

# **Authorized Generic Drugs, Price Competition and Consumers' Welfare**

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## **I. Introduction**

Recently considerable interest has focused on the effects that authorized generic prescription drugs have on competition among generic and branded drugs, and on the resulting implications for consumers' welfare. Authorized generics are prescription drugs whose ability to be sold legally in the US derives from the brand manufacturer's new drug application ("NDA"), yet are marketed and sold as a generic version of the brand drug.<sup>1</sup>

The presence of authorized generics can benefit consumers through increased generic competition and lower prices, along with making available to patients a generic version of a drug that exactly matches the brand drug profile. It has been argued, however, that increased short-run competition created by authorized generics could undermine incentives created by the Hatch-Waxman Act of 1984 – incentives that were designed to foster long-run competition and earlier generic entry. The purpose of this paper is to assess which of these effects dominates in practice. We conclude that on balance authorized generics are unlikely to harm competition and can indeed benefit consumers.

## **II. Background**

With products totaling over \$30 billion in US sales facing potential generic competition in the next three years, the impact of authorized generics on consumers could be substantial.

Figure 1 identifies some of these pharmaceutical products, and their associated sales volumes.

### Hatch-Waxman Legislation

To foster competition, the Hatch-Waxman Act established a 180-day marketing "exclusivity" period for the first generic manufacturer to file an abbreviated new drug

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<sup>1</sup> Authorized generic drugs may be produced and sold by the brand manufacturer (perhaps through a subsidiary), or through a licensing agreement with another pharmaceutical company. When distributed through a licensing agreement, the brand manufacturer does not determine the retail price of the authorized generic.

application (“ANDA”) with a successful “paragraph IV certification” (a successful patent challenge or claim of non-infringement of the patent). Authorized generics rely on the brand manufacturer’s NDA rather than on an ANDA and are thereby allowed to compete against ANDA-based generics even during the 180-day exclusivity period (if there is one).

ANDA-based generics face several forms of potential competition in relation to the exclusivity period. Generic manufacturers compete to be the first to file an ANDA for a specific drug and dose in order to be granted the exclusivity period. The exclusivity is granted on a dose-by-dose basis allowing for cross-dose competition if different manufacturers are the first to file and are granted exclusivity for different doses of the same drug. For example, in the case of fluoxetine (generic Prozac), Sandoz received 180-day exclusivity for the 10mg dose but it had to compete against Barr Labs, which received 180-day exclusivity for the 20mg dose.

Generic manufacturers must also account for the probability that their paragraph IV certification will be unsuccessful. Despite the above risk factors limiting the value of the exclusivity period to the generic manufacturer, in recent years there has been a growing incidence of paragraph IV certifications. Between 1984 and 1989 only two percent of ANDA submissions contained a paragraph IV certification. This increased to 12 percent between 1990 and 1997, and further increased to 20 percent between 1998 and 2000.<sup>2</sup>

#### Recent Developments Regarding Authorized Generics

A highly publicized launch of an authorized generic occurred with the multi-billion dollar drug Paxil (paroxetine) in 2003.<sup>3</sup> GlaxoSmithKline (GSK) licensed Par Pharmaceuticals to

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<sup>2</sup> Federal Trade Commission, “Generic Drug Entry Prior to Patent Expiration: An FTC Study,” July 2002, page 10 (<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> – as of October 7, 2005).

<sup>3</sup> Authorized generic entry is not a recent phenomenon. The Congressional Budget Office (“CBO”) states that branded manufacturers produced generic versions of their drugs in the early 1990s including Hamilton’s generic versions of Syntex’s drugs Naprosyn and Anaprox (CBO, “How Increased Competition from Generic Drugs Has

market and sell an authorized generic version of paroxetine under GSK's NDA, which then competed against Apotex's generic paroxetine during Apotex's 180-day exclusivity period. An August 2004 *Wall Street Journal* article discusses this case along with the potential for authorized generics to deter generic entry, and/or to serve consumers by making prescription drugs more affordable.<sup>4</sup>

In February 2004, Mylan filed a citizen's petition requesting the FDA to prohibit the marketing and distribution of any authorized generic drug during the exclusivity period for that drug, arguing that authorized generics should be considered the same as other generics, and that allowing them to enter the market violates provisions of the exclusivity period.<sup>5</sup> Johnson & Johnson filed a comment challenging Mylan's petition.<sup>6</sup> Other generic manufacturers, however, such as Watson Pharmaceuticals and Par Pharmaceuticals, supported the availability of authorized generics, claiming that partnering with brand manufacturers benefits consumers.<sup>7</sup> The FDA appeared to take issue with Mylan's arguments, stating: "[n]ot only does FDA lack authority to justify delaying the marketing of authorized generics solely to protect 180-day

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Affected Prices and Returns in the Pharmaceutical Industry, July 1, 1998, <http://www.cbo.gov/showdoc.cfm?index=655&sequence=4> – as of August 25, 2005). Other drugs experiencing authorized generic entry in the 1990s include: albuterol, alprazolam, clindamycin, clotrimazole, erythromycin, flurbiprofen, glyburide, griseofulvin, ibuprofen, medroxyprogesterone, nadolol, principen, sulfasalazine, tamoxifen, theophylline, triazolam, trimox, veetids, and others.

<sup>4</sup> Hovey, Hollister H., "Big Pharma Courts Copycats' Rivals," *Wall Street Journal*, 11 August 2004 (A8).

<sup>5</sup> Citizen Petition, February 17, 2004 (<http://www.fda.gov/ohrms/dockets/dailys/04/feb04/021804/04p-0075-cp00001-vol1.pdf> – as of August 24, 2005). The Generic Pharmaceutical Association and the generic manufacturer Apotex filed comments supporting Mylan's petition. Comment of Apotex Corp in Support of Citizen Petition Docket No. 2004P-0075/CP1, March 24, 2004, and Comment of the Generic Pharmaceutical Association in Support of Citizen Petition Docket No. 2004-0075/CP1, May 21, 2004 (<http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf> and <http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf> – as of August 24, 2005).

<sup>6</sup> Docket No. 2004P-0075/CP1 May 11, 2004 (<http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf> – as of August 24, 2005).

<sup>7</sup> Sipkof, Martin, "Battle Over Authorized Generics Grows Increasingly Heated," *Drug Topics*, April 1, 2005 (<http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=152726> – as of September 14, 2005).

exclusivity, the Agency does not believe their marketing should be delayed in this manner, as this marketing appears to promote competition in the pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch-Waxman amendments.”<sup>8</sup>

### Impact of Authorized Generics on Consumers

The potential implications for consumers of an authorized generic depend on the effects an authorized generic entrant has on at least four factors:

1. The timing of independent<sup>9</sup> generic entry – potentially delayed if an authorized generic reduces the expected net benefits to independent generics of paragraph IV certifications;<sup>10</sup>
2. Relative generic and brand shares of the molecule – greater generic share in the short term when an authorized generic is present;
3. Relative generic-to-brand price – lower generic price in the short term when an authorized generic is present, but relative price ambiguous in the longer term;

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<sup>8</sup> Docket Nos. 2004P-0075/CP1 & 2004P-0261/CP1, July 2, 2004 (<http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0075-pdn0001.pdf> – as of August 24, 2005).

<sup>9</sup> An “independent” generic entrant is a generic entrant whose ability to be sold derives from an FDA-approved ANDA, and is not authorized by the brand-name manufacturer. The terms authorized and independent generics as used in this paper are distinct from the practices pursued by some brand manufacturers in the 1970s who introduced a branded competitor to the innovator’s brand after the latter’s patent had expired, and in the mid-to-late 1980s after passage of the Hatch-Waxman Act, when ANDA-based drugs were given brand names; these products are sometimes called “branded generics.” For examples in the context of antidepressant drugs, see Ernst R. Berndt, Iain M. Cockburn and Zvi Griliches, “Pharmaceutical Innovations and Market Dynamics: Tracking Effects on Price Indexes for Antidepressant Drugs,” *Brookings Papers on Economic Activity*, 1:1996, pp. 133-188, but especially pp. 147-149.

<sup>10</sup> For some drugs the gains to the exclusivity period appear to be substantial and it is unlikely that the presence of an authorized generic would discourage paragraph IV filings or delay generic entry. Indeed, the mere threat of an authorized generic entry may even accelerate launch of independent generics. For example, if successful with their paragraph IV certification Barr would have the rights to an exclusivity period for generic Allegra, but is in ongoing patent litigation with Sanofi-Aventis, the manufacturer of Allegra. Barr has agreed to let Teva launch an exclusive version of generic Allegra prior to the resolution of the patent litigation, where Barr and Teva share the rewards of the exclusivity period and the potential costs of entering prior to a resolution in the patent litigation case (“Teva Launches Generic Allegra ‘At Risk’ Under Barr’s Exclusivity,” *The Pink Sheet*, September 12, 2005, 67(037), page 17).

4. Perceived quality of the authorized generic in comparison with the brand and independent generics – identical to brand, versus the independent generics’ AB-bioequivalent rating.

The potential, but unobserved, effect of (1) could be to increase long-run costs for consumers if paragraph IV certifications were less aggressively filed and resulted in some brands facing generic competition later than they would have in the absence of an anticipated authorized generic entrant. The combined effect of (2) and (3) is to benefit consumers in the short term when more generics are sold at lower relative prices; over a longer time period, the combined effects are not as clear, as we discuss in greater detail below. The effect of (4), if material, likely would be to increase generic share further, benefiting consumers to the extent the price of the authorized generic is less than that of the brand. We now examine each of these factors in greater detail. We conclude that on balance authorized generics are unlikely to harm competition and can indeed benefit consumers.

In this paper we limit our focus to traditional small molecule, chemically synthesized drugs. Since data on authorized generic entry are limited, some of our findings are inferred based on the historical experiences of independent generics. We also note that several of the pioneer biologic (living organism) products will be facing patent expiration over the next few years. Regulatory issues involving follow-on biologics (“biosimilars”)<sup>11</sup> will likely become increasingly prominent, and may well include a biologic analog to authorized generic entry of traditional small molecules. In this paper we do not address these complex and evolving policy issues, although

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<sup>11</sup> The terms follow-on biologic and biosimilars are used rather than generic to reflect the complexity of assessing bioequivalence compared to that for traditional small molecule, chemically synthesized drugs. A *Wall Street Journal* article discusses the difficulties faced in copying biotechnology drugs, resulting in no “biogeneric” drugs existing on the US market today. Momenta Pharmaceuticals Inc. claims to have innovated a new process for reverse engineering biotech drugs with more certainty and hopes to use the process to gain FDA approval to copy the drug Lovenox (Abboud, Leila, *Wall Street Journal*, August 16, 2005, B1).

many of the factors we discuss may also apply to a biologic analog to authorized generic entry. In particular, in the case of biologics the importance of perceived and real differences between the original biologic and any follow-on biologics may be even more pronounced, since biologics are living organisms that can mutate stochastically, thereby complicating assessment and characterization of “bioequivalence.”<sup>12</sup>

### Previous Literature

Few if any peer-reviewed articles discuss authorized generic entry. Reiffen and Ward (2005a) investigate the effects of authorized generic entry on the generic and branded segments, but do not focus on potential impacts on consumers.<sup>13</sup> There is a sizable literature, however, on generic entry, brand and generic prices, and generic penetration for traditional small molecule drugs. One of the most recent articles in this literature is also by Reiffen and Ward (2005b).<sup>14</sup> It utilizes data for 31 drugs that went off patent in the late 1980s and early 1990s, and explores the dynamic effects of the number of generic entrants on generic-to-brand price ratios, along with the effects of molecule-specific characteristics on generic entry. Caves, Whinston, and Hurwitz (1991) as well as Grabowski and Vernon (1992) investigate the impact of the Hatch-Waxman Act on drug prices, generic entry, and generic penetration for drugs that lost patent protection between 1976 and 1988.<sup>15, 16</sup> Frank and Salkever (1992, 1997) examine generic and brand

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<sup>12</sup> For a recent discussion, see Steven Usdin, “Biogen Idec’s case for FOBs,” *BioCentury*, 13:33, July 25, 2005, pp. A14-A15; an earlier discussion of a range of related issues is found in the April 15, 2002 (Vol. 10, No. 17) issue of *BioCentury*, including Steve Usdin, “Countdown to biogenerics” (pp. A1-A6), Usdin, “CDER’s abbreviated route” (pp. A6-A8), and Keith Haan and Steve Usdin, “Improving biologics” (p. A13).

<sup>13</sup> Reiffen, David and Michael R. Ward, “‘Branded Generics’ As A Strategy To Limit Cannibalization of Pharmaceutical Markets,” Working Paper, May 2005 (<http://www.uta.edu/faculty/mikeward/brandedgenerics.pdf> – as of October 7, 2005).

<sup>14</sup> Reiffen, David and Michael R. Ward, “Generic Drug Industry Dynamics,” *The Review of Economics and Statistics*, February 2005, 87(1), pp. 37-49.

<sup>15</sup> Caves, Richard E., Michael D. Whinston, and Mark A. Hurwitz, “Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry,” *Brookings Papers on Economic Activity: Microeconomics*, 1991, pp. 1-67.

pricing for drugs going off patent in the 1980s, and the impact of the number of generic entrants on prices.<sup>17</sup> Other studies by government and academic researchers have also examined patterns of generic entry, and brand and generic price trends; almost all of these are based on data ending before or up to the late 1990s.<sup>18</sup> In this paper we report on findings based on more recent data, up through 2003.

### III. Market Features Relevant to the Impact of Authorized Generic Entry

By way of background, in Figure 2a we outline the framework through which generic entry occurs and the market features that may be impacted by authorized generic entry. In Figure 2b we summarize potential effects of authorized generic entry on consumers. The market features relevant to authorized generic entry are categorized in two stages: First, whether the branded drug would encounter an ANDA filing with a paragraph IV certification in the absence of authorized generic entry (and subsequently, if the paragraph IV certification were to be successful); and second, the extent of generic entry experienced for the drug in the absence of authorized generic entry. Under each of these two market scenarios, the impact of authorized

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<sup>16</sup> Grabowski, Henry G. and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law & Economics*, October 1992, 35, pp. 331-350.

<sup>17</sup> Frank, Richard G., and David S. Salkever, "Pricing, patent loss and the market for pharmaceuticals," *Southern Economic Journal*, October 1992, 59(2), pp. 165-180. Frank, Richard G., and David S. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics & Management Strategy*, Spring 1997, 6(1), pp. 75-90.

<sup>18</sup> See, for example, U.S. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Washington DC: US Government Printing Office, July 1998; Suh, Doug-Churl, Willard G. Manning, Jr., Stephen Schondelmeyer and Ronald S. Hadsall, "Effect of Multiple-Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry," *Health Services Research*, 35(2), 2002; Scott-Morton, Fiona M., "Barriers to entry, brand advertising, and generic entry in the US pharmaceutical industry," *International Journal of Industrial Organization*, 2000, 18, pp. 1086-1104; Berndt, Ernst R., Margaret K. Kyle and Davina C. Ling, "The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches", ch. 8 in Robert C. Feenstra and Matthew D. Shapiro, eds., *Scanner Data and Price Indexes*, Chicago: University of Chicago Press for the National Bureau of Economic Research, 2003, pp. 229-267.

generic entry could subsequently affect consumers through the timing dynamics of generic entry, generic prices, and generic shares.<sup>19</sup>

#### Paragraph IV Certifications: Successful, Unsuccessful, and None

As depicted in Figures 2a and 2b, a major difference across drugs affecting generic entry market features is whether independent generic entry occurs through a paragraph IV certification resulting in a 180-day exclusivity period.<sup>20</sup> Consumer benefits from generic entry are typically more limited during the exclusivity period as price competition remains highly constrained, with the sole generic entrant typically offering only a modest (10-20%) discount off the brand. Authorized generic entry allows for a second generic product during the exclusivity period, potentially lowering generic prices and benefiting consumers.<sup>21</sup> On the other hand, the anticipation of an authorized generic entrant reduces the expected profitability during the exclusivity period, thereby possibly deterring patent challenges in the first place. If some of those patent challenges would have been successful, then independent generic entry may be delayed given the absence of the challenge.

Between 1984 and 1989, only two percent of ANDA submissions contained paragraph IV certifications. This share increased to 12 percent between 1990 and 1997, and then to 20 percent between 1998 and 2000.<sup>22</sup> One possible explanation for the increase in patent challenges is that

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<sup>19</sup> The framework presented in Figures 2a and 2b could be the basis for a model that would more precisely quantify the effects of authorized generic entry on consumers. Such a model would identify the relative likelihood of the different paths presented in the framework and the potential impact on consumers of authorized generic entry (through its effect on the timing of generic entry and the dynamics of generic prices and shares over time).

<sup>20</sup> Exclusivity is granted for specific doses. As a result, different generic manufacturers may receive exclusivity for the same drug, but in different dose forms.

<sup>21</sup> Here we consider a single authorized generic entry, although in principle there could be more than one.

<sup>22</sup> Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," July 2002, page 10. The impact of paragraph IV certifications on consumers may be larger than the 20 percent of ANDA filings suggests. ANDA submissions containing paragraph IV certifications may be for drugs with higher than average revenues. Also, the 20 percent is for ANDA submissions not for drugs, and as there may be more ANDA

they may have become more speculative, since the profits realized by the successful paragraph IV challenger during the exclusivity period have been considerable, and the number of top-selling drugs facing patent expiration was substantial.<sup>23</sup> An FTC study found that out of 53 ANDA submissions containing paragraph IV certifications that were challenged by the patent holder and for which a resolution was reached, 22 (42%) resulted in a win for the generic applicant.<sup>24</sup> Additional speculative paragraph IV certifications may have been pursued if the expected profits associated with the exclusivity period had increased (e.g., due to public policies encouraging higher generic penetration during the exclusivity period, and developments in patent law). An alternative possible explanation is that the patents protecting the brand manufacturers' drugs may have been weaker than in the past, making patent challenges more likely to succeed.

#### Extent of Generic Entry

As shown in the right panel of Figure 2a, the extent of generic entry can also differ substantially across drugs, potentially impacting generic prices and shares, and thereby affecting consumers. The existing literature (based on data up through the late 1990s) has typically found that a larger number of generic entrants for a drug is associated with lower generic-to-brand price ratios and higher generic shares. However, this literature also suggests that the marginal effect

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submissions for some drugs the percentages based on ANDA submissions do not directly translate to the percent of drugs facing paragraph IV patent challenges.

<sup>23</sup> A working paper by Henry Grabowski suggests that generic firms are prospecting in patent suits "spending millions of dollars in filing and litigation fees with their portfolio of patent challenges for the rights to obtain a very large payoff from the 180-day exclusivity period if they win a few of these suits." The paper also suggests that these lawsuits crowd the court system and can result in firms abandoning R&D projects on future drug candidates (Grabowski, Henry, "Competition Between Generic and Branded Drugs," Duke University, unpublished manuscript, May 2005, page 24).

<sup>24</sup> Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," July 2002, page 15. Of the remaining 31 resolutions, in two cases the patent expired prior to a litigation resolution, in 20 cases the litigation was settled, in eight cases the brand-name company won the litigation, and in one case the NDA was withdrawn prior to the litigation being resolved. Seven of the 20 settlements involved the brand-name company licensing the generic applicant to market the drug under the brand-name company's NDA.

of each additional generic entrant on generic prices and shares tends to be negligible after the first few entrants.<sup>25</sup> Using a set of data on drugs that have experienced generic entry more recently (from 1999 to 2003), we have obtained empirical evidence consistent with these earlier findings.<sup>26</sup> Specifically, we find evidence suggesting that an additional generic entrant beyond the first four or five entrants has little or no effect on the generic-to-brand price ratio and share. While we rely primarily on summary statistics (and have not performed a detailed multivariate statistical analysis), these results are essentially similar to those found by Reiffen and Ward (2005b) using a more rigorous statistical approach on data for an older set of drugs.

Figure 3 reveals that the impact of an additional generic is negligible after the fourth or fifth entrant. At 24 months since initial generic entry, drugs with fewer than five generic entrants had generic-to-brand price ratios ranging from 0.07 to 0.82. For drugs with more than five generic entrants and at 24 months since initial generic entry, generic-to-brand price ratios exhibit a much smaller range, from 0.03 to 0.25. Also, the drugs with more than five generic entrants show no discernible downward trend in generic-to-brand price ratios as the number of generic entrants increases. As a result, unless there are fewer than four or five generic entrants, a reduction in the long-run number of generics (e.g., due to authorized generic entry) is unlikely to

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<sup>25</sup> Reiffen and Ward (2005b) specify a model including dummy variables for the number of entrants one through ten with a constant term representing eleven or more entrants. This approach allows the marginal effect of an additional entrant between one and ten to vary in a non-smooth manner, but assumes no further marginal impact from an additional entrant past eleven entrants. Using average revenue divided by quantity as a measure of price, Reiffen and Ward (2005a) find no statistically significant effect of additional generic entrants on the generic-to-brand price ratio following the sixth generic entrant. None of their model specifications reveal a statistically significant effect of additional generic entry on generic-to-brand price ratios following the ninth entrant. These other specifications also reveal little difference in generic-to-brand price ratios when there are between five and nine generic entrants. Caves, Whinston, and Hurwitz (1991) also specify a nonlinear model for the effect of generic entry on generic-to-brand price ratios, and find a declining impact for each additional entrant.

<sup>26</sup> See Appendix A for a description of the data used in our analysis.

affect long-run generic prices, since the number of additional entrants has a negligible effect on generic-to-brand relative prices.

An important implication of this finding is that consumers will be impacted by authorized generic entry only if it influences the number of generic entrants to the point where generic prices and shares are materially affected; in cases where there would be substantial generic entry (more than, say, four or five entrants) with or without authorized generic entry, consumers would not be materially affected.

#### Other Factors

Historically both the generic share of the molecule and the generic-to-brand price ratio have differed substantially across drugs. Drugs that are less challenging for an independent generic to develop, get approved, manufacture, and market typically have lower generic-to-brand price ratios and higher generic shares. Other drugs, fewer in number, are more difficult for an independent generic manufacturer to engineer and produce, may carry greater risk for adverse outcomes, or may be perceived by a minority of consumers/physicians as possessing material differences between the brand and the generic, in spite of FDA AB-equivalence ratings. These drugs frequently exhibit higher generic prices and greater brand share retention than do those in the first group. An authorized generic entrant, which is identical to the brand by manufacturing criteria, may provide additional consumer benefits not available through independent generics.

It should be noted that many of the historical differences across drugs in generic penetration and generic-to-brand price ratios appear to have decreased for traditional small molecule drugs in the past few years, as generic manufacturers have become more sophisticated, and public policy decisions and private and public cost containment efforts have supported increased utilization of generics. As noted earlier, however, with respect to biologic agents, how

one characterizes and assesses “biosimilarity” for biologics is currently an issue involving considerable scientific and regulatory debate. For biologics, perceptions of biosimilarity between original and follow-on versions may be a much larger issue than it currently is for traditional small molecule drugs. We defer additional discussion of these issues to a future study.

#### **IV. Impact on Consumers of Authorized Generics**

We now examine the impact of authorized generic entry in terms of the effects it potentially has on consumers, given the different market features discussed in the previous section (also see Figures 2a and 2b). The primary effects on consumers relate to the timing and extent of generic entry, through the dynamic effects of authorized generic entry on generic share and generic/brand relative prices. We first consider the case of no paragraph IV certification, and then discuss the case with a paragraph IV certification.

##### No Paragraph IV Certification

###### *Timing of Generic Entry*

If independent generics would not have pursued a patent challenge through a paragraph IV certification in the absence of a prospective authorized generic, it follows that prospective authorized generics are unlikely to affect the timing of generic entry. Independent generics would continue to wait until patent expiration before they entered.

###### *Generic Share and Price*

For most small molecule drugs, the incentives for independent generic entry should be unchanged with the prospect of an authorized generic, since generic manufacturers would anticipate intense competition with or without the authorized generic. Because the extent of

generic entry will be largely unaffected by the prospect of an authorized generic, short-run and particularly long-run generic shares and prices will also be largely unaffected.<sup>27</sup>

For the minority of drugs that experience relatively few generic entrants and lower levels of generic penetration (compared to the norm), the effects of authorized generic entry are somewhat ambiguous, but most likely small in any case. An authorized generic entrant has attributes identical to the brand, and for otherwise brand-loyal consumers its availability may encourage additional switching from the brand to the authorized generic, benefiting these consumers to the extent the price of the authorized generic is less than that of the brand. In addition, consumers who purchase the independent generic even in the presence of an authorized generic are no worse off, unless average independent generic prices rise due to displaced independent generic entry.

The presence of an additional (authorized) generic could therefore increase price competition and reduce the average price of the molecule over all of its marketed versions (brand, authorized generic, and independent generic).<sup>28</sup> Alternatively, authorized generic entry could displace independent generic entry for the molecule, thereby reducing price competition. Either effect is likely to be small, since even in the absence of authorized generic entry, with only a limited amount of independent generic entry the price differentials between the brand and generic would be relatively small for this minority of drugs. It is worth noting again (see

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<sup>27</sup> Authorized generic entry may be unlikely for drugs with no paragraph IV certification and few unique attributes suggestive of higher than average brand share retention because intense competition and the lack of any exclusivity period means there are few profits to be gained by the brand manufacturer considering authorized generic entry. As a result, authorized generics are likely to have a negligible effect on consumers of drugs that face substantial independent generic erosion and that would not face paragraph IV certifications in the absence of the authorized generic.

<sup>28</sup> The authorized generic is able to fill a niche in the market that the independent generics are unable to fill (that is, a generic version of the molecule that is identical to the brand in all attributes). As a result, authorized generic entry may not displace independent generic entry, but instead displace brand sales.

footnote 3 above) that various forms of post-patent entry by branded firms have long existed, even before paragraph IV certifications became more common in the late 1990s.

### Paragraph IV Certification

#### *Timing of Generic Entry*

The timing of generic entry may be affected by prospective authorized generics in the case where independent generics would have pursued a patent challenge through a paragraph IV certification. For most drugs the prospect of authorized generic entry during the exclusivity period is unlikely to decrease incentives significantly for paragraph IV certification submissions (and therefore not alter the timing of generic entry), for several reasons. First, for many of the drugs that would face authorized generic entry, the expected profits accruing to an exclusive independent generic may be sufficient to encourage patent challenges even with authorized generic entry. Second, independent generics already face potential competition in the form of cross-dose competition during the exclusivity period. Finally, independent generics compete to be the first filer of a paragraph IV certification; and even if they are the first filer their paragraph IV certification may not be successful. Paragraph IV certifications have historically been submitted in the face of all of these factors that diminish their expected value, and it is not clear that one additional factor, authorized generic entry, is sufficient to discourage many patent challenges. However, the exact determination of the size of the effect of anticipated authorized generic entry on the number of *successful* paragraph IV certifications remains an open question. The evidence thus far shows little impact of anticipated authorized generic on paragraph IV certifications. Indeed, as noted in footnote 10 above, a recent case suggests that the threat of authorized generic entry induced independent generic entry prior to resolution of paragraph IV litigation.

Even if authorized generic entry discourages some patent challenges, the timing of generic entry may not be affected and consumers may not be harmed. To the extent independent generic firms are risk averse, or at least risk neutral, if authorized generic entry deters patent challenges, it is likely to do so in those cases where a challenge has the least likelihood of success, and therefore low expected profits. In such a case, even a small negative impact on expected profits resulting from anticipated authorized generic entry may be enough to deter a patent challenge. Historically, generics have won in trial verdicts 42 percent of the cases for drugs facing paragraph IV certification that the brand manufacturer challenges. The paragraph IV certifications that may be deterred by the prospect of authorized generic entry would most likely have a lower likelihood of success than the average. The reduction in speculative patent challenges has the added benefits of avoiding “wasteful” litigation expenses on failed challenges and increasing brand manufacturers’ expected profits from innovation and potentially increasing their incentives to innovate new drugs.<sup>29</sup> Even if a potentially successful paragraph IV certification is deterred by the prospect of authorized generic entry, the timing of generic entry will be unaffected so long as at least one generic with the resources to support a paragraph IV certification (including any legal challenges) chooses to file as early as those who have been deterred and devotes comparable resources to the filing and litigation effort.<sup>30</sup>

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<sup>29</sup> While the present value to a branded manufacturer of additional post-patent expiration profitability from authorized generic entry is rather small when viewed prospectively during the clinical development process, there is empirical evidence supporting the notion that the current increased profitability of branded pharmaceutical firms results in contemporaneous increased R&D outlays; see, for example, F. M. Scherer, “The Link Between Gross Profitability and Pharmaceutical R&D Spending,” *Health Affairs*, Vol. 20, No. 5, September/October 2001, pp. 216-220.

<sup>30</sup> The effect on the timing of generic entry will depend on the respective ANDA filing dates, time to approval, and the time to any relevant court decisions for the independent generic manufacturer that was deterred from entering compared to the independent generic manufacturer that was not deterred from entering and is the first filer.

### *Generic Share and Price*

For drugs with paragraph IV certifications, the added competition introduced by the authorized generic during the exclusivity period would result in lower generic prices and greater generic penetration, benefiting consumers. Beyond the exclusivity period, the key issue for determining the overall impact on consumers is whether the prospect of authorized generic entry could change the long-run number of generic entrants, and if so, whether this would affect long-run generic prices and shares.

As with drugs that would not face a paragraph IV certification, the effect of authorized generic entry on the long-run number of generics is ambiguous for the minority of drugs that face lower levels of generic penetration from independent generics (the number of generic entrants could increase or decrease). For drugs that are expected to face substantial generic erosion, authorized generic entry will either decrease or not affect the long-run number of generic entrants.<sup>31</sup> Again, any changes in the long-run number of generics are unlikely to affect generic price and share for the many drugs with more than four or five generic entrants, as was illustrated above in Figure 3.

Based on recent data on patent expirations, the exclusivity period appears to significantly increase short-run generic-to-brand price ratios, but has little or no effect on long-run generic-to-brand price ratios and generic shares. Figure 4a shows the average generic-to-brand price ratios for drugs with and without successful paragraph IV certifications in the 3<sup>rd</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> month following initial generic entry. In the 3<sup>rd</sup> month following initial generic entry we find that drugs not subject to an exclusivity period have significantly lower generic-to-brand price

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<sup>31</sup> For example, if the prospect of authorized generic entry deters an ANDA containing a paragraph IV certification that would not have been the first filer then the timing of generic entry may be unaffected but the long-run number of generic entrants may decline.

ratios.<sup>32</sup> In the 24<sup>th</sup> month following initial generic entry, the average generic-to-brand price ratio for drugs with successful paragraph IV certifications was 0.27 compared to an average of 0.29 for drugs without successful paragraph IV certifications.<sup>33</sup>

Figure 4b shows the average generic share for those drugs with and without successful paragraph IV certifications at the same time intervals following initial generic entry. In the 24<sup>th</sup> month following initial generic entry, the average generic share for drugs with successful paragraph IV certifications is 85 percent compared to an average of 83 percent for drugs without successful paragraph IV certifications.<sup>34</sup> The comparisons in Figures 4a and 4b do not control for inherent differences among drugs with and without successful paragraph IV certifications. They are also based on a relatively small sample of drugs facing successful paragraph IV certifications. However, the results are consistent with the finding that high generic penetration and low generic-to-brand price ratios are achieved in the long run regardless of whether successful paragraph IV certifications occurred.

Authorized generic entry for drugs that face lower levels of independent generic penetration may have the additional consumer benefit of substantially increasing generic penetration. Greater generic penetration may be achieved because the authorized generic is identical to the brand-name drug, whereas in certain special cases some differences may be

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<sup>32</sup> The null hypothesis that there is no difference between these price ratios is rejected, with a p-value of 0.02.

<sup>33</sup> The null hypothesis that there is no difference between these price ratios is not rejected, with a p-value of 0.90.

<sup>34</sup> The median generic-to-brand price ratio 24 months following generic entry for drugs without successful paragraph IV certifications is somewhat greater than the median for those with successful paragraph IV certifications (0.25 compared to 0.09), but the null hypothesis that there is no difference between these price ratios is not rejected with a p-value of 0.66. Similarly, the median generic share 24 months following generic entry is somewhat lower for drugs without successful paragraph IV certifications compared to drugs with successful paragraph IV certifications (84% compared to 92%), but the null hypothesis that there is no difference between these shares is not rejected with a p-value of 0.66.

perceived with respect to the independent generic.<sup>35</sup> Depending on the price of the authorized generic relative to that of independent generics, consumers may benefit from the availability of an authorized generic identical to the brand but with a lower price. Figure 5 summarizes our conclusions regarding the impact of authorized generics on consumers.

## V. Recent Evidence on Authorized Generic Entry

We have examined data on generic shares and generic prices for three brand drugs that have recently experienced authorized generic entry: Paxil (paroxetine), Cipro (ciprofloxacin), and Ortho Tri-Cyclen.<sup>36</sup> For all three products, authorized generics competed aggressively against independent generics on price, and both authorized and independent generics captured substantial market share from the brand manufacturer. Figure 6 plots quantity shares over time for authorized and independent generics following initial generic entry for Paxil (paroxetine). Generics captured about 70 percent of unit sales within two months and about 85 percent within 16 months.

Figure 7 portrays the generic-to-brand price ratios over time for Paxil (paroxetine), along with the number of independent generic entrants. While the price of the authorized generic is higher than the average independent generic price during the first year following initial generic entry, after that both the authorized and independent generic prices are roughly 50 percent of the

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<sup>35</sup> For certain drugs for which the beneficial dose range is relatively small in comparison to the dosage range that entails greater risk for the patient (commonly known as narrow therapeutic index drugs), the availability of an authorized generic at a price below that of the brand would benefit some consumers. However, in such cases the brand may instead not increase, or possibly even decrease, its price post-patent expiration. Two relatively well-known narrow therapeutic index drugs, Coumadin and Synthroid, have maintained relatively low prices post-patent expiration.

<sup>36</sup> Ortho Tri-Cyclen is a combination of three molecules, and does not have a single generic molecular name. Teva's independent generic version is called Tri-Previfem, Barr Labs' independent generic version is called TriSprintec, and Watson Lab's authorized generic version is called TriNessa.

brand price for Paxil. These price and share trends are qualitatively similar for Ortho Tri-Cyclen and Cipro.

## **VI. Conclusions**

Authorized generics provide several potential benefits to consumers. For prescription drugs being sold during 180-day exclusivity periods, authorized generics introduce additional competition that places downward pressures on overall generic prices during the exclusivity period. For drugs facing lower levels of independent generic penetration, overall generic shares may increase more quickly and reach higher levels of long-run penetration due to the fact that the authorized generic is identical to the brand. Any potential costs to consumers appear to be small and in our judgment are likely to be outweighed by the expected benefits.

It has been argued that authorized generics will deter paragraph IV certifications and potentially delay generic entry. Most drugs, however, do not face a paragraph IV certification (historically approximately only 20 percent have). If the anticipation of authorized generic entry decreases incentives for paragraph IV certifications for the drugs that do face paragraph IV certification, it will do so in those cases with the least likelihood of success. As a result, generic entry will not be delayed for most drugs (if any).

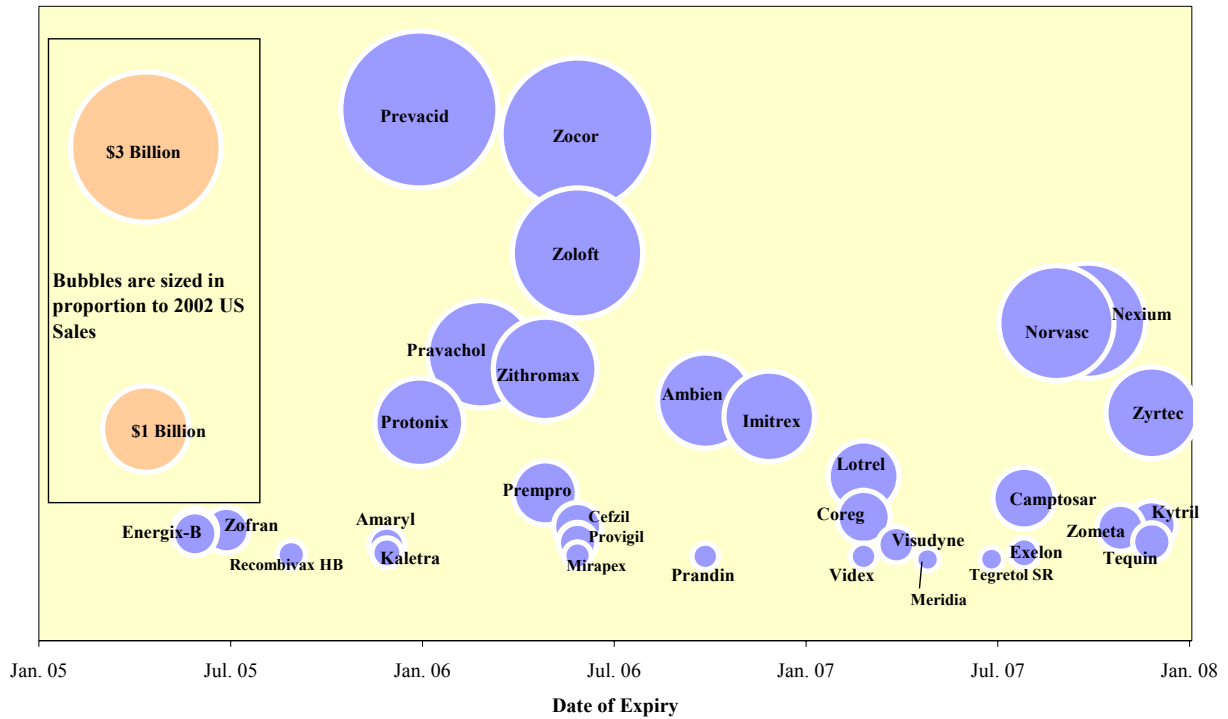
A second claim is that the anticipation of authorized generic entry could deter independent generic entry resulting in higher long-run generic prices. However, both the existing literature and the more recent data presented here demonstrates that additional generic entrants after the first four or five do not appear to affect significantly long-run generic-to-brand price ratios. Furthermore, although the analysis is preliminary, we find that the 180-day exclusivity period does not appear to result in lower long-run generic-to-brand price ratios or higher long-run generic penetration. Any effect that authorized generics may have on the

incentives created by the 180-day exclusivity period is unlikely to affect consumers through long-run generic prices and shares.

An additional policy issue associated with authorized generic entry, not discussed in this paper, involves the treatment of authorized generics in calculating Medicaid rebates. It has been proposed that the authorized generic price should be considered when determining the “best price” Medicaid rebate calculation for the brand-name drug, thereby possibly reducing the costs of the Medicaid program. We discuss this proposal very briefly in Appendix B, along with the potential for it to have the opposite of the intended effect, i.e., to increase Medicaid costs for some drugs. A subsequent paper will examine this issue in greater detail.

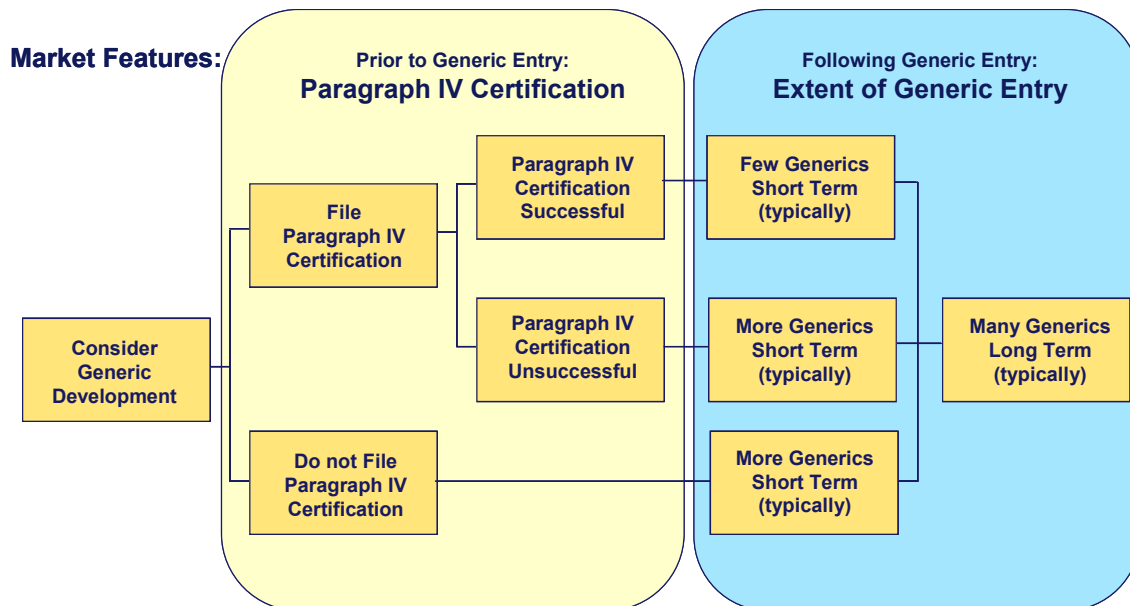
Finally, looking to the future, we note that biologics are becoming an increasingly important share of the biopharmaceutical industry, that soon several of the pioneer biologics will face patent expiration, thereby raising regulatory and policy issues regarding conditions for allowing follow-on biologic entry. While issues of authorized follow-on biologics are complex and controversial, there may be insights from the experience with authorized generics of traditional small molecule pharmaceuticals, with respect to how to structure appropriate policies for follow-on biologics. Authorized follow-on biologics are likely to play a large role in the future, in part due to their potential to offer consumers substantial benefits over other follow-on drugs by more closely matching the brand. However, it is also possible that following loss of patent expiration, other brand manufacturers (particularly those with proven manufacturing expertise) may enter with branded competitive biologic products. Just how different the post-patent expiration market environment will be for biologics versus traditional small molecules remains to be seen.

**Figure 1: Pharmaceutical Products Whose Exclusivity Expires in the Next Three Years**

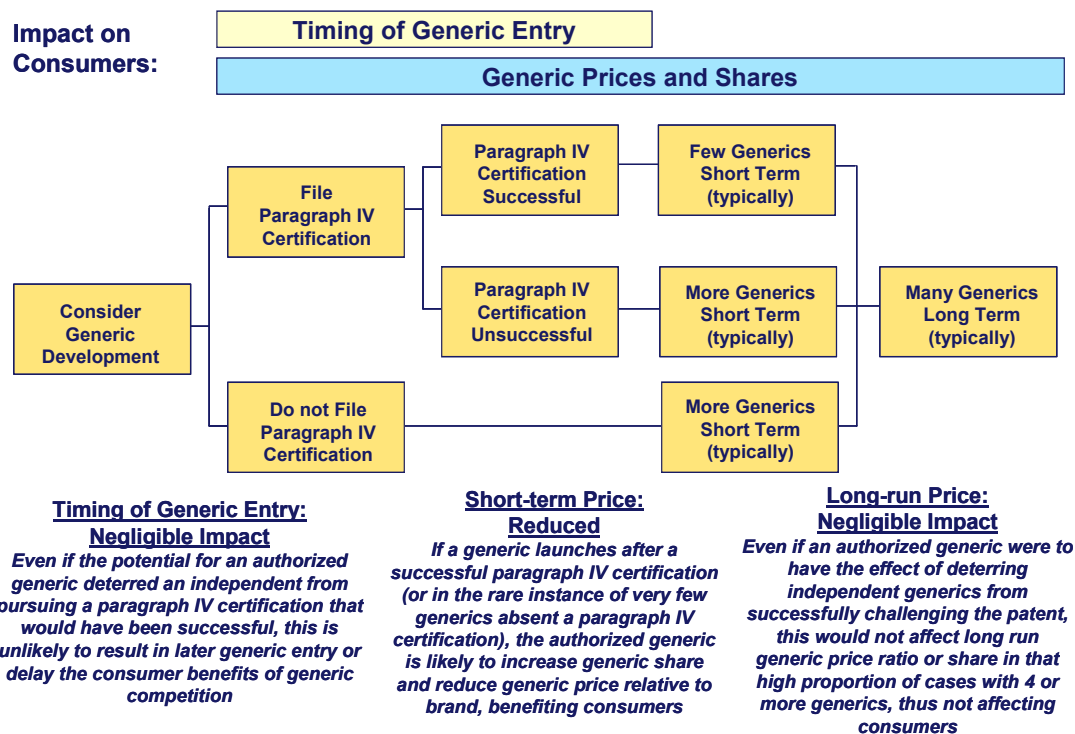


Sources: SG Cowen, Pharmaceutical Industry Pulse, January 2004. These data were cross checked against the Drugs@FDA website, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>, to remove any drugs that experienced generic entry prior to the expiry date noted in the SG Cowen report.

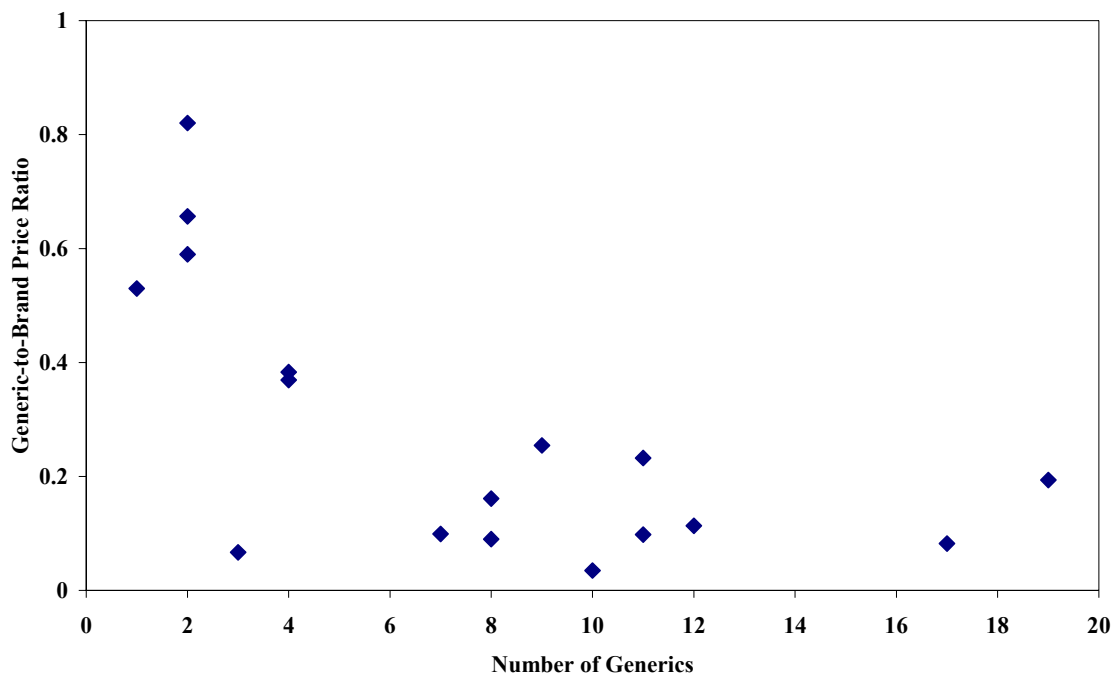
**Figure 2a: Independent Generic Path to Market**



**Figure 2b: Possible Consumer Impact of Authorized Generics**

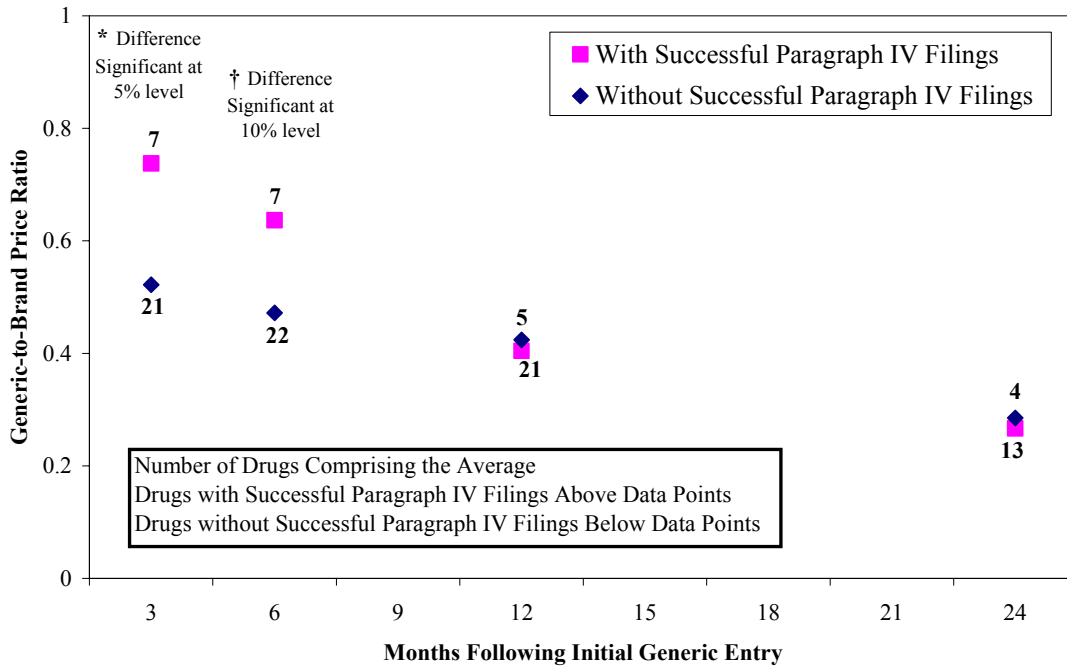


**Figure 3: Generic-to-Brand Price Ratio vs. Number of Generics (24 Months Following Initial Generic Entry)**



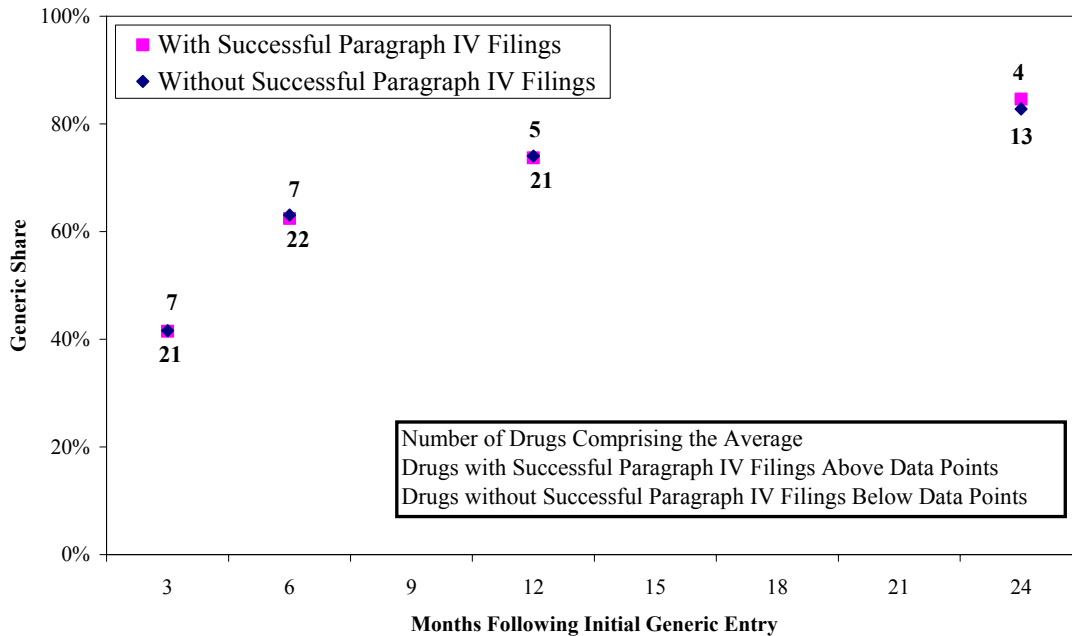
Source: The analysis is based on IMS Retail and Non-Retail National Sales Perspective data and IMS Retail NPA data for drugs that experienced generic entry between 1999 and 2003 and for which data were available 24 months following initial generic entry.

**Figure 4a: Average Generic-to-Brand Price Ratios**



Note: Eulexin was excluded from the calculation of average generic share and generic-to-brand price ratio for the 3rd month following initial generic entry due to a single outlier month where the calculated generic-to-brand price ratio was greater than one.  
 Difference in means between drugs with and without successful paragraph IV filings is statistically insignificant for 12 and 24 months following initial generic entry.

**Figure 4b: Average Generic Share**



Note: Eulexin was excluded from the calculation of average generic share and generic-to-brand price ratios for the 3rd month following initial generic entry due to generic-to-brand price ratios greater than one.  
 Difference in means between drugs with and without successful paragraph IV filings is statistically insignificant for 3, 6, 12 and 24 months following initial generic entry.

**Figure 5: Summary of Findings on the Impact of Authorized Generics on Consumers**

**No Paragraph IV Certification**

**Timing of Generic Entry:**

- Timing of generic entry likely unaffected by authorized generic entrant

**Generic Prices and Shares:**

- For drugs that typically experience substantial generic erosion, an authorized generic entrant has no competitive advantage over other generics, and generic shares are likely unaffected
- For drugs that typically experience lower levels of generic penetration, an authorized generic encourages switching from brand to lower-priced generic because it is identical to the brand
- Authorized generic may discourage some generic entry but is unlikely to affect long-run prices and generic shares

**Paragraph IV Certification**

**Timing of Generic Entry:**

- Paragraph IV certifications with the least likelihood of success may be deterred by authorized generic entry

Successful Paragraph IV Certifications:

- If the deterred certification would have been successful then generic entry may be delayed

Unsuccessful Paragraph IV Certifications:

- If the deterred certification would have been unsuccessful then speculative litigation expenses are avoided

**Generic Prices and Shares:**

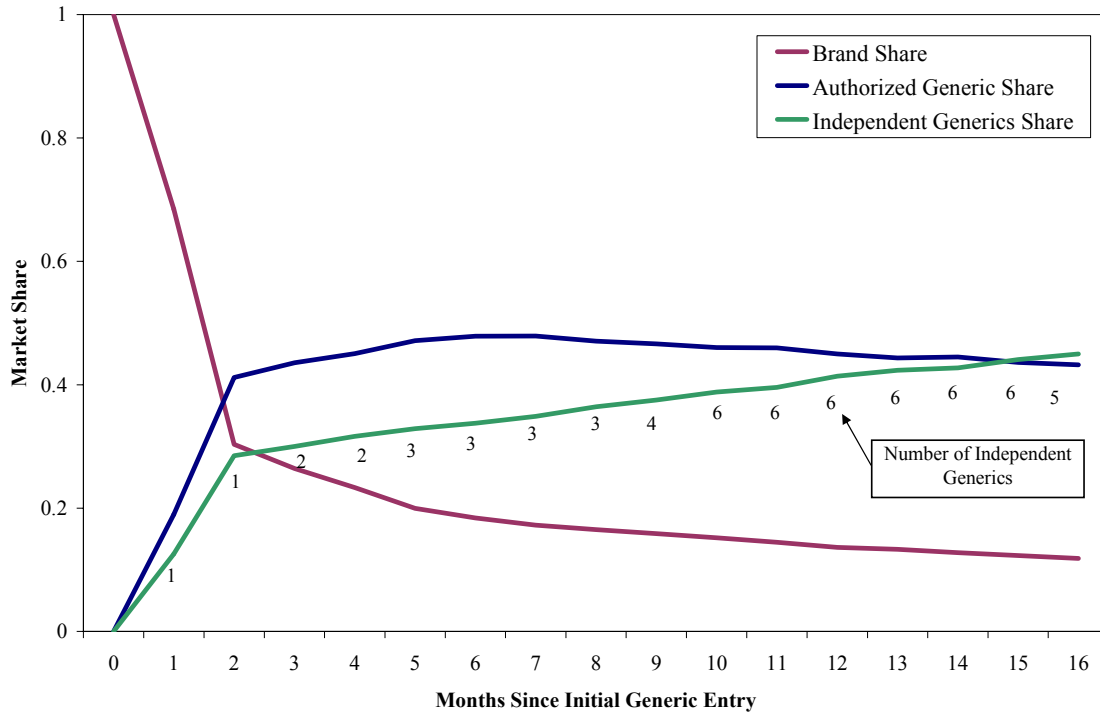
Successful Paragraph IV Certifications:

- Authorized generic entrant may lead to higher generic penetration during the exclusivity period due to lower prices
- Authorized generic creates competition and reduces generic prices during the exclusivity period

Successful and Unsuccessful Paragraph IV Certifications:

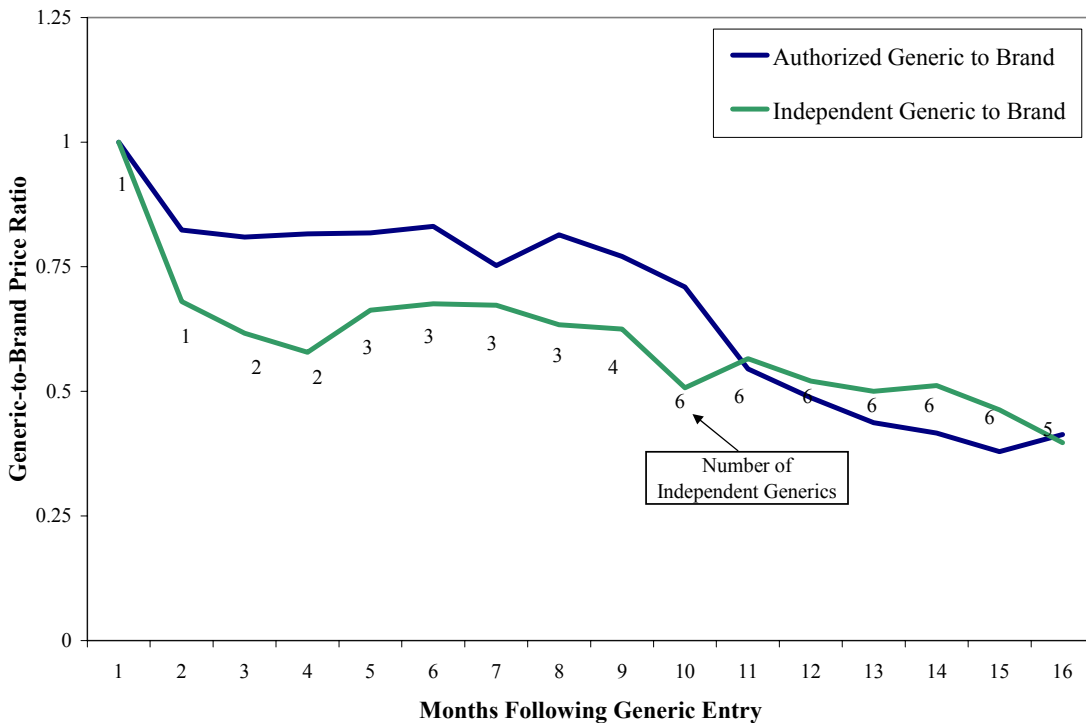
- For drugs that typically experience lower levels of generic penetration, an authorized generic encourages switching from brand to lower-priced generic because it is identical to the brand
- Authorized generic entrant is unlikely to affect long-run generic prices and shares

**Figure 6: Paxil – Brand, Authorized Generic, and Independent Generic Share**



Note: Market shares are based on extended units from IMS data.

**Figure 7: Paxil – Generic-to-Brand Price Ratios vs. Number of Months Post Generic Entry**



Notes: The generic-to-brand price ratio in the first month is constrained to 1 as an apparent mismatch in the timing of revenues and units results in unreasonable average generic revenue (price) in those months. Prices are calculated monthly based on revenues and extended units as reported in IMS data.

## Appendix A

### Data Description

We have analyzed generic entry, generic-to-brand price ratios, and generic shares for a set of 29 drugs that experienced generic entry between 1999 and 2003. The drugs we analyzed include: Adalat CC/Procardia XL, Adderall, Aredia, Augmentin, Axid, Betapace, Buspar, Cardura, Ceclor, Cipro, Daypro, Eulexin, Fioricet with Codeine, Glucophage, Luvox, Mevacor, MS Contin, Pepcid, Prinzide, Prozac, Remeron, Rythmol, Spectazole, Tambocor, Ultram, Vicoprofen, Zanaflex, Zestril/Prinivil, and Ziac.

IMS National Sales Perspective (retail and non-retail) and National Prescription Audit (retail) data were collected for these drugs. The measure of quantity used for our analysis is days of therapy units. This quantity is calculated for each drug as total extended units (tablets/capsules) divided by the average number of tablets administered per day. Prices are calculated as total revenues divided by days of therapy (i.e., price per day of therapy). The generic-to-brand price ratios are calculated at the wholesale level. We have assumed that distribution margins on authorized generics are comparable to those for independent generics and that these wholesale price ratios provide reasonable proxies for relative consumer impacts at the retail pharmacy level. Both prices and shares were smoothed using three-month moving averages. Finally, the number of generic entrants is calculated as the number of unique manufacturers marketing a generic version for any dose form of the drug, as recorded in the IMS data.

For the preliminary recent evidence on authorized generic entry, IMS National Prescription Audit data were collected for Paxil, Ortho Tri-Cyclen, and Cipro.<sup>37</sup> Because data on the average number of tablets administered per day were not available, units were calculated in milligrams for Paxil and Cipro, and in tablets for Ortho Tri-Cyclen.<sup>38</sup> Prices are calculated as revenues divided by units.

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<sup>37</sup> The Cipro data described in the first paragraph of this appendix covered the first three months following initial generic entry. Cipro data for just revenues and extended units covering the first 19 months following initial generic entry were also obtained.

<sup>38</sup> It is not practical to calculate total milligrams for Ortho Tri-Cyclen because there are three molecules involved. Also, since Ortho Tri-Cyclen is sold in only one dose form there would be no difference in shares and price ratios calculated in tablets or milligrams.

## Appendix B

### Authorized Generics and Medicaid Best Price Rebate

In addition to controversy concerning the potential impact of authorized generics on generic competition and consumers, a debate has emerged regarding the appropriate treatment of authorized generics for purposes of determining Medicaid rebates. Senator Charles Schumer (D-NY) has argued that the authorized generic price should be taken into account when determining the Medicaid “best price” rebate calculation for the brand-name drug.<sup>39</sup> Brand-name drugs currently pay rebates to Medicaid equal to 15.1 percent of the average manufacturer’s price (AMP) or the difference between the AMP and the best price offered by the brand manufacturer to any purchaser of the drug, whichever is greater. Branded manufacturers pay an additional rebate when the AMP increases at a rate faster than the Consumer Price Index, equal to the difference between the AMP and the inflation adjusted price.<sup>40</sup>

Currently the “best price” used for calculating the brand-name drug Medicaid rebate is the best price offered for that brand-name drug, but this calculation does not incorporate the price offered for the authorized generic version. Senator Schumer and others claim that failure to factor in the authorized generic price in the best price calculation for the brand name drug adds

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<sup>39</sup> “Senior HHS Officials Address ‘Best Price’ Issues,” *Federal Drug Discount and Compliance Monitor*, March 2005, Volume 2, no. 3.

<sup>40</sup> The inflation adjusted price is determined by taking the AMP in the first month of the drug is marketed, and letting it increase at the consumer price index – urban rate (CPI-U). If the AMP increases at a rate faster than the CPI-U, then the AMP will exceed the inflation adjusted price and an additional rebate is calculated. The calculation is per the Centers for Medicare & Medicaid Services website (<http://www.cms.hhs.gov/medicaid/drugs/mrphistory.asp> and <http://www.cms.hhs.gov/medicaid/drugs/drug12.asp> – as of August 25, 2005).

to the costs of the Medicaid program.<sup>41</sup> It is simple to demonstrate that this claim may not be true for all drugs and that the claim fails to consider the overall structure of the rebate program.

A subset of the authors has investigated several hypothetical examples and find that under some rather general conditions, a large increase in the best price portion of the Medicaid rebate due to the inclusion of the authorized generic is more than offset by a reduction in the rebates associated with the rate of inflation and the rebates applied to the authorized generic sales. It is unknown how likely these circumstances are. As a result, additional research is necessary to determine the overall impact on Medicaid costs of changing the method for determining the best price for rebate purposes.

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<sup>41</sup> “Schumer Charges CMS Gives Authorized Generics ‘Good Deal’,” *FDA Week*, March 7, 2005. Schumer’s argument appears to be based on the premise that authorized generics may be priced above the average independent generic, yet still capture market share, increasing Medicaid costs. Where authorized generics price competitively with independent generics and even contribute to a more rapid generic price decline, this argument may not apply. Further, as we discuss in the text, Schumer’s proposed remedy of linking the authorized generic rebate calculation to the brand can have the effect of increasing total Medicaid costs, regardless of authorized generic price.