IMS Consulting

Assessment of Authorized Generics in the U.S.

Prepared for:
PhRMA

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I. Executive Summary

The practice of marketing an "authorized generic" has been growing in the pharmaceutical industry. In it, branded pharmaceutical companies employ a generics subsidiary or a third-party to market their products, under the same NDA[1] as the brand product. A "generic" drug is simply a copy of a drug discovered by an innovator, that relies on the safety and efficacy data developed by the innovator, to gain approval by the Food and Drug Administration (FDA) without conducting trials (except to demonstrate bioequivalence). Thus, generics do not involve the drug discovery and development process.

Typically, marketing of authorized generics begins during the 180-day exclusivity period awarded the first-to-file challenger of the brand patent under a Paragraph IV certification. Likewise, as part of the Medicare Modernization Act (MMA) of 2003 multiple applicants that file ANDAs[2] with paragraph IV certifications on the same day as the first, are all entitled to exclusivity. This provision results in multiple generic manufacturers sharing the 180-day exclusivity period and, presumably, competing on the basis of price. In effect, this competition is similar to that of generics to authorized generics.

With an authorized generic in the market, along with a single A/B-rated generic (the holder of the 180-day exclusivity period) the average generic price discount to the branded product is greater than comparable Paragraph IV examples in which there is no authorized generic. At the outlet level (price to a pharmacy, clinic, etc.) the generic discount to brand (during the

1 New Drug Application (NDA) -- When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDA's are assigned an NDA number.

2 Abbreviated New Drug Application (ANDA) -- An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug).

180-day exclusivity period) is about 16 percentage points greater than comparable examples without an authorized generic.

The healthcare system savings attributable to an authorized generic across nine case studies included in this analysis ranged from $699 thousand to $101.5 million per drug during the 6-month exclusivity period. The average savings attributable to these nine case studies was $23.6 million.
After the 180-day exclusivity period, in examples with less than 6 generics the discount to brand remains greater in the presence of an authorized generic compared to examples without an authorized generic. In examples with 6 or more generics in the market (after 180-day exclusivity), discounts to brand are nearly identical (on average) from authorized generic to no authorized generic examples. Therefore, in instances in which there are fewer than 6 competing products, authorized generics play a role in providing greater discounts to the U.S. healthcare system even after the 180-day exclusivity period.

In these instances (fewer than 6 generics) savings to the healthcare system extend beyond the 180-day exclusivity period. Lower generic prices result in a reduced total drug cost for the volume of generic drugs purchased.

II. Introduction

In accordance with the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman), generic pharmaceutical manufacturers who successfully challenge (via Paragraph IV certification included in the ANDAs) patents covering branded pharmaceuticals before the brands' patents expire receive 180-day exclusivity in which they were free to market their generic product without competition from other generics approved after the first date of submission as ANDAs. During this time, generic manufacturer(s) could penetrate the market without the lower price that would be likely with more generic competitors. After the 180-day exclusivity period, more generic versions of the drug are typically launched. Revisions made in MMA of 2003 were designed in part to promote more competition among generics during the 180-day exclusivity period.

Authorized generics have gained momentum in recent years[3]. An authorized generic is defined by the FDA as "any marketing by an NDA holder or authorized by an NDA holder, including through a third-party distributor, of the drug product approved under the NDA in a manner equivalent to the marketing practices of holders of an approved ANDA for that drug."[4]

The practice of authorizing generics allows the holder of the NDA to market a competing product, during the 180-day exclusivity period of the first-to-file Paragraph IV challenger(s). Authorized generic agreements predominantly come in one of 2 forms. The branded manufacturer with the NDA can either license its product to a generic pharmaceutical company (licensees have included a range of generic companies, including generic industry leaders such as Barr, Andrx, Mylan and Teva); or the brand manufacturer can market the product through an in-house generic subsidiary.

[3] *Sources include: Prudential Equity Group LLC research report 3/2005 "Authorized Generics: Looks Like They're Here to Stay"; Bear Stearns report "FDLI'S Conference on Two Decades of Hatch-Waxman December 1-2, 2004, Washington D.C.: Financial Aspects of 180-Day Generic Exclusivity"; www.paragraphfour.com as well as other desk research.*
[4] *FDA Decision Letter, July 2, 2004*

For the analysis, IMS considered a subset of 27 authorized generics which were on the market as of November 2005 (see the following list).

Brand Name	Molecule	Innovator	AG Marketer
1. Accupril	Quinapril	Pfizer	Greenstone
2. Celexa	citalopram	Forest	Forest (Thru Inwood Sub)
3. Cipro	ciprofloxacin	Bayer	Barr
4. Cutivate	fluticasone	GSK	Taro
5. Diflucan	fluconazole	Pfizer	Greenstone
6. Duragesic	Fentanyl	J&J	Sandoz
7. Glucophage XR	metformin XR	BMS	Par
8. Glucotrol XL	glipizide ER	Pfizer	Andrx
9. Glucovance	Glyburide/metformin	BMS	Par
10. Macrobid	nitrofurantoin macrocrystals/monohydrate	P&G	Watson
11. Mestinon	pyridostigmine	Valeant	Watson
12. Monopril	Fosinapril	BMS	Sandoz
13. Neurontin	gabapentin	Pfizer	Greenstone
14. Ortho Tri-Cyclen	norgestimate, ethinyl estradiol	J&J	Watson (TriNessa)
15. Ortho-Cyclen	norgestimate	J&J	Watson (Mononessa)
16. Ortho-Novum7/7/7	norethindrone, ethinyl estradiol	J&J	Watson (Necon 7/7/7)
17. OxyContin	oxycodone	Purdue	IVAX
18. Paraplatin	carboplatin (injection)	BMS	Teva (thru sub Sicor)
19. Paxil	paroxetine	GSK	Par
20. Pletal	Cilostazol	Otsuka/Lilly	Prasco
21. Rebetol	Ribavirin	Schering-Plough	Warrick (sub of S-P)
22. Remeron SolTab	mirtazapine	Organon	Prasco
23. Salagen	pilocarpine	MGI Pharma	Alpharma (Purepac)
24. Tambocor	Flecainide	3M	Mylan
25. Terazol 3	terconazole	J&J	Watson
26. Wellbutrin SR	bupropion SR	GSK	Watson
27. Zyban	bupropion SR	GSK	Watson

PhRMA has asked IMS Consulting to examine the effects that authorized generics have on the market. Specifically, IMS was asked to investigate whether authorized generics enhance competition and benefit patients.

III. Research Objectives

PhRMA has asked IMS Consulting to examine whether authorized generics enhance competition and benefit patients. More specifically, the key objective of this study is to research authorized generics to determine:

- Their extent
- Their impact, if any, on short and long-term generic pricing
- Whether any pricing impacts have led to a financial benefit for patients.

IV. Methodology

IMS Consulting first examined the list of 27 potential analogs compiled from a search of publicly available information (see list on page 4) and determined that many of them did not meet the criteria for inclusion in the analysis. [See section VII. Appendix A.] Nine authorized generic examples, meeting this usability condition, were retained for this analysis. They are:

- Glucophage XR (metformin ER)
- Glucotrol XL (glipizide ER)
- Glucovance (glyburide/metformin)
- Mestinon (pyridostigmine)
- Paxil (paroxetine)
- Rebetol (ribavirin)
- Tambocor (flecainide)
- Zyban (bupropion SR)
- Macrobid (nitrofurantoin monohydrate/macrocrystals)

Additionally, criteria were developed for screening and selecting potential no-authorized generic analog cases to create a set of comparison products for the authorized generic cases. There were three main criteria:

- A single A/B rated generic launched with 180 days of market exclusivity. This implied that market exclusivity was the result of a Paragraph IV aNDA application. The FDA's list of 300 Paragraph IV applications provided the starting point for this process (see Appendix D). In these instances, there was no authorized generic that launched during the A/B-rated generic's exclusivity.
- The analog case was relatively recent (last 3 years). This is because attention has been focused on authorized generics in the past few years. Other IMS Consulting work has shown that brand products are experiencing accelerated rates of generic erosion, therefore recency of no-authorized generic cases was important to maintain comparability with the available authorized generics cases.
- Lastly, the case had to be relatively free of other market complications and/or data issues.

The list of no-authorized generic analogs included:

- Florinef (fludrocortisone acetate)
- Demadex (torsemide)
- Prozac (fluoxetine)
- Relafen (nabumetone - limited to 750 mg strength)
- BuSpar (buspirone - limited to 30 mg strength)
- Cytovene (ganciclovir)
- Lariam (mefloquine)
- Permax (pergolide)
- Vicoprofen (ibuprofen/hydrocodone)

Prices from IMS's National Sales Perspectives were used to address the research objective. The analysis focused on the impact of authorized generics using outlet-level prices[5]. More specifically, differences in generic prices (in terms of discount to brand) were analyzed. Price differentials were applied to the generic volumes. More detail about the methods is provided within the analysis.

[5] *Outlet-level prices are the cost to outlets (either retail such as pharmacies, or non-retail such as hospitals) for the products, whether purchased directly from a manufacturer or indirectly through a wholesaler. Although prompt-payment discounts, bottom-line invoice discounts and chargebacks may exist for particular products, they are not captured in the database or reflected in the dollar purchase amounts. However, invoice line-item discounts are reflected. Outlet-level prices were used in the analysis to capture any savings resulting from authorized generics, at any point in the drug distribution channel; these are interpreted as savings to the healthcare system.*

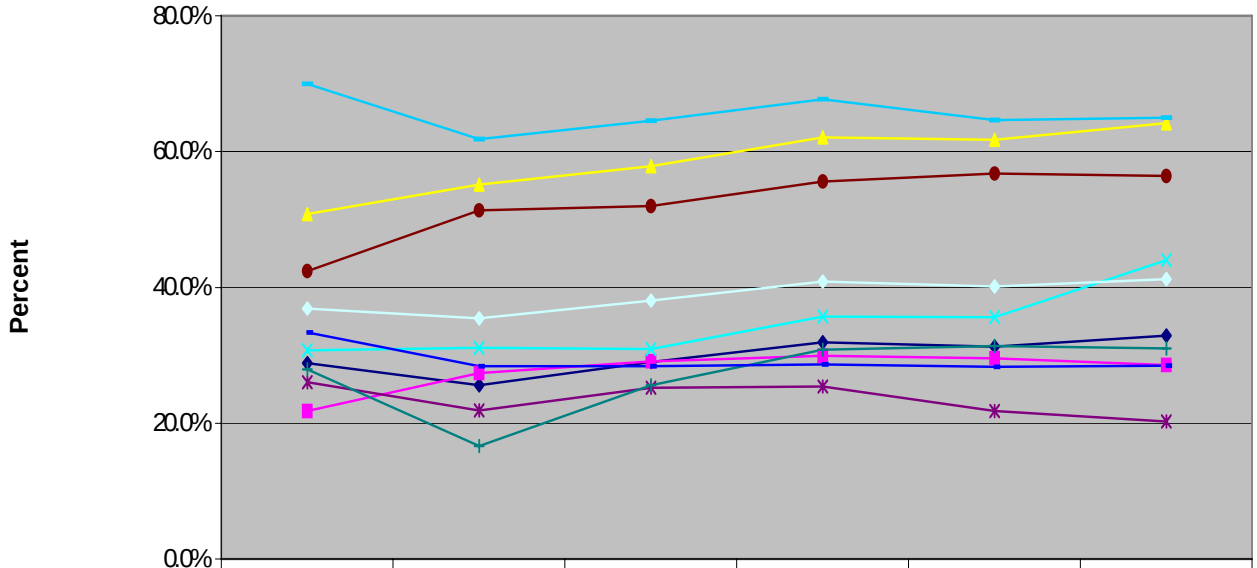
V. Detailed Findings

A. Average Discounts to Brand – Authorized Generic vs. No-Authorized Generic Scenarios

Using outlet-level prices from IMS's National Sales Perspective, IMS Consulting calculated the average generic discount to brand for the nine authorized generic analogs. Within each product, the generic discount to brand was calculated by weighting the A/B rated generic and the authorized generic discounts to brand by their respective sales unit (extended unit) volumes. An overall average authorized generic discount to brand was calculated by taking a simple weighted average across the nine authorized generic examples.

The discount to brand for scenarios where an authorized generic was present ranged from 21.8% to 70.0% in month 1 (average 36.9%). Month 6 discounts to brand ranged from 20.3% to 65.0%, averaging 41.2%. When the average discounts to brand were calculated (simple un-weighted average) across all seven brands, the discounts yielded a six-month average of 38.8%.[6]

Generic Discounts to Brand: Authorized Generics Analogs
Outlet-Level Prices

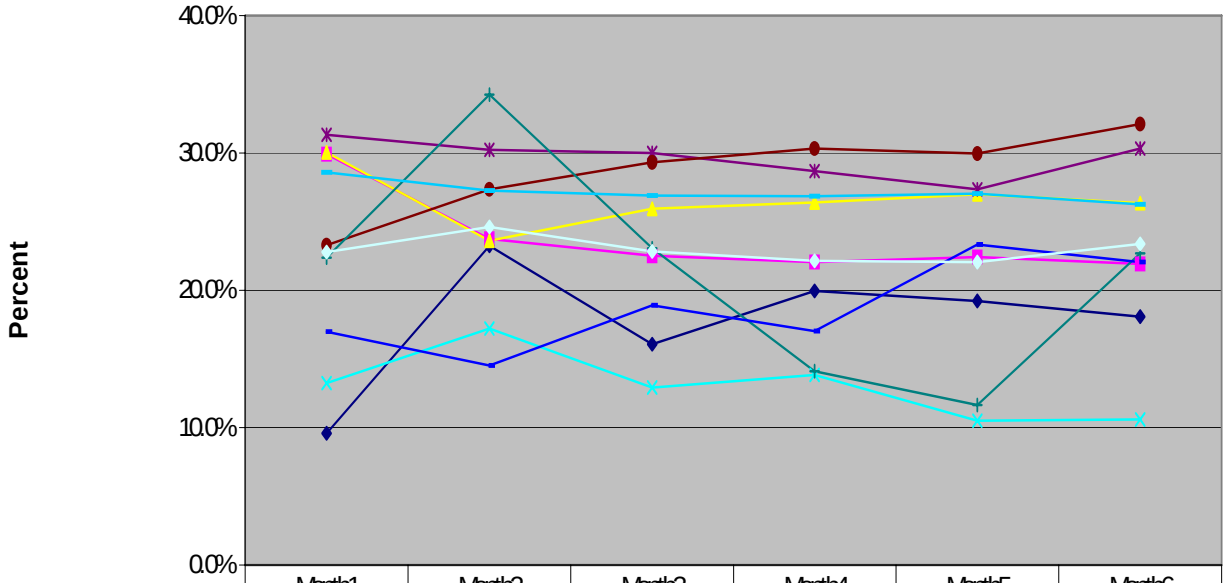


	Month1	Month2	Month3	Month4	Month5	Month6
AG1	28.9%	25.6%	29.0%	31.9%	31.3%	32.9%
AG2	21.8%	27.4%	29.1%	29.9%	29.6%	28.6%
AG3	50.8%	55.1%	57.8%	62.1%	61.7%	64.2%
AG4	30.7%	31.1%	30.9%	35.7%	35.6%	44.0%
AG5	26.0%	21.9%	25.3%	25.4%	21.8%	20.3%
AG6	42.4%	51.3%	52.0%	55.6%	56.8%	56.4%
AG7	27.9%	16.6%	25.6%	30.8%	31.4%	31.0%
AG8	33.4%	28.4%	28.4%	28.6%	28.3%	28.5%
AG9	70.0%	61.8%	64.5%	67.7%	64.6%	65.0%
Simple AG Avg	36.9%	35.5%	38.1%	40.8%	40.1%	41.2%

[6] *Note, however, that actual differences between brand and generic drugs are likely to be smaller, since our data do not back-out rebates on brand drugs (generics typically do not provide rebates). Since this is the case for both authorized generic and no authorized generic scenarios though, it is likely not to affect the relative price differences of these scenarios.*

The same methodology was then applied to the scenarios that did not include an authorized generic. As with the authorized generic examples, the no-authorized generic analogs show a discount range, and also follow a similar pattern. In this case, there was no within product average to consider (since there is a single generic with 180-day exclusivity). In month 1, the discounts ranged from 9.6% to 31.3%, averaging 22.8%. In month 6, the discounts ranged from 10.6% to 32.1%, averaging 23.4%. The simple average discount to brand across products for the 6-month period was 23.0%.

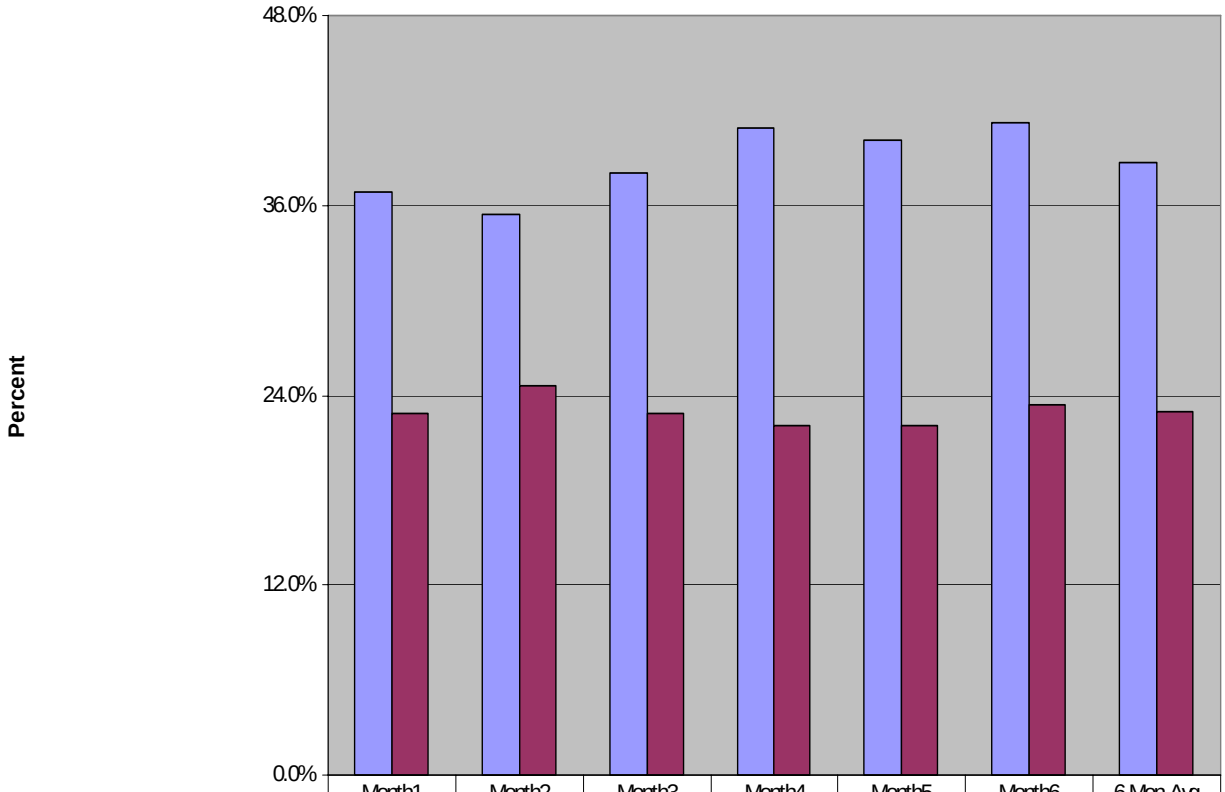
Generic Discounts to Brand: No-Authorized Generics Analogs
Outlet-Level Prices



	Month1	Month2	Month3	Month4	Month5	Month6
No-AG1	9.6%	23.2%	16.1%	20.0%	19.2%	18.1%
No-AG2	29.9%	23.7%	22.5%	22.1%	22.4%	21.9%
No-AG3	30.0%	23.6%	26.0%	26.4%	27.0%	26.3%
No-AG4	13.2%	17.2%	12.9%	13.8%	10.5%	10.6%
No-AG5	31.3%	30.2%	30.0%	28.7%	27.4%	30.3%
No-AG6	23.3%	27.4%	29.3%	30.3%	29.9%	32.1%
No-AG7	22.4%	34.2%	23.0%	14.1%	11.6%	22.7%
No-AG8	17.0%	14.5%	18.9%	17.0%	23.3%	22.1%
No-AG9	28.6%	27.3%	26.9%	26.9%	27.0%	26.2%
Simple No-AG Avg	22.8%	24.6%	22.9%	22.1%	22.0%	23.4%

When the average discount to brand for the authorized generic scenarios (38.8%) was compared to that of scenarios without an authorized generic (23.0%), the discount to brand was greater (+15.8 percentage points) in the scenarios that included an authorized generic than in those that did not. In other words, the presence of an authorized generic led to generic discounts that were 15.8 percentage points lower on average (15.8 percentage points greater discount to brand) than the average for comparable examples in which there was no authorized generic. These differences attributable to authorized generics pertain to the 6-month period during which the A/B-rated product held generic exclusivity.

Average Generic Discounts to Brand: AG vs. No-AG Analogs
Outlet-Level Prices



	Month1	Month2	Month3	Month4	Month5	Month6	6-Mon Avg
Authorized Generic Examples	36.9%	35.5%	38.1%	40.8%	40.1%	41.2%	38.8%
No-Authorized Generic Examples	22.8%	24.6%	22.9%	22.1%	22.0%	23.4%	23.0%

B. Impact of Authorized Generics on Cost to Healthcare System

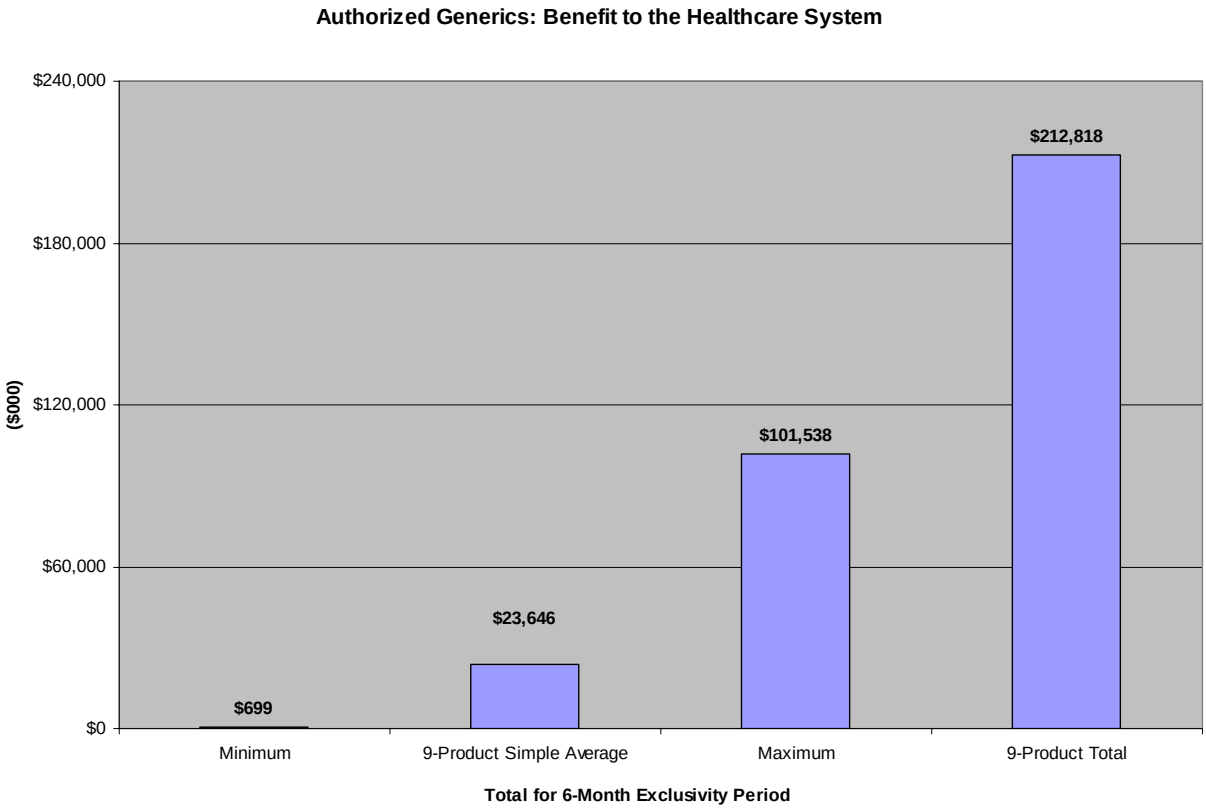
In order to quantify the savings to the healthcare system attributable to the presence of an authorized generic, the following variables were factored into the calculation:

- Number of generic units sold (since brand prices are unaffected by the presence or absence of an authorized generic)
- Brand unit average price ($/unit, since the impact of an authorized generic was calculated in terms of average discount to the price of the brand to which it is comparable)
- Outlet price differential: average generic discount to brand for authorized generic examples less average for no-authorized generic examples (%, the estimate of the price-lowering impact of authorized generics)
- Generic unit price differential due to the presence of an authorized generic (brand unit average price x outlet price differential)

From this, the savings (benefit) per month to the healthcare system for the nine analog products of interest was derived (generic unit price differential x number of generic units sold). Below is an example of the savings from one of the products in our sample.

Benefit to Healthcare System						
Brand XYZ	**Month1**	**Month2**	**Month3**	**Month4**	**Month5**	**Month6**
Generic Units (000)	#	#	#	#	#	#
Brand Unit Average Price ($/Unit)	$2.23	$2.11	$2.17	$2.22	$2.22	$2.24
Outlet Price Difference: AG vs No-AG (%)	14.1%	10.9%	15.2%	18.7%	18.1%	17.8%
Generic Unit Price Diff Due to AG ($)	$0.31	$0.23	$0.33	$0.41	$0.40	$0.40
$ Benefit to System ($000)	$16,375	$9,242	$14,212	$23,410	$19,203	$19,096
Six-Month Total ($000)	**$101,538**					

This same approach was applied to the other eight analogs. The healthcare system savings attributable to an authorized generic across our nine case studies ranged from $699 thousand to $101.5 million during the 6-month exclusivity period, and totaled $212.8 million across all nine case studies.



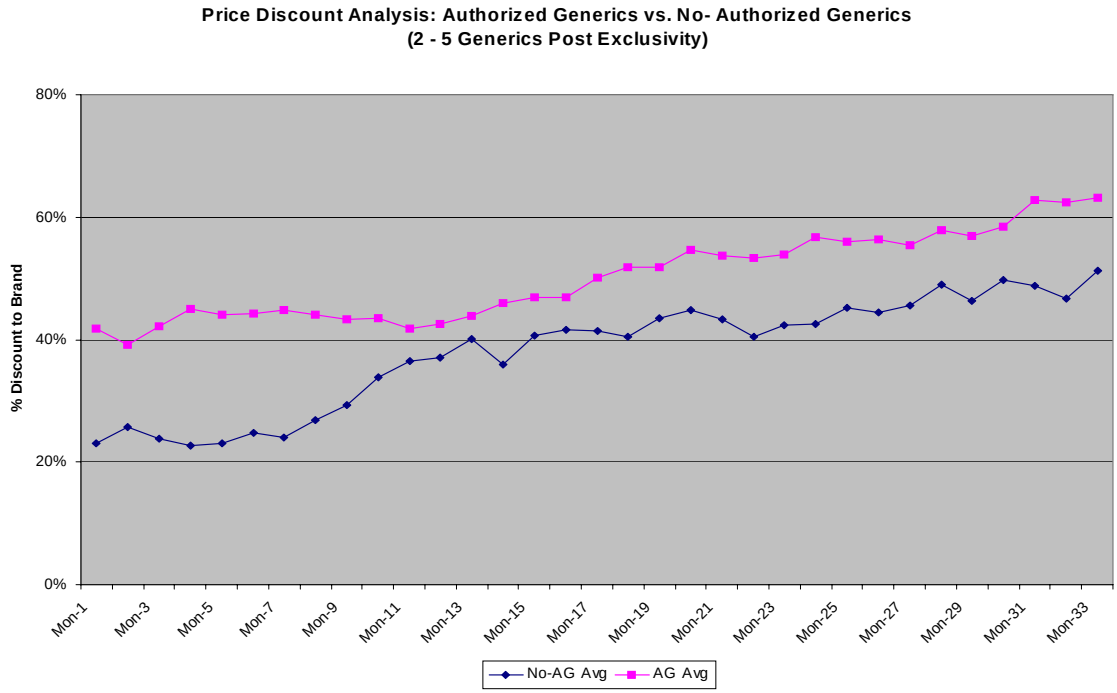
C. Impact of Authorized Generics on Discounts to Brands Post 180-Day Exclusivity Period

Next, we examined the differences in discounts at outlet-level prices post 180-day exclusivity to determine if there was any lasting impact from the presence of an authorized generic. The same authorized generic and no-authorized generic analog case studies were used, as were the same outlet level prices and the discounts to brand. These discounts to brand were extended for as many months of data as were available for each analog.

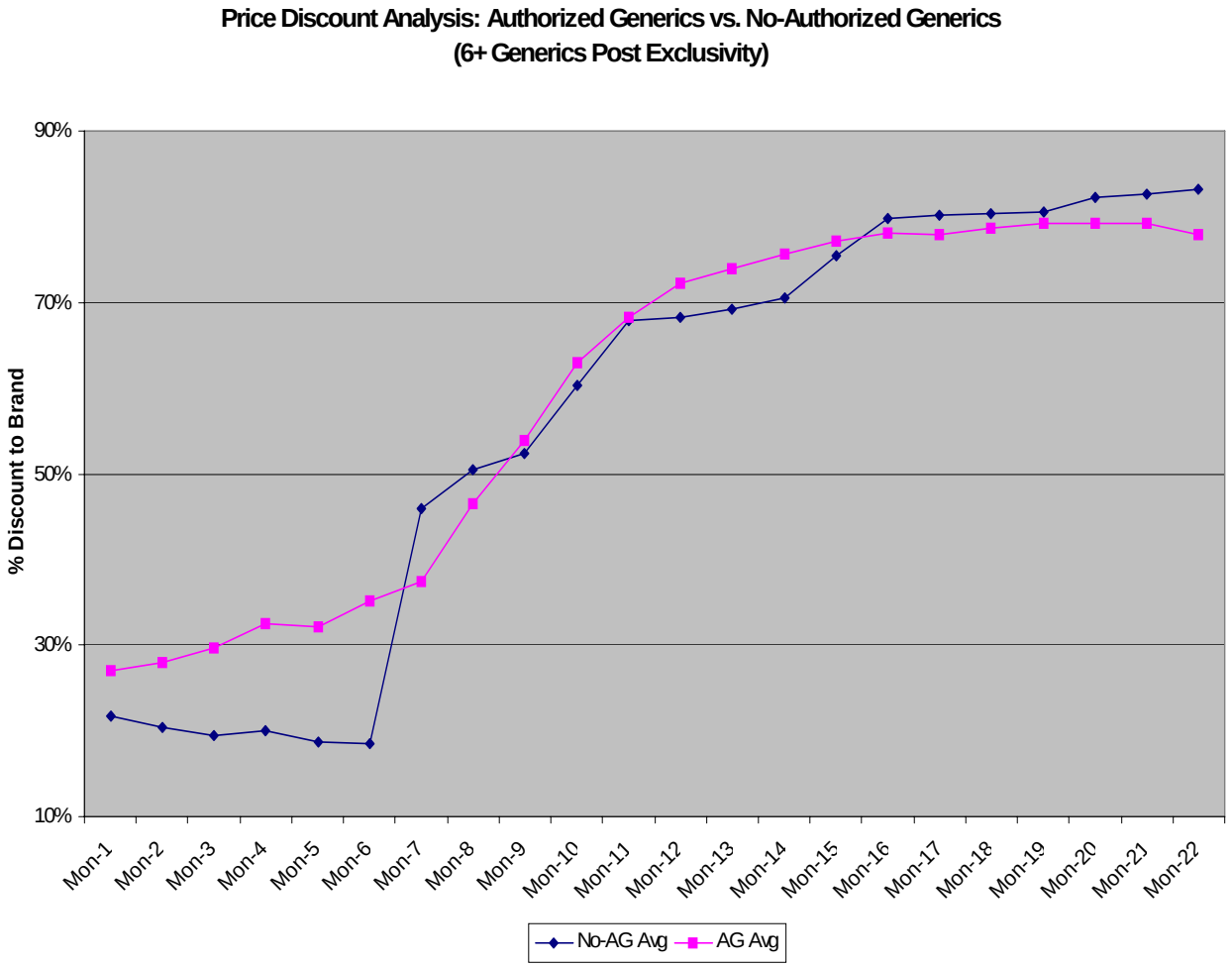
In order to test a hypothesis that generic discounts to brand post 180-day exclusivity were dependent on the number of generics in the market at that time, we segmented both authorized generic and no-authorized generic cases by whether there were 2-5 generics available, or 6^{+} generics available, post exclusivity.

Grouping the analogs by number of generic competitors yields an observable correlation between discount to brand for authorized generic cases and no-authorized generic cases.

When looking at the average discount to brand when there are 2-5 generics post exclusivity, greater discount to brand, driven by the presence of an authorized generic, persists beyond the exclusivity period.



When looking at the average discount to brand when there are 6^+ generics post exclusivity, there is really no difference between the discount to brand for authorized generic scenarios and non-authorized generic scenarios after exclusivity ends. Therefore, it can be concluded that there is no price impact from an authorized generic beyond the 6-month exclusivity period with 6+ generics. This correlation is particularly evident when viewed as an average. The 6+ generics segment shows virtually the same discount to brand post exclusivity for no-authorized generics cases as for cases involving authorized generics.



VI. Conclusions

With an authorized generic in the market, along with a single A/B-rated generic (the holder of the 180-day exclusivity period) the average generic price discount to the branded product is greater than comparable Paragraph IV examples in which there is no-authorized generic. At the outlet level (price to a pharmacy, clinic, etc.) the generic discount to brand is about 16 percentage points greater than comparable examples without an authorized generic (during the 180-day exclusivity period).

After the 180-day exclusivity period, the difference in discounts to brand from authorized generics to examples with no authorized generic depends on the number of generic competitors. In examples with fewer than 6 competing products, the discount to brand remains greater in the presence of an authorized generic compared to examples with no authorized generic. Therefore, authorized generics play a role in providing greater discounts to the U.S. healthcare system even after the 180-day exclusivity period. In examples with 6 or more generics in the market (after 180-day exclusivity), discounts to brand are nearly identical (on average) from authorized generic to no authorized generic examples.

These documented differences in average discount to brand, from authorized generic examples to no authorized generic examples, result in cost savings to the U.S. healthcare system. With an authorized generic in the market, the average generic price is lower (relative to the comparable brand) than it would be if there was no authorized generic (and only the single generic holding 180-day exclusivity). These lower generic prices result in a reduced total drug cost for the volume of generic drugs purchased.

VII. Appendix

A. Analogs Excluded from Analysis and Reasons

Eighteen analogs were excluded from the analysis for the various reasons documented in the following table. In most cases (13) the analog was eliminated because there was not a single AB-rated generic in addition to the authorized generic (no 180-day exclusivity). In four cases, multiple forms of the brand made a clear analysis difficult. In two cases, data issues led to their exclusion.

Brand Name	Molecule	Reason
Accupril	quinapril	Not a 'true' AG analog because Teva and Par had **shared exclusivity** when Greenstone launched the AG. Three generics launched instead of two
Celexa	citalopram	Not a 'true' AG analog because **several generics** launched at the same time
Cipro	ciprofloxacin	Not a 'true' AG analog because **several generics** launched at the same time
Cutivate	fluticasone	Not a 'true' AG analog because **several generics** launched at the same time
Diflucan	fluconazole	Not a 'true' AG analog because **several generics** launched at the same time
Monopril	fosinopril	**Outlier** based on market dynamics
Neurontin	gabapentin	Not a 'true' AG analog because Teva and Alpharma had **shared exclusivity** when Greenstone launched the AG. Three generics launched instead of two
Ortho Tri-Cyclen	norgestimate, ethinyl estradiol	**Too many forms** of norgestimate molecule for a clean analysis
Ortho-Cyclen	norgestimate	**Too many forms** of norgestimate molecule for a clean analysis
Ortho-Novum7/7/7	norethindrone, ethinyl estradiol	**Too many forms** of norethindrone molecule for a clean analysis
OxyContin	oxycodone	**Too recent**, there was insufficient data at the time to analyze
Paraplatin	carboplatin	Not a 'true' AG analog because **several generics** launched during the exclusivity period
Remeron SolTab	mirtazapine	Not a 'true' AG analog because **several generics** launched during the exclusivity period
Salagen	pilocarpine	Not a 'true' AG analog because **several generics** launched at the same time
Terazol 3	terconazole	**Only AG** available, **no AB** rated generic
Wellbutrin SR	bupropion	Not a 'true' AG analog because Teva launched a **branded generic** during the exclusivity period
Duragesic	fentanyl	**Too recent**, there was insufficient data at the time to analyze
Pletal	cilostazol	Not a 'true' AG analog because **several generics** launched during the exclusivity period

B. Authorized Generic Cases

Brand Name	Molecule	AG Launch Date	AB Launch Date
Accupril	quinapril	Dec-04	Dec-04
Celexa	citalopram	Oct-04	Oct-04
Cipro	ciprofloxacin	May-03	Jun-04
Cutivate	fluticasone	May-04	May-04
Diflucan	fluconazole	Jul-04	Aug-04
Duragesic	fentanyl	Feb-05	Feb-05
Glucophage XR	metformin XR	Dec-03	Oct-03
Glucotrol XL	glipizide ER	Nov-03	Nov-03
Glucovance	glyburide/metformin	May-04	May-04
Macrobid	nitrofurantoin macrocrystals/monohydrate	Mar-04	Jan-04
Mestinon	pyridostigmine	Feb-03	Jan-03
Monopril	fosinapril	Dec-03	Dec-03
Neurontin	gabapentin	Oct-04	
Ortho Tri-Cyclen	norgestimate, ethinyl estradiol	Dec-03	Dec-03
Ortho-Cyclen	norgestimate	Jan-03	Sep-02
Ortho-Novum7/7/7	norethindrone, ethinyl estradiol	Dec-02	Jan-03
OxyContin	oxycodone	Jun-05	Jun-05
Paraplatin	carboplatin (injection)	Jun-04	
Paxil	paroxetine	Sep-03	Sep-03
Pletal	cilostazol	Oct-04	Apr-05
Rebetol	ribavirin	Apr-04	
Remeron SolTab	mirtazapine	Oct-04	Dec-03
Salagen	pilocarpine	Feb-05	
Tambocor	flecainide	Mar-02	May-02
Terazol 3	terconazole	Apr-04	Apr-04
Wellbutrin SR	bupropion SR	Jan-04	Jan-04
Zyban	bupropion SR	Jun-04	Jun-04

C. Description of the Audits

IMS National Sales Perspectives™: Retail and Non-Retail

The IMS National Sales Perspectives™ are the industry standard for measuring sales within the U.S. pharmaceutical market. They are the only sources to report 100% channel coverage of national pharmaceutical sales at actual transaction prices to ensure that our pharmaceutical clients receive the most accurate and comprehensive intelligence of the U.S. market.

IMS National Sales Perspectives™: Retail

This is a continuing monthly report measuring, in dollars and units, pharmaceutical products purchased by independent pharmacies, chain drugstores, mass merchandisers (with and without pharmacies), proprietary stores (without pharmacies), food stores with pharmacies, and mail service pharmacies in the United States. The universe includes data going back to 1998 with unprojected mail service data since 2000 (meaning raw data, not projected to universe of mail order pharmacies). IMS National Sales Perspectives: Retail is often used in conjunction with the IMS National Sales Perspective Non-Retail, which measures the same activity in non-retail channels does not include mail order pharmacies. National Perspective: Retail is often used in conjunction with the National Perspective: Non-Retail, which measures the same activity in non-retail channels.

The report is based on national projections of the following types of products:

- Prescription pharmaceuticals, both branded and generic
- Over-the-counter pharmaceuticals
- Diagnostic products normally self-administered, *e.g.*, take-home pregnancy tests

The unit and dollar purchase price reflected in the data is the actual cost to retailers for the products, whether purchased from a manufacturer or a wholesaler (96% of total pharmaceutical retail purchases are from wholesalers and chain warehouses). However, prompt-payment cash discounts and bottom-line invoice discounts are not reflected in the dollar purchase amounts. Also, it should be noted that volume purchase estimates may not always reflect drop shipment activity.

IMS Health obtains data for National Perspective: Retail from two basic sources. The first is a panel of retail outlets that give direct (from the manufacturer) purchase information. The second source is a near-census of warehouses that supply indirect purchase data.

IMS National Sales Perspectives™: Non-Retail

IMS National Sales Perspectives: Non-Retail service is a continuing monthly report measuring, in projected dollars and units, pharmaceutical product (prescription and over-the-counter) purchases. IMS National Sales Perspectives: Non-Retail tracks purchases in non-federal hospitals (short-term private, city/county/state and psychiatric hospitals), federal facilities (VA hospitals, federal outpatient facilities and military supply depots), long-term care facilities (residential care and long-term care facilities, and nursing home pharmacies and providers), clinics (outpatient clinics and surgicenters, family planning centers, group practice offices and cancer treatment facilities), closed-wall HMOs, home healthcare facilities and miscellaneous outlets, including prisons and residential schools and colleges without a hospital in the United States. As noted above, the IMS National Sales Perspectives audits are often used in conjunction with one another.

The report is based on national projections of the following types of products:

- Prescription pharmaceuticals, both branded and generic
- Over-the-counter pharmaceuticals
- Diagnostic products normally self-administered, *e.g.*, take-home pregnancy tests

Diagnostic products used in laboratories are not included.

The prices reflected in IMS National Sales Perspectives: Non-Retail are the costs to outlets for the products, whether purchased directly from a manufacturer or indirectly via a wholesaler. Although prompt-payment discounts and bottom-line invoice discounts exist, they are not reflected in the dollar purchase amounts. Also, estimates may not always reflect drop shipment activity.

IMS Health obtains data for each IMS National Sales Perspectives Non-Retail channel from two basic sources: DDD warehouses that supply indirect pharmaceutical purchases to outlets and manufacturer-reported direct sales to outlets. In addition, the Non-Federal hospital channel is supplemented by a panel of hospitals to track purchases of non-DDD covered products and direct data for non-reporting manufacturers.

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