

Authorized Generic Drugs, Price Competition and Consumers' Welfare

Ernst R. Berndt
MIT Sloan School of Management and NBER

Richard Mortimer
Andrew Parece
Edward Tuttle
Analysis Group Inc.

Ashoke Bhattacharjya
Johnson & Johnson

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Outline of Presentation

Authorized generics – background and policy issues

Framework for assessing impact of authorized generics

Impact on timing of entry, generic prices and shares

Evidence from recent authorized generics

Conclusions and discussion

Hatch Waxman and Authorized Generics

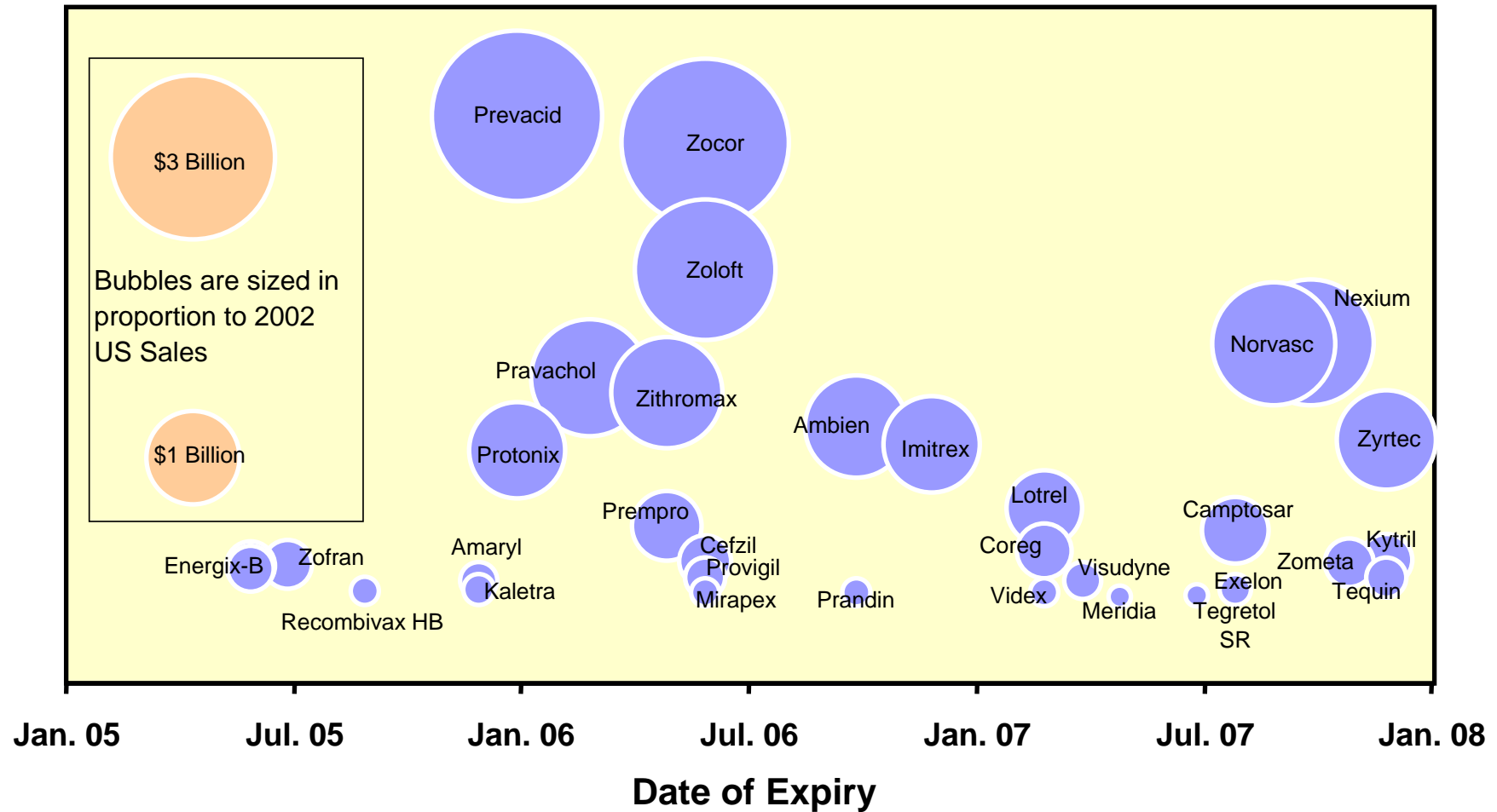
- **The Hatch-Waxman Act established a 180-day marketing exclusivity period for the first generic to file an ANDA with a successful paragraph IV certification**
 - **Paragraph IV certifications challenge the validity of a patent or claim non-infringement of the patent**
- **Authorized generics are prescription drugs whose ability to be marketed is based on the brand manufacturer's new drug application (NDA), yet are marketed and sold as generics**
 - **Authorized generic can enter during an independent (non-authorized) generic manufacturer's 180-day exclusivity period**

Authorized Generic Entry

- **Authorized generic entry occurred for several drugs during the 1990s**
- **The frequency of authorized generic entry appears to be increasing**
 - **More authorized generics using brand NDA**
 - **Many significant brands will be going generic over the next 3 years (estimated \$30 billion in US sales)**
- **Authorized generics have become the focus of debate, challenged by some generic manufacturers but recognized by the FDA with respect to promoting competition**
 - **“...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.”**

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

A Significant Number of Patents Are Soon to Expire



Authorized Generics – Key Policy Questions

- **Widespread agreement that authorized generics increase short-run competition and reduce generic prices in the case where an independent generic has been awarded ANDA exclusivity**

Policy questions:

- **Does increased short-run competition deter generic manufacturers from filing Paragraph IV ANDAs, delaying generic entry for future products?**
- **Do authorized generics decrease price competition for a given product in the long run?**

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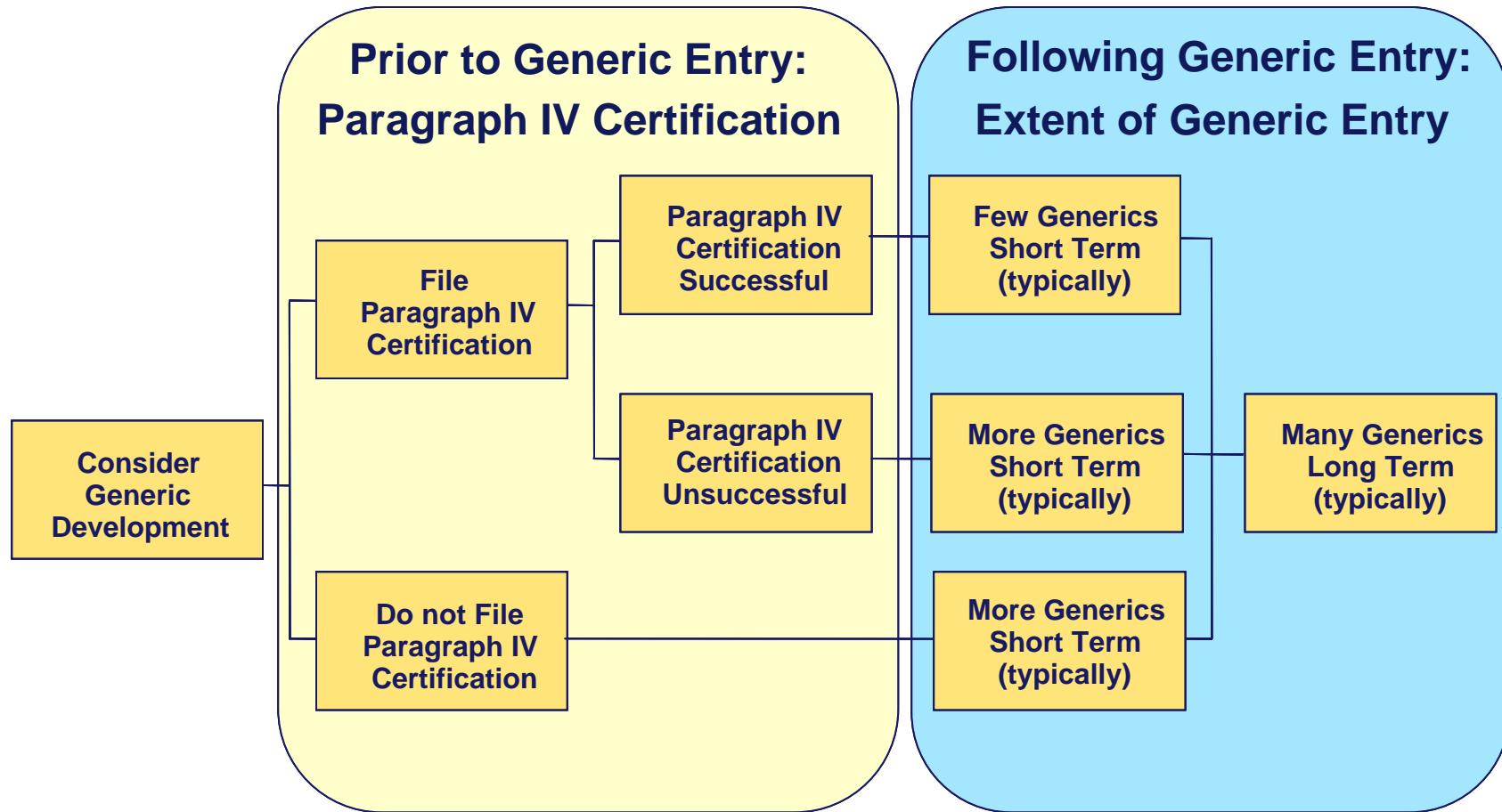
Timing of Generic Entry: Incentives for Future Paragraph IV Filings

- Paragraph IV filings are increasing despite existing competitive factors limiting the gains to the exclusivity period
 - Competition to be the first filer
 - Early experience with authorized generics does not appear to have slowed the rate of Paragraph IV filings
- In order to delay generic entry, an authorized generic would have to deter successful filings
 - Less than half of all challenged Paragraph IV filings (42%) result in a ruling in favor of the generic; many challenges are settled (38%) including some allowing licensing to the generic applicant (13%)
 - Filings with the least likelihood of success are deterred, avoiding costly litigation and enhancing incentives for drug innovation
- Costs of potentially delayed generic entry must be weighed against consumer benefits from lower short-run prices

Implications for Consumers

- **Impact on consumers depends on three factors:**
 - **The timing of independent generic entry**
 - **The relative generic-to-brand price (brand prices generally have no significant response to generic entry)**
 - **The generic versus brand shares of the molecule sales**
- **For some drugs, consumers may also benefit from the fact that authorized generics are identical to the brand**

Framework for Assessing Impact of Authorized Generics



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Overview of Paragraph IV Certifications

- **Paragraph IV certifications can result in earlier generic entry by challenging a patent or claiming no infringement**
 - **Authorized generic entry during the exclusivity period can diminish profit incentives to independent generics**
- **Use of paragraph IV certifications is increasing as generic drug manufacturers seek to accelerate the timing of generic entry**
 - **ANDA filings containing paragraph IV certifications increased from 2% in the 1980s to 20% between 1998 and 2000**
 - **Increased use of paragraph IV certifications could reflect paragraph IV certifications becoming more speculative**

Timing of Generic Entry

- **Authorized generic entry represents just one of many competitive factors affecting the exclusivity period**
 - **Independent generics face potential cross-dose competition**
 - Sandoz received exclusivity for the 10mg generic dose of fluoxetine; competed against Barr Labs who received exclusivity for the 20mg dose
 - **Independent generics compete to be the first ANDA filer**
 - **Paragraph IV certification may not be successful**
- **Even if some paragraph IV certifications are deterred by an authorized generic, it would not alter the timing of generic entry if:**
 - **The deterred paragraph IV certification would have been unsuccessful**
 - If firms are risk-neutral, paragraph IV certifications with the least likelihood of success (lowest expected profits) are the most likely to be deterred
 - Litigation expenses may be avoided, incentives to innovate new drugs may increase
 - **At least one generic with the resources to support a paragraph IV challenge/certification continues to file**

Extent of Generic Entry

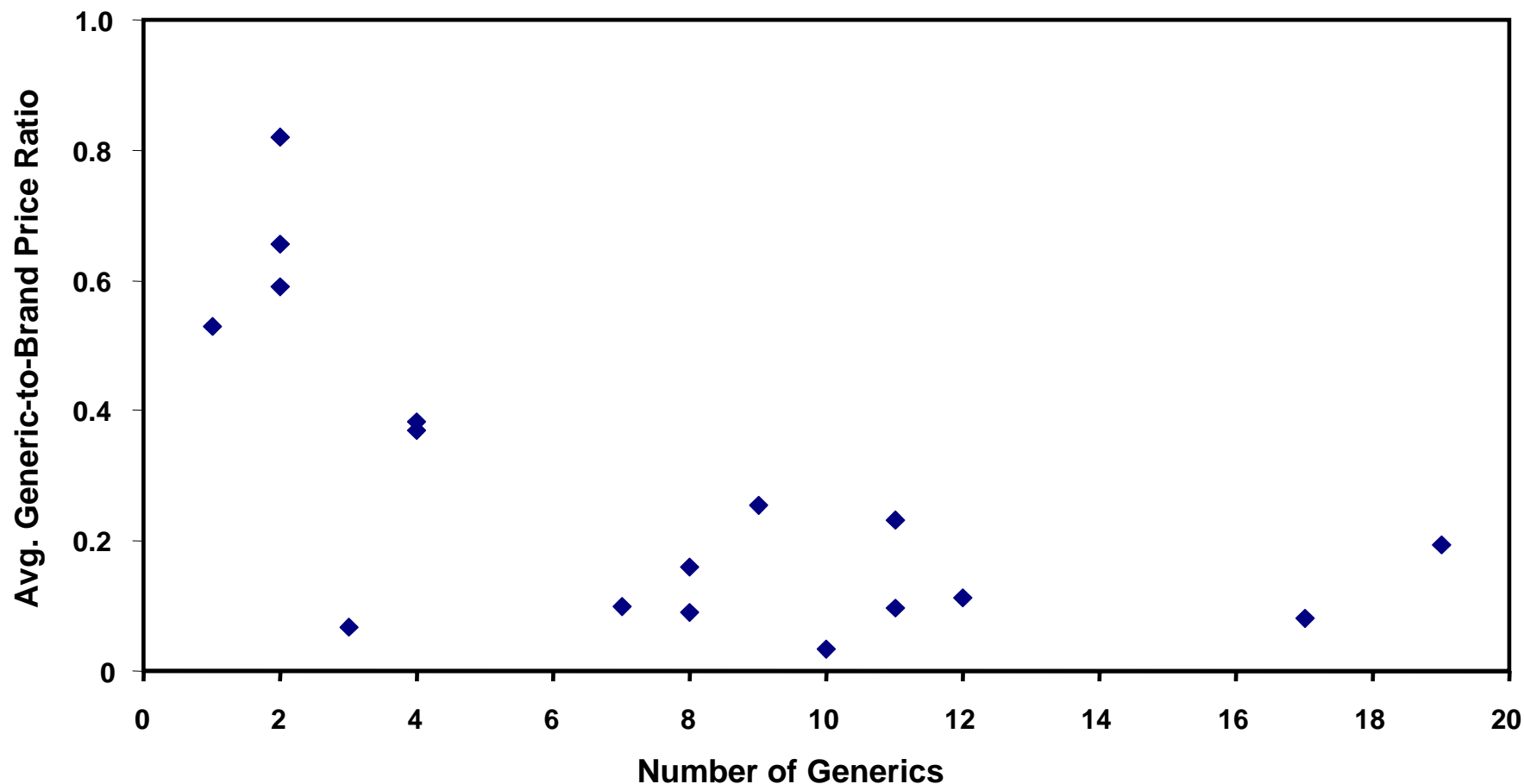
- **Consumers are affected if the long-run number of generic entrants is decreased to the point where long-run generic prices are affected**
 - **Authorized generics only affect long-run generic prices and shares if they impact the marginal generic entrant that affects prices and shares**
- **Peer-reviewed studies of generic entry support the finding that an additional generic entrant beyond the first five has little or no impact on generic-to-brand prices or generic share**
 - **To affect long-run prices, an authorized generic has to reduce generic entry to fewer than six (Reiffen and Ward, 2005)**
 - **Based on data through the late 1990s**

Recent Data on Generic Entry

- **Analysis of data for 29 drugs that had generic entrants between 1999 and 2003**
 - Analysis and observations based on descriptive statistics
 - Sample size limits extensive econometric analysis
- **Supports finding that an additional entrant beyond the first four or five has no impact on long-run prices**

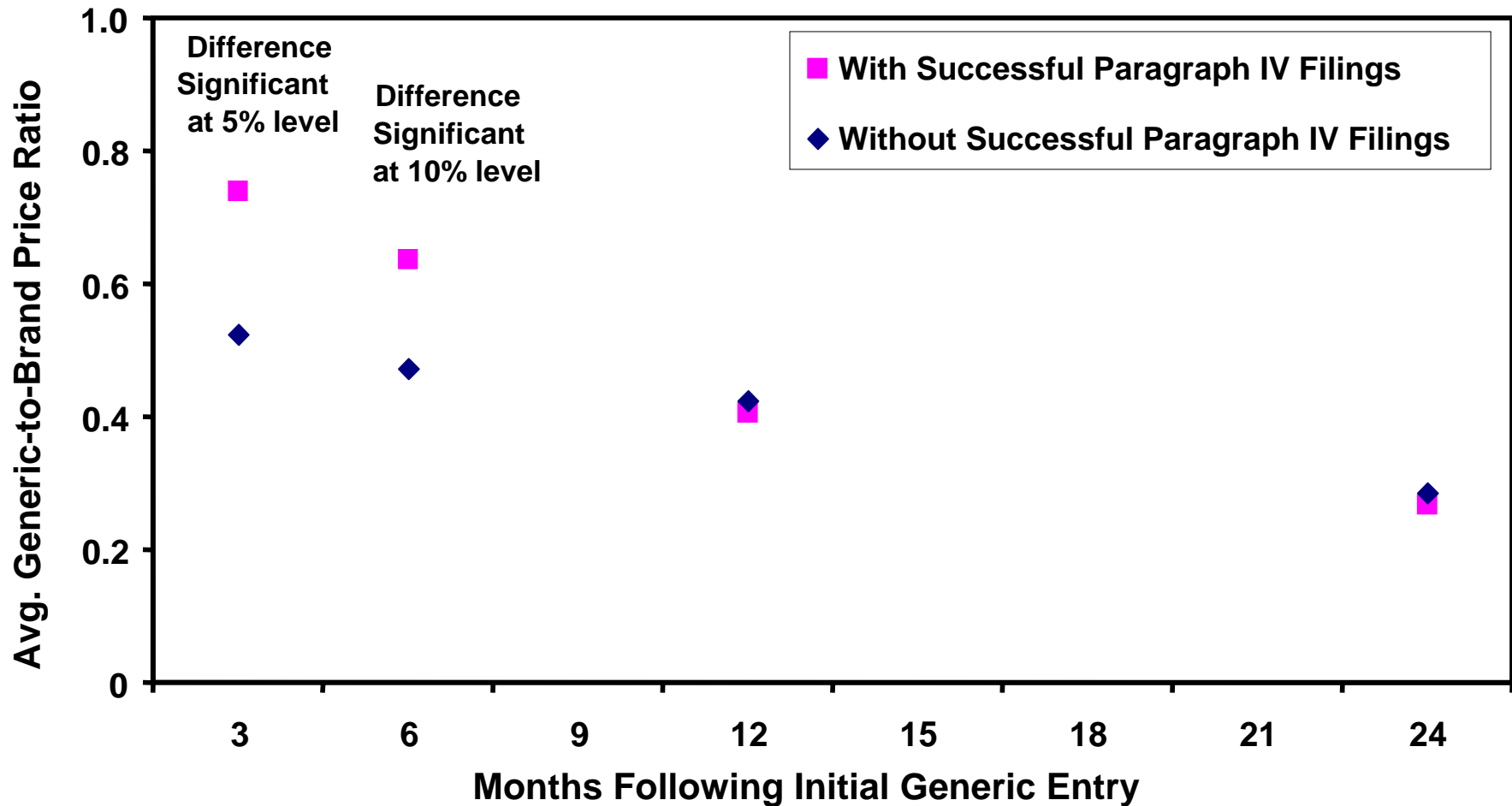
Long-Run Number of Generic Entrants and Generic-to-Brand Price Ratios (24 months post generic entry)

A reduction in the long-run number of generics is unlikely to affect generic prices unless there are fewer than four or five generic entrants



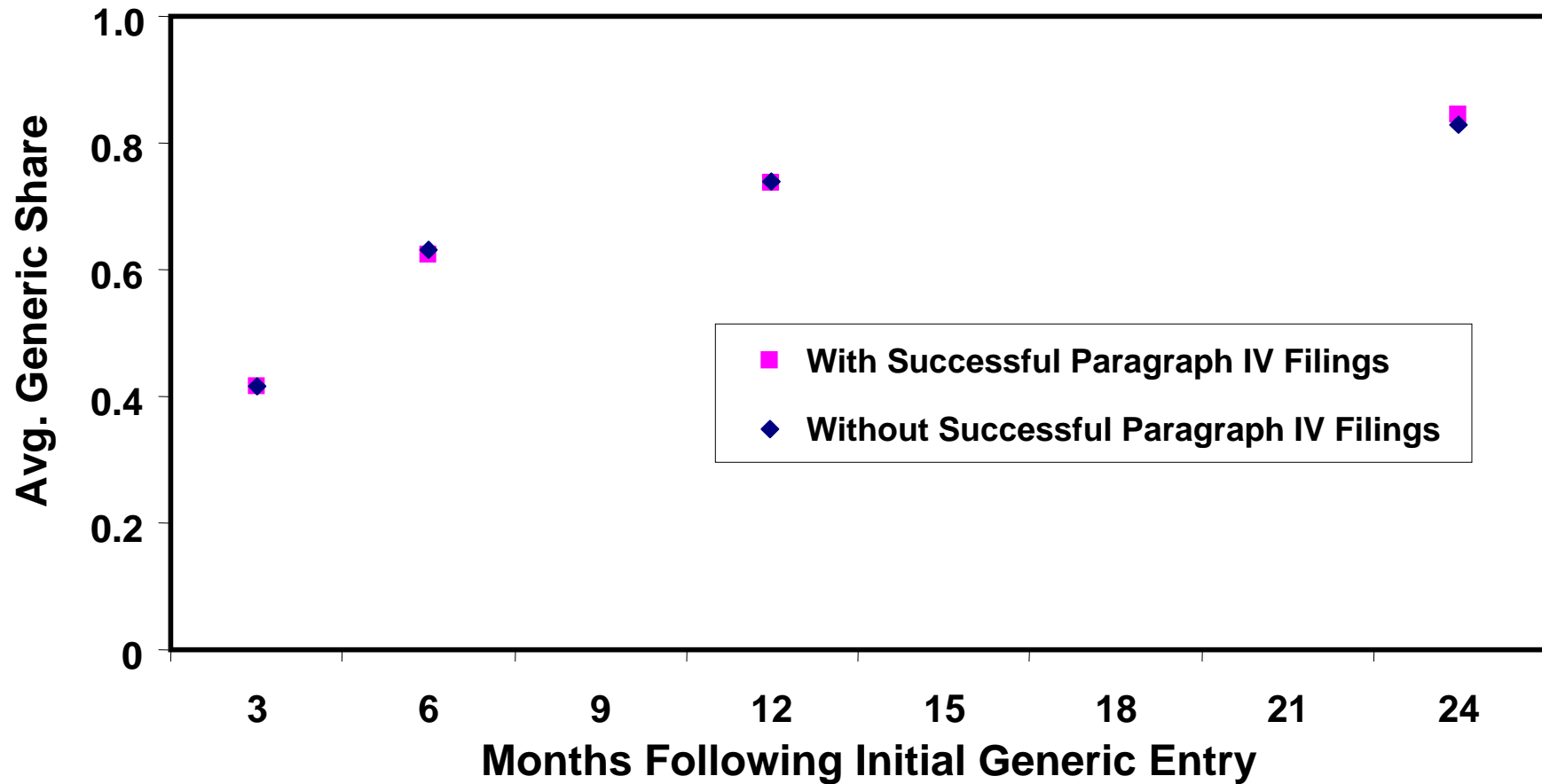
Generic-to-Brand Price Ratios

Higher generic-to-brand price ratios are associated with successful Paragraph IV filings in the short run; long run prices are unaffected



Generic Share

Long run generic share is unaffected by whether generic entry results from successful Paragraph IV filing



Drugs Facing Paragraph IV Certifications

Impact of Authorized Generics

- **In the short run, authorized generics introduce additional competition and lower average prices**
- **Even if an authorized generic affects the long-run number of generic entrants, it is unlikely to significantly affect long-run prices and shares**
- **Paragraph IV certifications with the least likelihood of success may be deterred**
 - **If the certification would have been unsuccessful then speculative litigation expenses are avoided**
 - **If the certification would have been successful then generic entry may be deterred, only if no other generic files a Paragraph IV certification**

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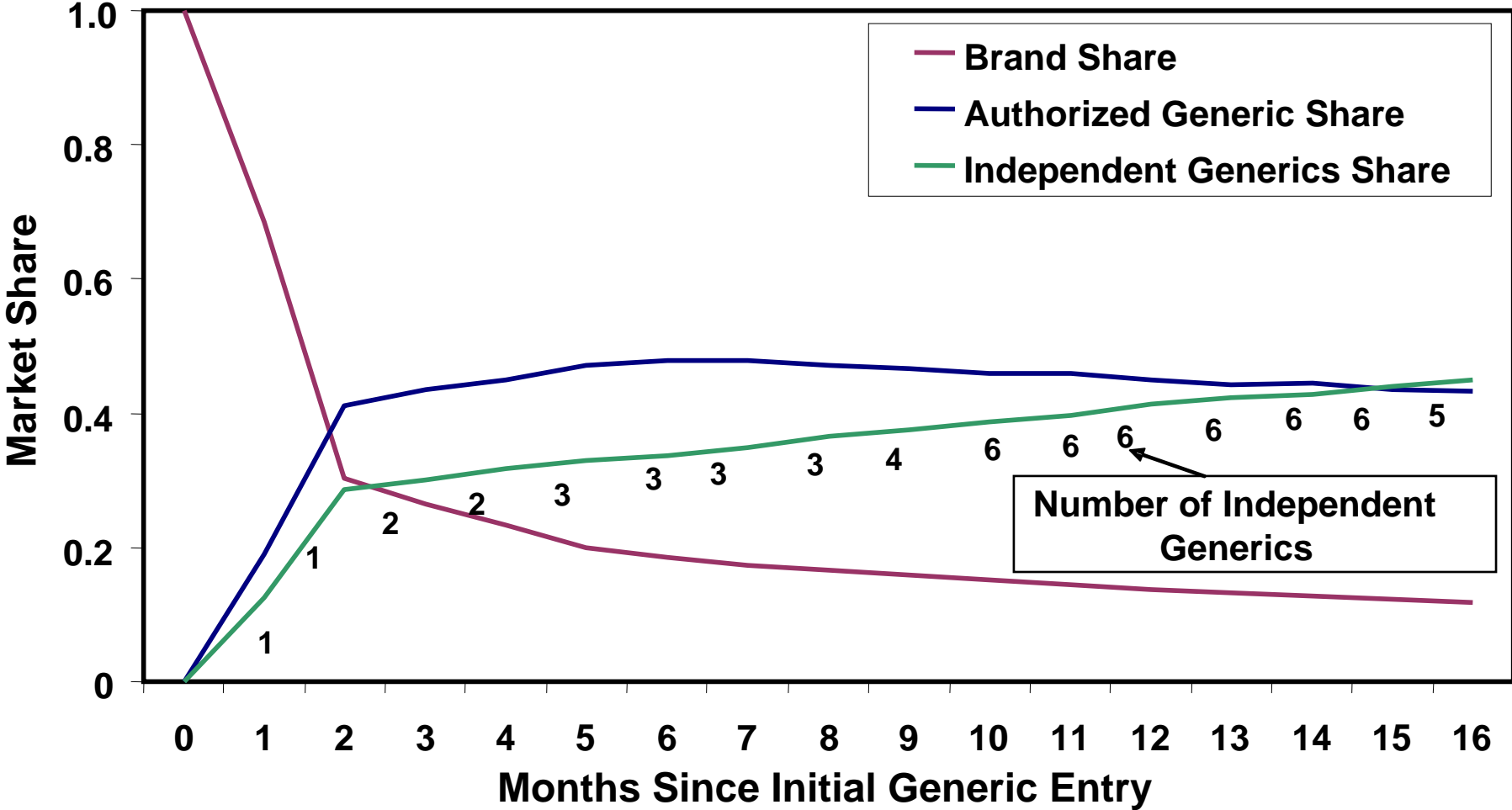
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Drugs Experiencing Authorized Generic Entry

- Evidence indicates that authorized and independent generics capture substantial market share from the brand
 - For Paxil, all generics capture approximately 85 percent share within 16 months
- Authorized generics offer a substantial price discount from the brand and compete with independent generics
 - Paxil authorized generic priced at half the brand price (independent generics comparable)
- Price and share trends are qualitatively similar for other drugs examined

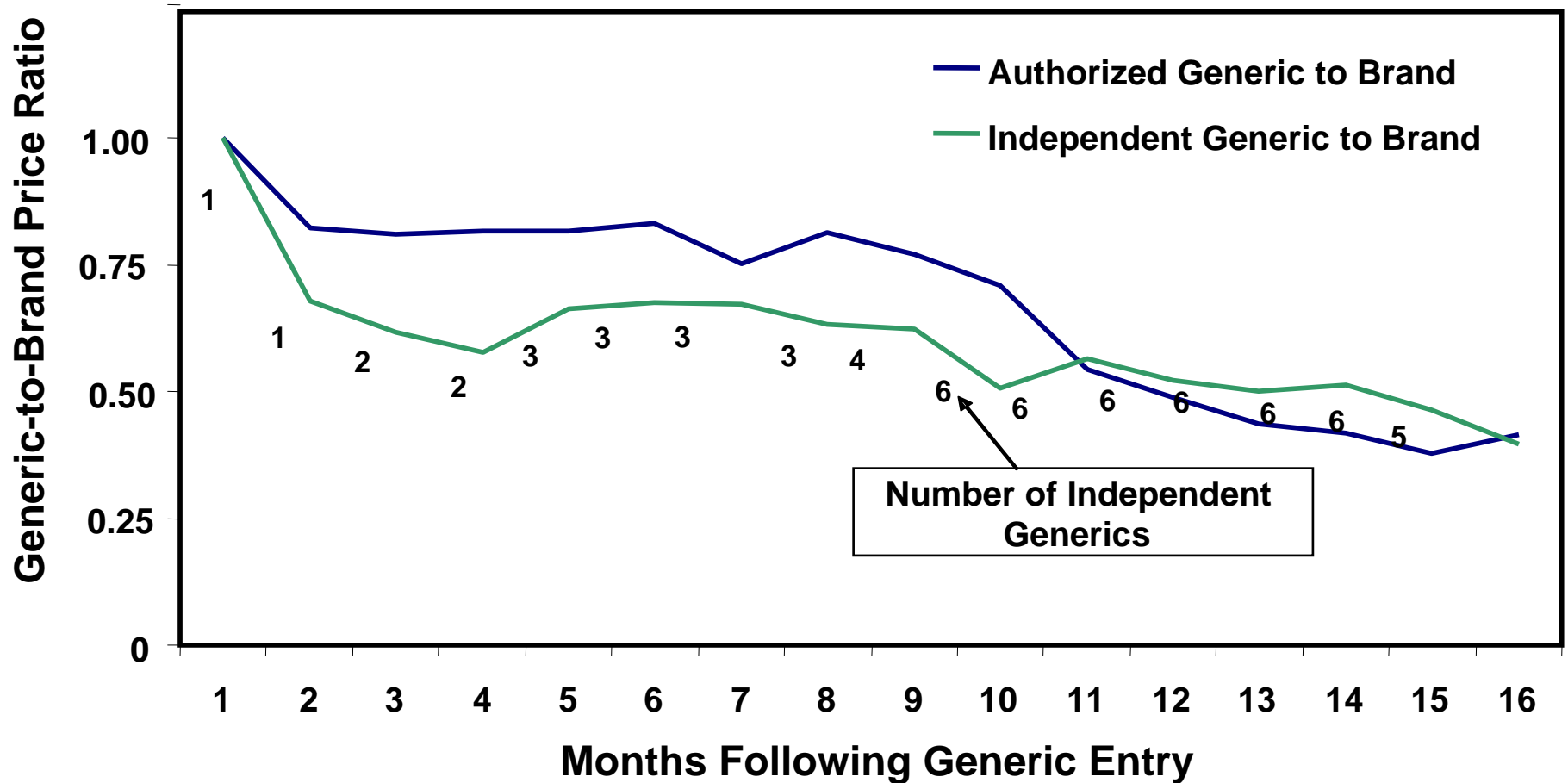
Generic Shares – Paxil

Authorized and independent generics capture substantial market share



Generic-to-Brand Price Ratios – Paxil

Authorized generics offer substantial price discounts from brand and compete with independent generics



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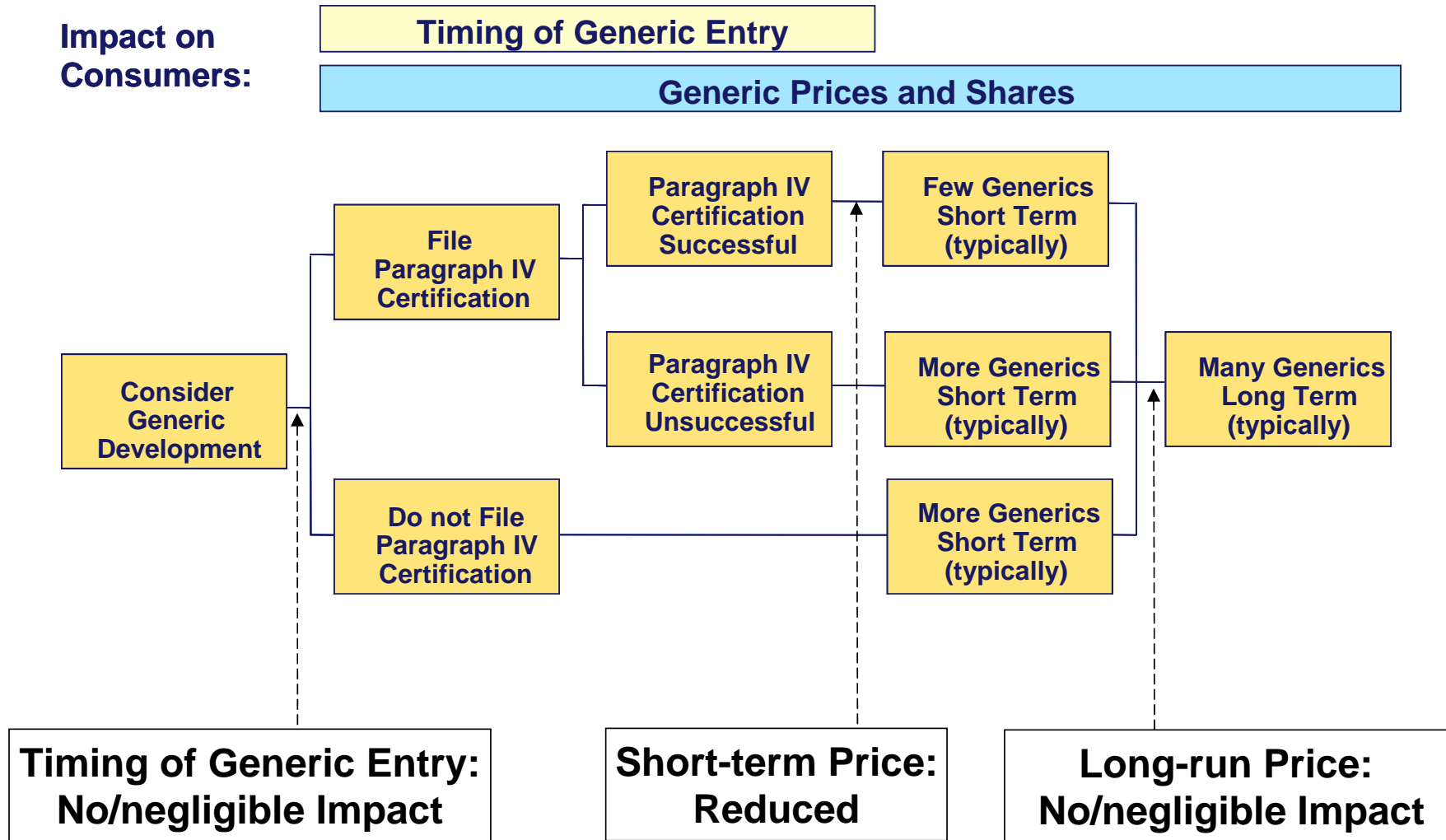
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Major Findings – Authorized Generic Entry

- **In the short run, authorized generics enhance competition – consumers clearly benefit from lower prices**
 - **Timing of generic entry is likely unaffected for most drugs**
 - **Authorized generics may even accelerate generic entry, e.g. Barr/Teva agreement for generic Allegra prior to resolution of patent litigation**
- **In the long run, authorized generics do not harm consumers**
 - **Generic-to-brand price ratios are likely unaffected**
 - **Effect of generic entry beyond four or five generics has little impact on generic-to-brand price ratios**
 - **Continue to observe ANDAs with Paragraph IV certifications**
- **On balance, authorized generics do not harm competition and can benefit consumers**
- **Further research on other drugs experiencing authorized generic entry would be useful for generalizing these findings**

Impact of Authorized Generics



Related Policy Issues

- **Findings on the impact of authorized generics for traditional small molecules may have relevance for biologics**
- **Inclusion of generic price for calculating Medicaid prices**
 - **Preliminary analysis suggests that impact on total Medicaid costs is ambiguous**
 - **Depends on relationships among generic-to-brand prices, shares, and CPI index for specific drugs**
- **Additional research on these issues is underway**

For further information....

“Authorized Generic Drugs, Price Competition and Consumers’ Welfare” working paper, October 2005 available upon request.

Contact:

**Ashoke Bhattacharjya (abhatta@janus.inj.com)
Johnson & Johnson**

**Ernst R. Berndt (eberndt@mit.edu)
MIT Sloan School of Management and NBER**

**Richard Mortimer (rmortimer@analysisgroup.com)
Andrew Parece(aparece@analysisgroup.com)
Edward Tuttle (etuttle@analysisgroup.com)
Analysis Group Inc.**