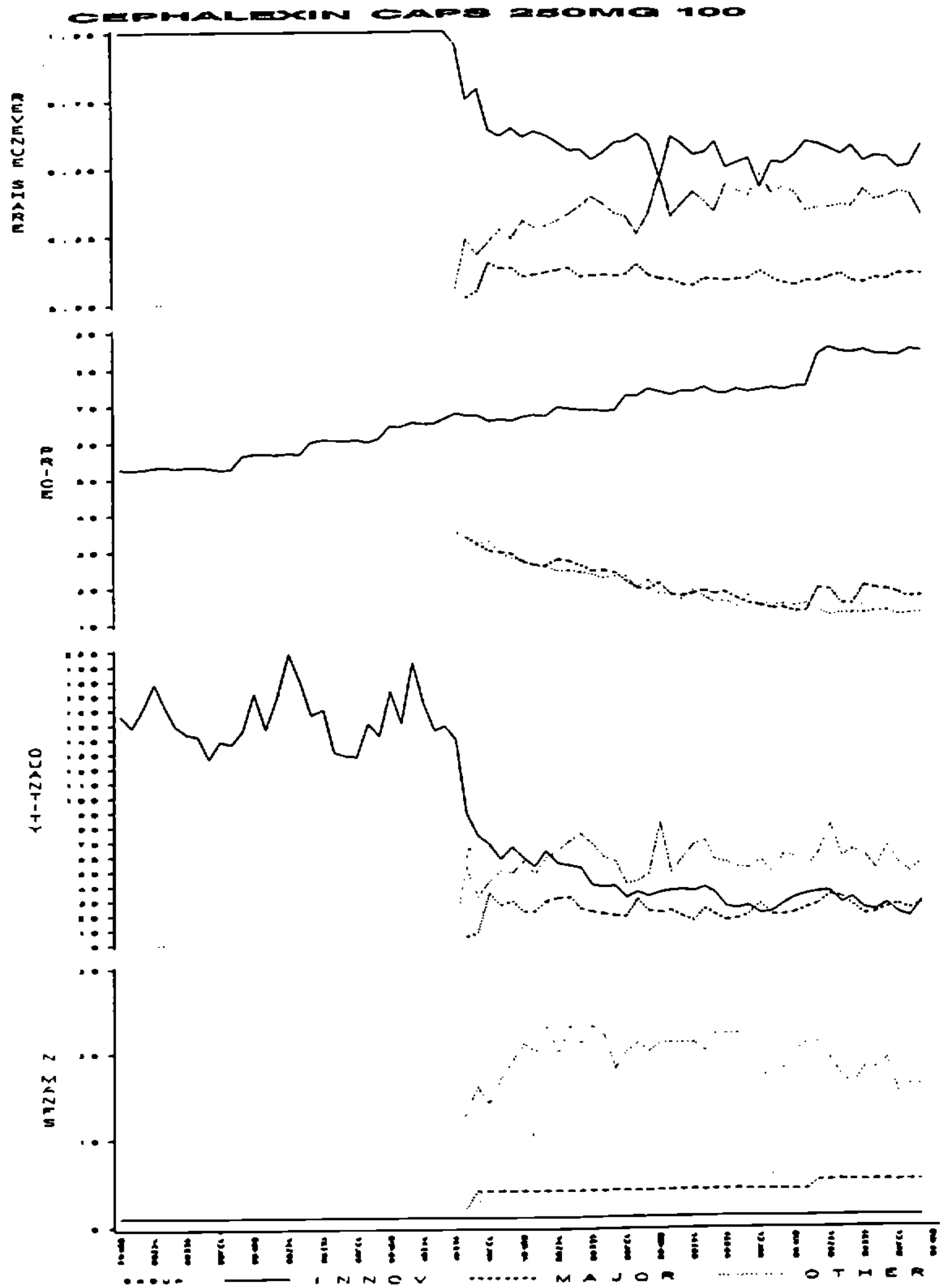


Figure 2. Cephalexin: Basic Price Indexes 1987:04-1990:09

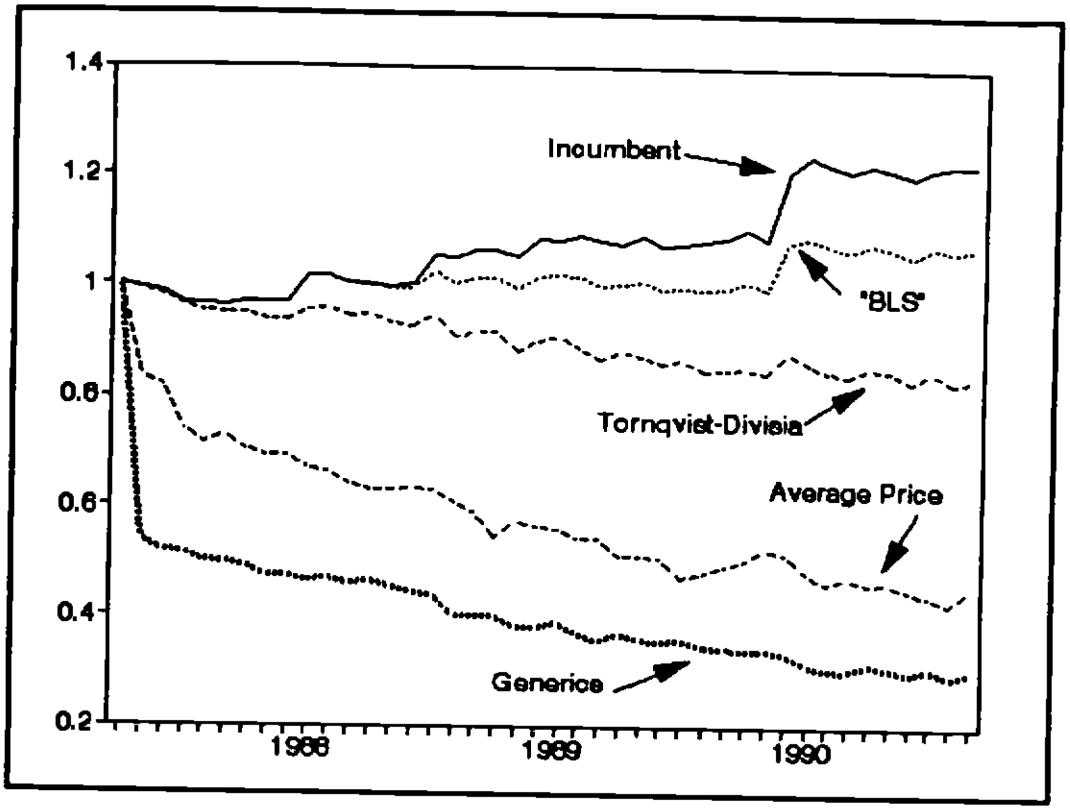
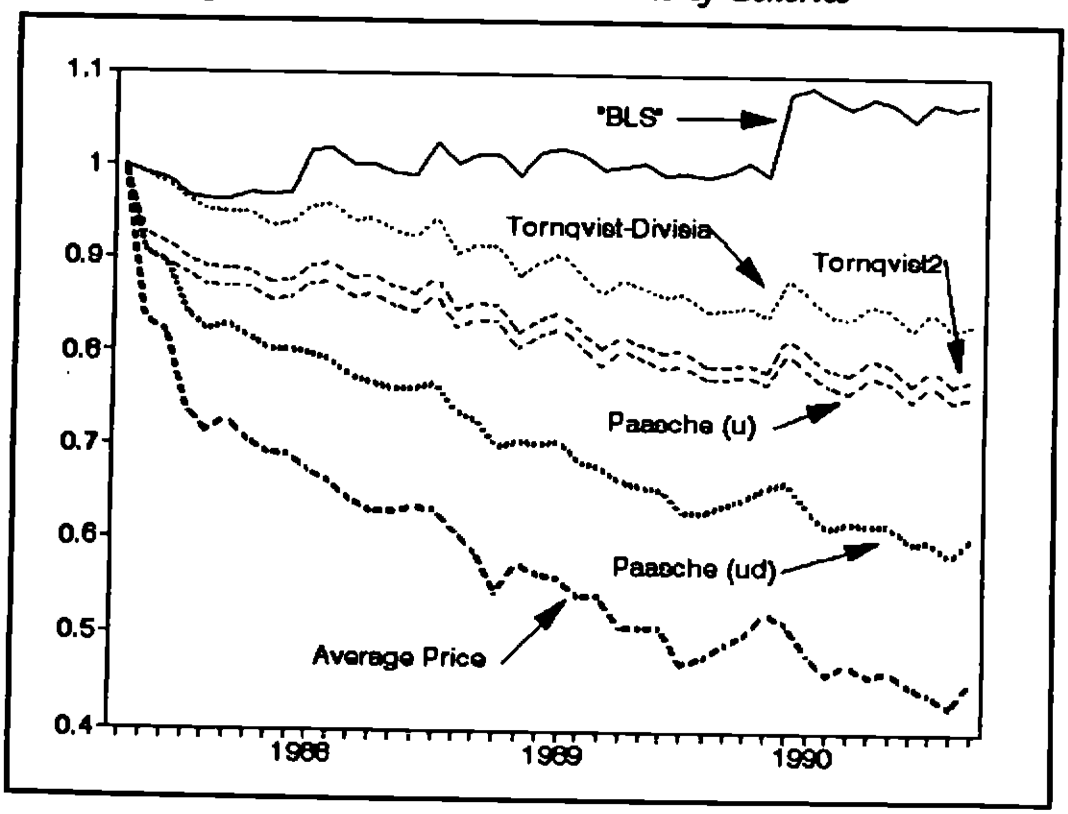


Figure 3. Cephalexin: Alternative Treatments of Generics



(u) denotes adjustment for uniform distribution of tastes for brandedness, (d) denotes adjustment for diffusion. See text and notes to Table 3.

Figure 4. Cephradine: Basic Price Indexes 1986.12-1990.09

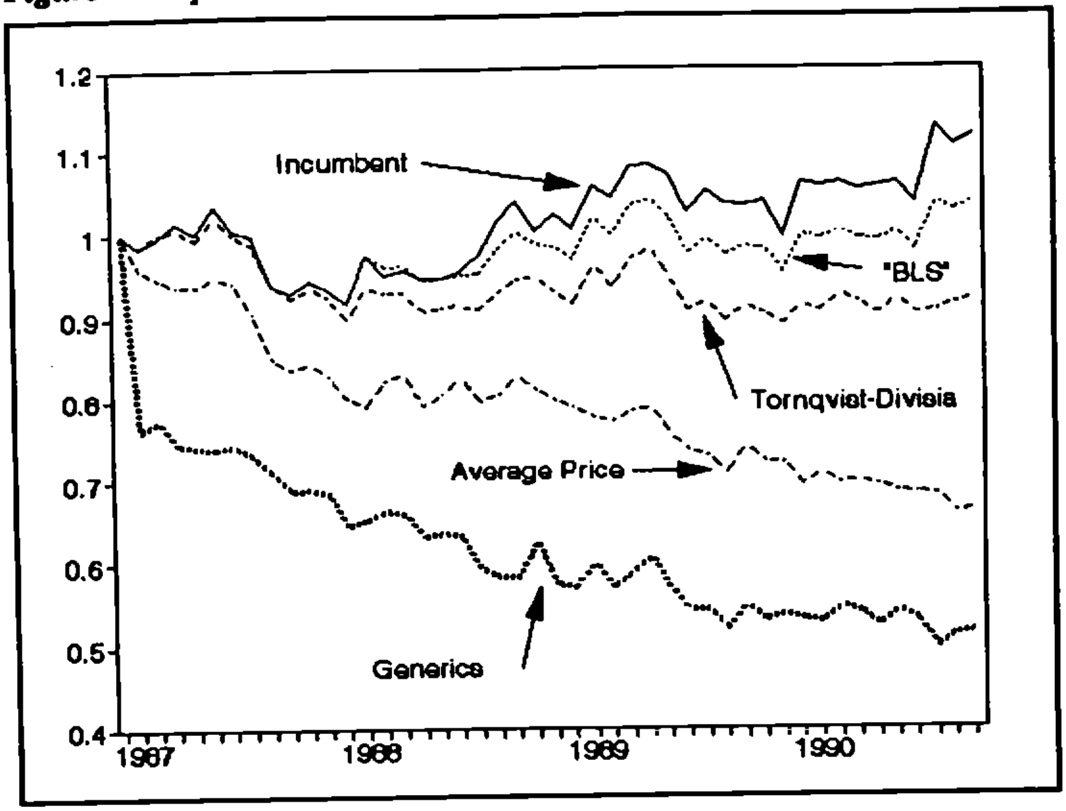
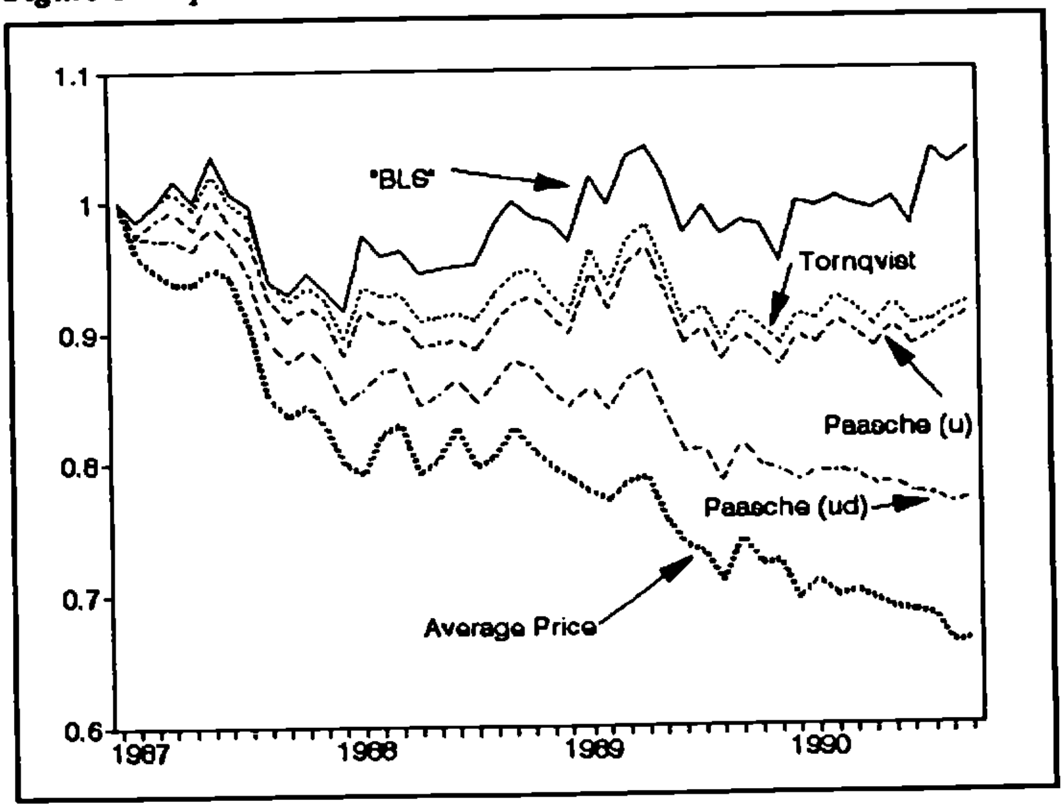


Figure 5. Cephradine: Alternative Treatments of Generics



(u) denotes adjustment for uniform distribution of tastes for brandedness, (d) denotes adjustment for diffusion. See text and notes to Table 3.

Figure 6. Cephalexin: Quantity Share of Generics vs. Price Differential

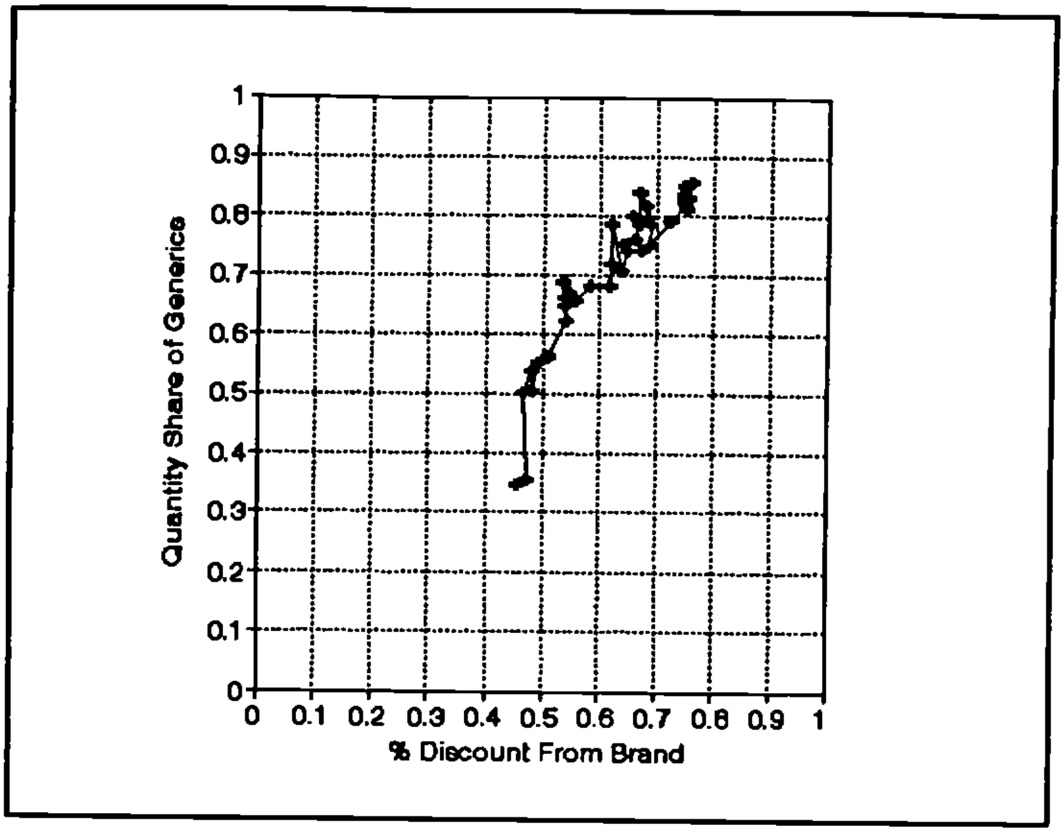


Figure 7. Cephradine: Quantity Share of Generics vs. Price Differential

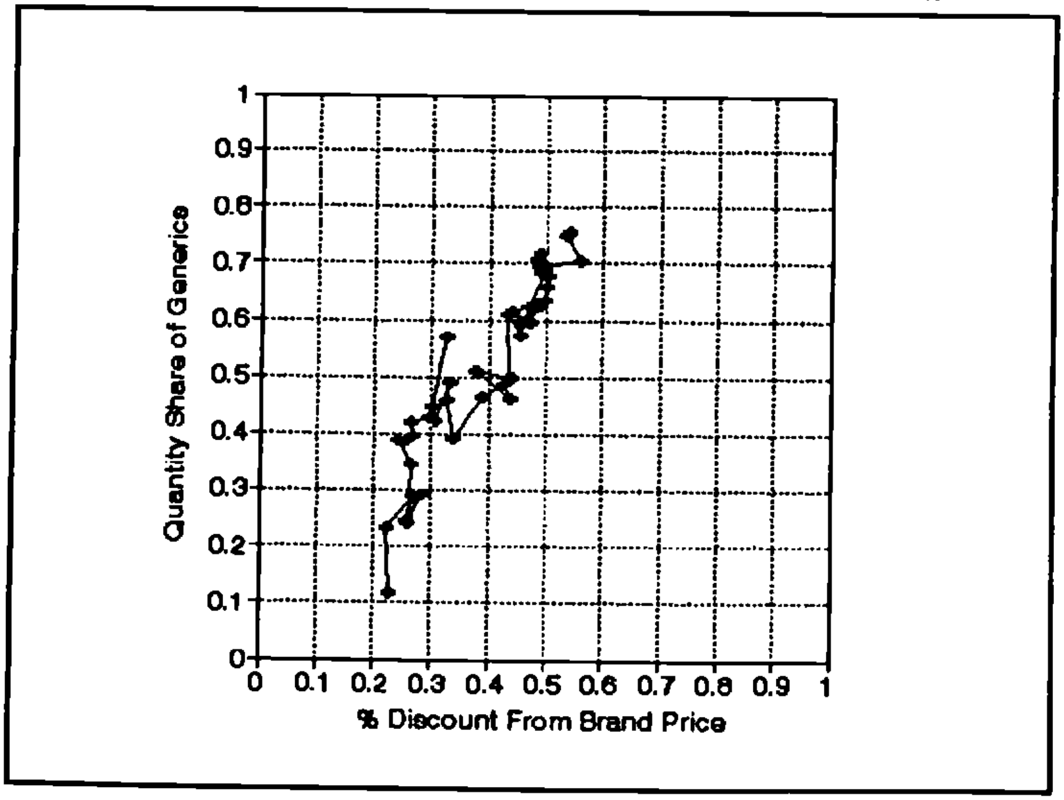


Table 1: Cephalexin

DATE	Divisia Indices: Incumbent	Divisia Indices: Entrants	Relative Price p_g/p_b	Quantity Share of Generics	Revenue Share of Generics	Total Market (Quantities)
1987.01	1.197					23064410
1987.02	1.195					19826570
1987.03	1.220					20147210
1987.04	1.244	.	1.000	0.000	0.000	19910790
1987.05	1.233	0.671	0.544	0.346	0.223	20818030
1987.06	1.227	0.646	0.526	0.354	0.224	17851430
1987.07	1.203	0.642	0.534	0.503	0.350	22555770
1987.08	1.199	0.622	0.519	0.538	0.377	20521920
1987.09	1.199	0.620	0.517	0.505	0.345	21639350
1987.10	1.206	0.613	0.508	0.554	0.387	21127260
1987.11	1.205	0.591	0.491	0.561	0.385	19251340
1987.12	1.207	0.592	0.491	0.564	0.388	22508830
1988.01	1.265	0.580	0.459	0.624	0.432	21841440
1988.02	1.265	0.583	0.461	0.648	0.459	22705070
1988.03	1.244	0.573	0.460	0.662	0.474	23797870
1988.04	1.241	0.577	0.465	0.688	0.506	20173300
1988.05	1.239	0.563	0.454	0.673	0.483	18551070
1988.06	1.245	0.550	0.442	0.656	0.457	18769810
1988.07	1.307	0.545	0.417	0.683	0.473	16607050
1988.08	1.306	0.499	0.382	0.681	0.449	18492860
1988.09	1.322	0.502	0.379	0.720	0.493	17974780
1988.10	1.322	0.501	0.379	0.786	0.582	25355580
1988.11	1.307	0.472	0.361	0.709	0.468	19364200
1988.12	1.347	0.475	0.353	0.742	0.504	21006700
1989.01	1.346	0.484	0.359	0.752	0.522	21195280
1989.02	1.356	0.460	0.339	0.763	0.522	23686810
1989.03	1.344	0.441	0.328	0.741	0.484	20507130
1989.04	1.336	0.458	0.343	0.800	0.579	19936910
1989.05	1.354	0.444	0.328	0.793	0.556	18390120
1989.06	1.334	0.442	0.331	0.786	0.549	19873610
1989.07	1.335	0.444	0.332	0.840	0.636	21379970
1989.08	1.342	0.428	0.319	0.816	0.586	19226010
1989.09	1.352	0.426	0.315	0.799	0.556	21698770
1989.10	1.371	0.424	0.310	0.788	0.536	22663610
1989.11	1.348	0.422	0.313	0.750	0.485	21088180
1989.12	1.503	0.415	0.276	0.793	0.515	26127180
1990.01	1.537	0.388	0.253	0.816	0.529	28021820
1990.02	1.522	0.378	0.249	0.830	0.548	24189280
1990.03	1.507	0.375	0.249	0.813	0.519	25384340
1990.04	1.518	0.388	0.255	0.837	0.568	22270440
1990.05	1.510	0.384	0.254	0.827	0.549	20415390
1990.06	1.492	0.370	0.248	0.832	0.551	25450330
1990.07	1.514	0.382	0.253	0.854	0.596	22683590
1990.08	1.518	0.366	0.241	0.858	0.593	21542260
1990.09	1.520	0.371	0.244	0.830	0.545	25263880

Table 2: Cephradine

DATE	Divisia Price Indices Incumbent	Divisia Price Indices Entrants	Relative Price p_g/p_b	Quantity Share of Generics	Revenue Share of Generics	Total Market (Quantities)
1986.12	1.217	.	1.000	0.000	0.000	2983383
1987.01	1.199	0.928	0.774	0.117	0.093	3007125
1987.02	1.214	0.943	0.777	0.233	0.191	3062388
1987.03	1.236	0.907	0.734	0.289	0.229	2961583
1987.04	1.218	0.903	0.742	0.244	0.193	3006396
1987.05	1.259	0.901	0.715	0.290	0.226	3122295
1987.06	1.224	0.906	0.740	0.242	0.191	2920654
1987.07	1.212	0.891	0.735	0.346	0.280	2635422
1987.08	1.143	0.864	0.756	0.388	0.324	2711761
1987.09	1.130	0.839	0.742	0.389	0.321	2824313
1987.10	1.150	0.842	0.732	0.397	0.325	2668288
1987.11	1.135	0.835	0.736	0.420	0.347	2504664
1987.12	1.116	0.785	0.704	0.429	0.346	2814143
1988.01	1.185	0.797	0.672	0.570	0.471	2894090
1988.02	1.157	0.809	0.699	0.447	0.361	2331275
1988.03	1.163	0.804	0.692	0.424	0.338	2419407
1988.04	1.152	0.769	0.667	0.490	0.391	2137194
1988.05	1.152	0.775	0.673	0.458	0.363	1917295
1988.06	1.160	0.769	0.663	0.392	0.299	2089519
1988.07	1.184	0.722	0.610	0.465	0.346	1700498
1988.08	1.236	0.711	0.575	0.487	0.353	2144769
1988.09	1.265	0.710	0.561	0.464	0.327	1609256
1988.10	1.221	0.762	0.624	0.511	0.394	1710695
1988.11	1.245	0.696	0.559	0.501	0.359	1711175
1988.12	1.223	0.692	0.565	0.497	0.359	1574291
1989.01	1.285	0.728	0.567	0.608	0.468	1837058
1989.02	1.268	0.692	0.546	0.572	0.422	1796399
1989.03	1.314	0.717	0.546	0.600	0.450	1806228
1989.04	1.316	0.738	0.560	0.615	0.473	1403721
1989.05	1.303	0.691	0.530	0.623	0.467	1435787
1989.06	1.248	0.660	0.529	0.597	0.439	1708884
1989.07	1.278	0.661	0.517	0.630	0.468	1569420
1989.08	1.259	0.632	0.502	0.634	0.466	1437199
1989.09	1.258	0.667	0.530	0.600	0.443	1418972
1989.10	1.264	0.646	0.511	0.623	0.458	1537663
1989.11	1.212	0.656	0.541	0.597	0.445	1531815
1989.12	1.290	0.648	0.503	0.691	0.529	1682657
1990.01	1.287	0.644	0.500	0.658	0.491	1701813
1990.02	1.289	0.666	0.517	0.707	0.555	1561310
1990.03	1.280	0.657	0.513	0.686	0.529	1565133
1990.04	1.285	0.639	0.497	0.679	0.513	1216456
1990.05	1.289	0.659	0.512	0.718	0.566	1419745
1990.06	1.261	0.649	0.514	0.697	0.542	1583795
1990.07	1.372	0.604	0.440	0.704	0.511	1181578
1990.08	1.345	0.625	0.465	0.750	0.582	1181859
1990.09	1.359	0.629	0.463	0.756	0.589	1456514

Table 3a: Price Indexes: Alternative Treatments of Generics

Cephalexin 87.04 = 1.00	Time After Entry				
	1st Month	6 Months	1 Year	2 Years	3 Years
Monthly					
1. "BLS"	.99	.97	1.06	1.03	1.14
2. Tornqvist-Divisia	.99	.95	.94	.88	.86
3. Paasche (u)	.91	.87	.86	.80	.78
4. Fisher Ideal, $p^r = p_b$	.93	.89	.88	.82	.80
5. Tornqvist-Divisia, $p^r = p_b$	.91	.88	.87	.79	.79
6. Tornqvist-Divisia (u), diffusion adj.	.92	.83	.78	.68	.66
7. Paasche (u), diffusion adj.	.91	.82	.77	.66	.62
8. Average Price	.83	.71	.63	.51	.47
Semi-yearly					
9. Paasche (u)		.85			
10. Tornqvist-Divisia, $p^r = p_b$		.85			
Yearly					
11. Paasche (u)			.81		
12. Tornqvist-Divisia, $p^r = p_b$			.82		
13. "Feenstra" CES index $\sigma=2.1$	0.79	0.62	0.52		

(u) signifies $p^r = (p_g^t + p_b^{t-1})/2$

diffusion adjustment described in footnote x

"Feenstra" CES index is computed as $P_g = P_I \cdot \lambda^{-\frac{(1-\theta)}{\theta}}$ where $\lambda = 1/(1-s_g)$, s_t being the value share of generics, and $0 \leq \theta \leq 1$ is related to the elasticity of substitution $\sigma = 1/(1-\theta)$.

Table 3b: Price Indexes: Alternative Treatments of Generics

Cephradine 87.01 = 1.00	Time After Entry				
	1st Month	6 Months	1 Year	2 Years	3 Years
Monthly					
1. "BLS"	0.99	1.01	0.92	0.97	1.00
2. Tornqvist-Divisia	0.99	1.00	0.90	0.91	0.91
3. Paasche (u)	0.97	0.98	0.88	0.90	0.89
4. Fisher Ideal, $p^r = p_b$	0.97	0.98	0.88	0.89	0.89
5. Tornqvist-Divisia, $p^r = p_b$	0.97	0.98	0.88	0.90	0.89
6. Tornqvist-Divisia (u), diffusion adj.	0.97	0.97	0.85	0.86	0.82
7. Paasche (u), diffusion adj.	0.97	0.97	0.85	0.84	0.79
8. Average Price	0.96	0.94	0.80	0.79	0.70
Semi-yearly					
9. Paasche (u)		0.97			
10. Tornqvist-Divisia, $p^r = p_b$		0.86			
Yearly					
11. Paasche (u)			0.88		
12. Tornqvist-Divisia, $p^r = p_b$			0.85		
13. "Feenstra" CES index $\sigma = 3.4$	0.95	0.93	0.77		

(u) signifies $p^r = (p_g^t + p_b^{t-1})/2$

diffusion adjustment described in footnote x

"Feenstra" CES index is computed as $P_g = P_f \cdot \lambda^{-\frac{(1-\theta)}{\theta}}$ where $\lambda = 1/(1-s_g)$, s_g being the value share of generics, and $0 \le \theta \le 1$ is related to the elasticity of substitution $\sigma = 1/(1-\theta)$.

Table 4a: Regression Results: Cephalexin 1987.04 - 1990.09

Dependent variable	Const	Price Ratio	Lagged Price Ratio	Lagged Dep. Var.	Other Variables	R^2 (SEE)	DW
quantity share of generics	1.15 (0.02)	-1.18 (0.06)				0.908 (0.052)	0.97
	1.13 (0.02)	-0.67 (0.08)	-0.40 (0.06)			0.959 (0.035)	1.20
	0.82 (0.012)	-0.60 (0.08)	-0.18 (0.10)	0.28 (0.10)		0.967 (0.032)	2.25
	0.25 (0.04)	-0.24[1] (0.04)	-0.23[1] (0.07)			0.867 (0.063)	0.62
	0.17 (0.02)	-0.19[1] (0.04)		0.55 (0.07)		0.940 (0.042)	2.45
logit (87.05 - 90.09)	-1.22 (0.16)	-2.14[1] (0.15)				0.834 (0.256)	0.66
	-0.59 (0.13)	-0.11[1] (0.28)	-1.60[1] (0.21)			0.936 (0.161)	1.37
	-0.74 (0.09)		-0.93[1] (0.30)		time, time-sq	0.950 (0.144)	1.68

Notes: [1] logs of price ratios

logit = $\log(\frac{s}{1-s})$ where s is the quantity share of generics

price ratio = p_g/p_b

lagged average price ratio = $[\Sigma_{i=1}^{6} (p_g/p_b)_{t-i}]\ /6$

Table 4b: Regression Results: Cephradine 1986.12 - 1990.09

Dependent variable	Const	Price Ratio	Lagged Price Ratio	Lagged Dep. Var.	Other Variables	R^2 (SEE)	DW
quantity share of generics	1.36 (0.05)	-1.38 (0.08)				0.876 (0.062)	1.07
	1.33 (0.04)	-0.49 (0.16)	-0.79 (0.13)			0.932 (0.046)	2.10
	-1.2 (0.02)	-0.23[1] (0.12)	-0.62[1] (0.11)			0.925 (0.048)	1.13
	0.07 (0.02)	-0.22[1] (0.11)	-0.24[1] (0.14)	0.44 (0.12)		0.943 (0.043)	2.20
logit (87.01 - 90.09)	-1.87 (0.15)	-3.75[1] (0.27)				0.812 (0.305)	0.84
	-1.49 (0.12)	-0.05[1] (0.58)	-3.34[1] (0.49)			0.910 (0.213)	1.34

Notes: [1] logs of price ratios

logit = $\log(\frac{s}{1-s})$ where s is the quantity share of generics

price ratio = p_g/p_b

lagged average price ratio = $[\Sigma_{i=1}^{6} (p_g/p_b)_{t-i}] / 6$