Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence

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I. Executive Summary

Over the past five years the prevalence of authorized generic entry has increased substantially, raising questions about the implications for competition between generic and brand drug manufacturers, and for consumers' welfare. One important issue in this debate is the impact of anticipated authorized generic entry on incentives provided under the Hatch-Waxman Act for generic manufacturers to file paragraph IV certifications and potentially expedite generic entry. In the past, data constraints have severely limited any empirical analysis of this issue. In this paper we analyze detailed data on paragraph IV certifications. We find no evidence that paragraph IV certifications have declined in response to increased authorized generic entry.

Previous research suggests that in the short run consumers benefit from the presence of authorized generics through lower prices. If authorized generics do not significantly reduce paragraph IV certifications, this enhanced consumer welfare is maintained. However, the lower prices that benefit consumers in the short run may reduce the expected gains from filing paragraph IV certifications. If the effect of authorized generics is to reduce these expected gains to the point that some paragraph IV certifications are deterred then generic entry may be delayed and consumers may be harmed.[1]

We analyze three datasets on paragraph IV certifications to examine the impact of authorized generic entry on paragraph IV certifications: one is compiled by the FDA; a second contains information based on a survey of PhRMA members; and a third reports information on court cases involving paragraph IV certifications. During the recent five-year period of increases in authorized generics, we find little overall change in the number of drugs facing paragraph IV certifications, the total number of paragraph IV certifications filed, or the timing of paragraph IV certifications relative to new chemical entity ("NCE") approvals.[2] We find that, despite

[1] In referring to "harm" or "benefits" to consumers in this paper we focus on brand and generic prices, generic shares, and the timing of generic entry, but do not consider the effect on consumers of other factors such as new drug innovation.

[2] There may be multiple new drug applications ("NDAs") for the same NCE. We use NCEs rather than NDAs in the timing analysis because the FDA prioritizes reviews for ANDAs involving an NCE with no generic entry for any NDAs under that NCE. By using NCEs we avoid concerns about generic competition and FDA priorities across NDAs for the same NCE affecting the timing of paragraph IV certifications.

increasing and relatively high rates of authorized generic entry, the rate of paragraph IV certifications is higher than it has ever been. We conclude that even when authorized generic entry reduces the expected gains from filing paragraph IV challenges, the recent evidence is clear that sufficient incentives remain so that in spite of recent increased authorized generic entry, the intensity of filing Paragraph IV challenges remains high. There is no evidence to suggest that authorized generic entry causes delayed generic entry.

We further find that drugs with relatively high pre-generic entry revenues are both more likely to experience authorized generic entry and to have a larger number of generic manufacturers filing paragraph IV certifications against them. While authorized generic entry reduces the gains of generic manufacturers that are eligible for the 180-day exclusivity period for these high-revenue drugs, the data suggest that substantial incentives for filing paragraph IV certifications remain.

Finally, the number and rate of paragraph IV filings increased significantly between 1991 and 1998, a time period when the FDA awarded *no* 180-day exclusivity periods to firms making paragraph IV certifications.[3] One factor contributing to the lack of awards was the FDA's position that 180-day exclusivity applied only if the first filer successfully defended its case. Despite this agency position, generic applicants continued to file applications containing paragraph IV challenges even though there did not appear to be a significant chance of actually obtaining 180-day exclusivity. This suggests that for the types of drugs where paragraph IV certifications are most likely, the value of the 180-day exclusivity period to generic manufacturers is not the sole or perhaps even the most important factor affecting the decision on whether to file a paragraph IV challenge.

[3] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (accessed 29 January 2007).

II. Introduction

A growing policy debate involves the possible effects of authorized generic prescription drugs on competition between generic and brand drug manufacturers, and on consumers' welfare. An increase in the prevalence of authorized generics in the past five years, and concerns that they could undermine incentives created by the 1984 Hatch-Waxman Act have sparked the debate. Authorized generic drugs are distinguished from other generic drugs because they rely directly on a brand manufacturer's new drug application ("NDA") for US marketing approval, rather than on an abbreviated new drug application ("ANDA") as is the case with traditional generic drugs.[4]

The Hatch-Waxman Act allows generic manufacturers to file an ANDA demonstrating bioequivalence to an innovator drug, rather than an NDA, which is far costlier as it requires data establishing safety and efficacy. Under the Hatch-Waxman Act, a generic manufacturer may file an ANDA prior to the expiration of the innovator's patents. Moreover, the first generic manufacturer to file a substantially complete ANDA with a paragraph IV certification (a patent challenge or claim of non-infringement) may be awarded an 180-day marketing "exclusivity" period during which no other ANDA filers can market their version of the drug dose.[5] Because competition is restricted during the 180-day exclusivity period, a generic manufacturer can earn substantial profits during the time it is the exclusive traditional generic supplier of a drug. These profits in part reflect higher prices to consumers compared to prices if multiple generics have entered. However, the high profits extracted during the 180-day exclusivity period also provide incentives for traditional generics to challenge innovator drug patents and potentially expedite the timing of generic entry, thereby benefiting consumers through lower prices.

Authorized generics rely on the brand manufacturer's NDA rather than on an ANDA. Consequently, authorized generics are currently allowed to enter during a traditional generic's 180-day exclusivity period. A specific focus of the current policy debate involves whether

[4] We use "traditional" generic to refer to a generic drug (or the manufacturer of a generic drug) that relies on an ANDA as opposed to the brand manufacturer's NDA.

[5] The generic manufacture will not obtain 180-day marketing exclusivity if their ANDA is challenged in court by the NDA holder and the court finds that the ANDA infringes on the NDA holder's patent(s).

marketing of authorized generic drugs should be allowed during a traditional generic manufacturer's 180-day exclusivity period.

In previous research we have demonstrated that authorized generic entry is likely to benefit consumers through lower prices during the 180-day exclusivity period and that long-run prices and shares are unlikely to be affected.[6] An important issue in this debate that previously has not been fully addressed due to a lack of data is the impact of anticipated authorized generic entry on incentives for generic manufacturers to file paragraph IV certifications and potentially expedite generic entry. The concern is that additional competition from authorized generic drugs during the 180-day exclusivity period means lower profits for generic manufacturers and reduced incentives to file paragraph IV certifications. If incentives to file paragraph IV certifications are reduced to the point that no generic manufacturer files a paragraph IV certification against a drug that otherwise would have been successfully challenged, then generic entry could be delayed.[7] In such a case, payers and out-of-pocket consumers would need to wait longer for the cost reduction of generic drugs to be realized.

In this paper we analyze several detailed datasets on paragraph IV certifications from the FDA, PhRMA members, and Paragraphfour.com. The evidence documents that as the prevalence of authorized generic entry has increased, there has been little overall change in the number of drugs facing paragraph IV certifications, the number of paragraph IV certifications filed per drug, or the timing of paragraph IV certifications relative to NCE approval. We find no evidence that authorized generic entry has adversely affected the extent and timing of paragraph IV certifications. Therefore, while consumer savings have been generated by authorized generics when they compete with traditional generics, consumers have not borne higher costs due to foregone paragraph IV certifications.

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[6] E. Berndt et al., "Authorized Generic Drugs, Price Competition, and Consumer Welfare," *Health Affairs*, forthcoming May/June 2007.

[7] If anticipated authorized generic entry deters a paragraph IV certification that would have been found to violate at least one of the NDA holder's patents in subsequent litigation, then generic entry is not delayed despite at least one paragraph IV certification being deterred.

III. Background

Over the past decade the frequency of paragraph IV certifications has grown substantially. 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.[8] The FDA's granting of 180-day exclusivity to generic manufacturers has also increased in recent years. The FDA granted 180-day exclusivity for 31 drugs between 1998 and 2002, compared to zero between 1992 and 1998.[9]

These changes in paragraph IV certifications and 180-day exclusivity in part reflect changes in the FDA's interpretation of the law governing the granting of an 180-day generic exclusivity period to the first generic to file a paragraph IV certification, made in light of relevant court decisions. First, in 1998, the FDA changed its interpretation of eligibility for 180-day exclusivity to include generic manufacturers whose paragraph IV certifications the NDA holder did not subsequently challenge. Prior to that time, a generic manufacturer had to defend successfully its paragraph IV certification in court in order to be granted the 180-day marketing exclusivity period. Second, in 2000 the FDA began allowing generics to enter the market and start their 180-day marketing exclusivity period following the first favorable court decision they received with respect to a challenged paragraph IV certification. Prior to that time, the generic was only granted the 180-day marketing exclusivity period following a favorable ruling by the "court that enters final judgment." Third, in 2003 the FDA started granting 180-day exclusivity to multiple applicants for the same drug/dose if those applicants filed their paragraph IV certifications on the same day as the first filer. The Medicare Modernization Act 2003 also confirmed in legislation this administrative rule change.

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[8] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (accessed 29 January 2007).

[9] Id.

Authorized generics have long existed and have attracted policy concerns in the past.[10] In the early 1990s, several brand-name drug manufacturers created subsidiaries that marketed generics. This resulted in a modest level of authorized generic entry at that time, but the frequency of authorized generic entry subsequently declined in the mid 1990s.[11] Authorized generic entry reemerged in the early 2000s, becoming increasingly frequent. These authorized generics were marketed both through subsidiaries of brand-name drug manufacturers and through contracts between separately held brand and generic drug manufacturers. The increase in authorized generics since 2003 has enabled brand manufacturers to capture some of the post-patent generic sales when only one traditional generic is present. Exhibit 1 illustrates the extent of authorized generic entry from 1992 through June 2006.[12]

In this paper, we focus on the effects of authorized generics on consumers through their possible impact on the extent and timing of generic entry. We do not focus on the implications for brand and generic drug manufacturer profits. The implications for consumers of authorized generic entry depend on the effects an authorized generic entrant has on at least three developments:

1. Relative generic and brand shares of the molecule;

2. Relative generic-to-brand price.

3. The timing of traditional generic entry;

In another paper (Berndt et al., 2007) we focus on the first two points, (1) and (2), and find that authorized generics likely benefit consumers through higher generic price discounts during the 180-day exclusivity period while having no significant effect on long-run generic price discounts

[10] Food and Drug Administration, "Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act," June 1998.

[11] M. Freudenheim, "All About Generic Pharmaceuticals; Now the Big Drug Makers are Imitating Their Imitators," The New York Times, 20 September 1992.

[12] Information on the prescription drugs experiencing authorized generic entry is based on a review of publicly available information. The results of this search are not necessarily exhaustive and there may be drugs that experienced authorized generic entry that were not identified in this research. To the extent that any authorized generic drugs are omitted from this list, we believe that there is no systematic bias in these omissions.

or generic shares of the molecule.[13] Specifically, we found evidence suggesting that a second generic entrant during the 180-day exclusivity period (e.g., an authorized generic entrant) substantially increases generic price discounts in the short-run, benefiting consumers. Also in Berndt et al., 2007, we present two findings supporting the argument that authorized generics are unlikely to adversely affect consumers in the long-run through generic prices and shares. First, we find that the incremental price discounts and generic penetration from additional generics tends to be negligible after the fourth or fifth entrant. As a result, even if anticipated authorized generics affect the long-run number of generic entrants it is unlikely to affect generic price discounts and shares for the many drugs with more than four or five generic entrants. Second, we find that the exclusivity period has no statistically significant effect on long-run generic price discounts or shares. We conclude that to the extent authorized generic entry may reduce traditional generic manufacturer expected gains from the exclusivity period, in most cases it will not harm consumers through lower long-run generic price discounts or shares.

In this paper we address the third possible impact, (3) the timing of traditional generic entry. The effects of authorized generics on the timing of traditional generic entry are complex and could either accelerate or delay traditional generic entry in some cases.[14] One possible impact of authorized generics could be to delay the timing of traditional generic entry if traditional generic drug companies were less aggressive in filing paragraph IV certifications. If traditional generic entry is substantially delayed, then the possible impact from (3) could be to increase consumer costs and offset the consumer benefits discussed above with respect to generic pricing and

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[13] E. Berndt et al., "Authorized Generic Drugs, Price Competition, and Consumer Welfare," *Health Affairs*, forthcoming May/June 2007.

[14] It is possible that for some drugs, authorized generic entry, or the threat thereof, could accelerate the timing of generic entry through "at-risk" launches to beat the authorized generic to market. In recent years some generic manufacturers have initiated "at risk" launches of products prior to a court decision on their challenged paragraph IV certifications. For example, Apotex initiated an at-risk launch of Plavix in August 2006, following settlement negotiations where the issue of authorized generics reportedly played a significant role; Teva and Barr entered into an agreement to initiate an at-risk launch of a generic version of Allegra in 2005; and Teva and Ranbaxy entered into an agreement to initiate an at-risk launch of a generic version of Accupril in 2004. Similarly, in some cases brand manufacturers have initiated authorized generic entry prior to the entry of an exclusive ANDA generic product. For example, Barr began marketing an authorized generic version of Bayer AG's Cipro in 2003, prior to entry of a traditional generic product.

shares. However, if authorized generics deter some, but not all, generic manufacturers from filing paragraph IV certifications for a drug (i.e., some generic manufacturers continue to file timely paragraph IV certifications), then generic entry is not delayed. For consumers to be harmed by increased costs, anticipated authorized generic entry would need to deter all generic manufacturers from filing a timely paragraph IV certification against a drug.[15]

[15] In referring to "harm" or "benefits" to consumers in this paper we focus on brand and generic prices, generic shares, and the timing of generic entry, but do not consider the effect on consumers of other factors such as new drug innovation.

IV. Data Description

We collected and analyzed three datasets on paragraph IV certifications, one maintained by the FDA,[16] a second based on a proprietary survey of PhRMA members,[17] and a third based on public court challenges and maintained by Paragraphfour.com,[18] as described below.

- The FDA data are available from the FDA website and contain all drugs facing at least one paragraph IV certification since March 2004. These data cover the universe of drugs facing paragraph IV certifications but contain little information beyond the fact of a certification, and the date on which the first paragraph IV certification was submitted to the FDA.

- PhRMA provided a dataset reflecting member survey responses to queries on their drugs that are either currently facing or have previously faced paragraph IV certifications since 1989. These data contain information on each paragraph IV certification filed against a drug/dose, such as which generic manufacturer filed the paragraph IV certification, when notice of it was received by the brand drug manufacturer, and NCE approval dates for the drug in question. However, the data only cover PhRMA members who chose to respond to the PhRMA survey and therefore do not represent all paragraph IV certifications. The PhRMA dataset contains data for about 73 percent of the products for which paragraph IV information was sought.[19]

- Paragraphfour.com provides data on all paragraph IV certifications that faced court challenges by brand drug manufacturers since 2003. These data contain information on

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[16] FDA, "Paragraph IV Patent Certifications As of August 18, 2006," <http://www.fda.gov/cder/ogd/ppiv.htm> (accessed 18 August 2006).

[17] Data were provided confidentially to the Analysis Group by PhRMA. The data are not publicly available.

[18] Data were acquired through an agreement with Paragraphfour.com <http://paragraphfour.com/> (accessed 1 September 2006).

[19] Product list was derived from a 2004 list of drugs that had faced a paragraph IV challenge, available from FDA's website, and supplemented with additional products not on this original list that were volunteered by PhRMA member companies.

generic companies whose paragraph IV certifications have been challenged in court by the brand drug manufacturer. Any paragraph IV certifications not facing a court challenge would not be included in the Paragraphfour.com data.

By relying on all three datasets and looking for common trends we mitigate drawbacks specific to the limitations of any individual dataset. Table 1 provides a brief summary of the data available from each of the data sources.

We analyzed these datasets for evidence that the increased frequency of authorized generic entry may delay independent generic entry by reducing generic manufacturer incentives to pursue paragraph IV certifications. Specifically, we examined the number of drugs facing paragraph IV certifications over time, the number of paragraph IV certifications per drug over time, and the length of time between NCE approval and the first paragraph IV certification over time. We also estimated the average number of drugs that could potentially receive a paragraph IV certification in order to provide some guidance on whether the rate or intensity of paragraph IV certifications is changing.[20]

[20] Using FDA data on NCE approvals, and assuming an average 12-year time span between NCE approval and initial generic entry, we calculate the stock of drugs potentially facing paragraph IV challenges as the total number of NCE approvals between the previous four and 12 years (e.g., the 2004 stock is the sum of NCE approvals between 1992 and 2000). Results are similar when 10 and 14 year time spans are employed instead of a 12-year time span.

V. Analysis of Paragraph IV Certifications Over Time

A variety of factors other than anticipated authorized generic entry may affect the extent of observed paragraph IV certification activity over time. As mentioned earlier in section III, changes in the FDA interpretation of the law governing the granting of 180-day generic exclusivity period may have encouraged greater paragraph IV certification activity in the late 1990s and early 2000s. Court rulings could have affected the anticipated success rate, and therefore incentives for paragraph IV certifications. Changes in the characteristics of the existing stock of drugs potentially vulnerable to paragraph IV certifications could also influence incentives for filing paragraph IV certifications. For example, the number of drugs available for potential paragraph IV certifications, their average revenues, or the perceived strength of their patents could all affect the extent of observed paragraph IV certifications. For the following analyses we are not able to directly control for all of these factors influencing incentives for paragraph IV certifications over time, although we are able to provide evidence on the stock of drugs available for potential paragraph IV certifications. Instead we look to broad trends in paragraph IV certifications to identify any influence of authorized generic entry.

A. Drugs Facing Paragraph IV Certifications

As a first analysis, we examined the number of distinct drugs facing their first paragraph IV certification over time using the FDA data. This dataset has the advantage of covering the universe of drugs facing paragraph IV certifications, but it only goes back to 2004. Exhibit 2 shows that although cyclicality is present, there is no downward trend in paragraph IV certifications. Instead, the number of distinct drugs facing their first paragraph IV certification increased from 41 in 2004 to 48 in 2005; the number of drug/doses facing their first paragraph IV certification also increased, from 47 in 2004 to 54 in 2005. Over that same time period the stock of drugs that could potentially receive a paragraph IV certification declined slightly from 268 in 2004 on average to 263 in 2005. Based on these data it appears that the rate of paragraph IV certifications may have increased modestly in recent years.[21]

[21] At the time the data were compiled, only the first two quarters of 2006 had available data. The number of drug/doses facing their first paragraph IV certification was 16 in the first two quarters of 2004, 25 in the first two

We then applied the same analysis that we used on the FDA data to the PhRMA and Paragraphfour.com data. Although neither the PhRMA nor the Paragraphfour.com data captures the universe of drugs facing paragraph IV certifications, we address this drawback by merging the two datasets in years where they overlapped. By relying on these merged data we are able to examine the number of drugs facing paragraph IV certifications over a much longer time frame. Our results in the early years are consistent with the findings of the FTC's 2002 study on generic drug entry prior to patent expiration.[22] Similar to the FTC study we find a dramatic increase in paragraph IV certifications between 1990 and 2000. Exhibit 3 shows an increase in the number of drugs facing their first paragraph IV certification by year from 1989 through 2006 (2003 to 2006 represent combined PhRMA and Paragraphfour.com data). This rapid increase in paragraph IV certifications appears to have leveled off in recent years, but remains at a very high level relative to prior years. Thirty-one drugs experienced a first paragraph IV certification in 2003 and 2004. This dropped slightly to 28 drugs in 2005, but in the first part of 2006, we observed 23 drugs experiencing their first paragraph IV certification. (The 2006 data is not full-year data, and only covers part of the year, i.e., through April for the PhRMA data and through August for the Paragraphfour.com data).

B. Number of Paragraph IV Certifications per Drug

The detailed information available in the PhRMA data allows us to examine additional trends in paragraph IV certifications that may influence consumers' welfare. For example, Exhibit 4 summarizes our finding that for the drugs in the PhRMA dataset, the average number of generic manufacturers filing a paragraph IV certification within six months of the first filing has increased from one and a half to almost two in recent years (the drop in 2006 is likely due to the fact that for many drugs experiencing paragraph IV certifications in 2006 we have less than six months of data to observe subsequent filings). This result suggests that for many drugs experiencing paragraph IV certifications there is not just one, but there are multiple generic

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quarters of 2005, and 23 in the first two quarters of 2006; the average stock of drugs potentially receiving a paragraph IV certification was 258 in 2006.

[22] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (accessed 29 January 2007).

manufacturers ready to challenge that drug's patents in a timely manner. Even if anticipated authorized generic entry deterred the generic manufacturer that would have been the first to file a paragraph IV certification, there are other generic manufacturers prepared to take its place. In order for generic entry to be substantially delayed, authorized generic entry would not only need to deter the first generic manufacturer that would file a paragraph IV certification, but all other generic manufacturers that could file a timely paragraph IV certification as well. In fact, in at least some cases anticipated authorized generic entry could accelerate the timing of generic entry. As noted in footnote 14, at-risk independent generic entry could be initiated in response to the prospect of authorized generic entry.

C. Timing of Paragraph IV Certification Following NCE Approval

We find that the number of drugs in the PhRMA data set experiencing paragraph IV certifications within six years following NCE approval has increased substantially in recent years. Two drugs experienced their initial paragraph IV certification within six years of NCE approval between 1991 and 1994, this increased to five drugs for the five year period 1995 to 1999 and further increased to 17 drugs for the five year period 2000 to 2005. The earliest that a paragraph IV certification can be filed is four years following initial NCE approval, so certifications occurring within the first six years following NCE approval are at a very early stage in the drug's life. Not only are more drugs facing paragraph IV certifications in recent years, but they are facing paragraph IV certifications at a very early stage.

All of these findings suggest that the recent increase in authorized generic drugs has had little or no impact on the extent and timing of paragraph IV certifications and therefore has not delayed independent generic drug entry. The level of paragraph IV certifications is at its highest historical level, indicating that substantial incentives must still exist for traditional generic entrants. At the same time, the rate of paragraph IV certifications has remained high, and even increased slightly in recent years, compared to the stock of potential drugs. As a result, the increase in authorized generic entry does not appear to have harmed consumers, and instead likely benefits them through lower generic prices during the 180-day marketing exclusivity period.

D. Authorized Generic Drugs, Paragraph IV Certifications, and Drug Market Size

Both the incentives to file a paragraph IV certification and to launch an authorized generic version of a drug are likely to increase with a drug's revenues. A branded drug with large pre-generic entry revenues represents a greater profit opportunity for traditional and authorized generic entrants. While anticipated authorized generic entry may reduce the amount of profits that a traditional generic could capture for these large revenue drugs, substantial potential gains from filing paragraph IV certifications are likely to remain.

To examine empirically whether large revenue branded drugs are more likely to experience both authorized generic entry and a larger number of generic manufacturers filing paragraph IV certifications, we merged drug revenue data from Verispan with the PhRMA paragraph IV data and the information on drugs experiencing authorized generic entry, as described in section III. One limitation of this analysis is that we only had revenues for the retail market. For some drugs this may substantially understate the true market size. In particular, drugs typically used in a hospital setting will have negligible retail revenues, but could in fact be very successful. Nevertheless, retail revenues do provide a sufficiently reliable measure for the vast majority of the drugs in our study.

In general, branded drugs experiencing authorized generic entry tend to have higher retail revenues than those not experiencing authorized generic entry. The median retail revenue in the year of the first paragraph IV certification for the 25 drugs experiencing authorized generic entry in our data set was $364 million, compared to $146 million for the 114 drugs not experiencing authorized generic entry.[23]

Exhibit 5 compares retail revenues and paragraph IV certifications for drugs experiencing and not experiencing authorized generic entry. Drugs experiencing authorized generic entry are more likely to be those with higher revenues prior to generic entry (56 percent of drugs

[23] The difference in mean revenues is smaller, with the 25 drugs experiencing authorized generic entry having a mean annual revenue in the year of paragraph IV certification of $510 million compared to $486 million for the 114 drugs not experiencing authorized generic entry.

experiencing authorized generic entry had revenues in excess of $250 million in the year they received their first paragraph IV certification compared to 41 percent for drugs not experiencing authorized generic entry). Furthermore, drugs with revenues exceeding $500 million (or even $50 million) and experiencing authorized generic entry had almost twice the number of generic manufacturers filing paragraph IV certifications (6.1 per drug) as drugs that did not experience authorized generic entry (3.4 per drug).

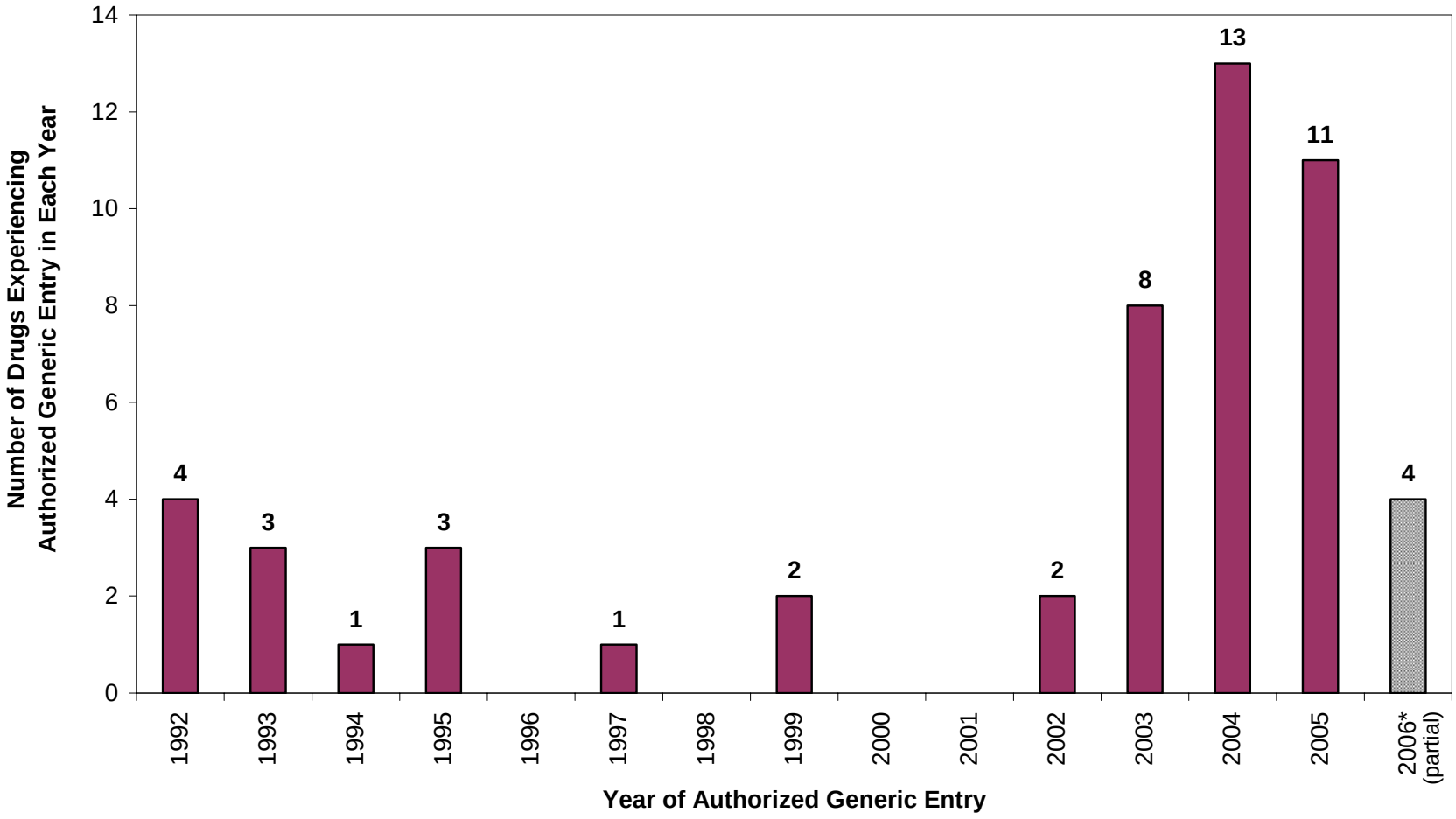
Drugs experiencing authorized generic entry are typically high revenue drugs, and these large revenue drugs are also likely to experience paragraph IV certifications from multiple generic manufacturers. Notwithstanding the potential impact of authorized generics on incentives for traditional generics to file paragraph IV certifications, significant financial incentives apparently still remain. Moreover, it is unlikely that anticipated authorized generic entry could deter all paragraph IV certifications and harm consumers through delayed generic entry.

VI. Conclusions

Based on an extensive review of multiple datasets we find no evidence that the recent increase in authorized generic drugs has had any negative impact on paragraph IV certification activity. We further find that much of the authorized generic activity is focused on relatively large revenue drugs. The potential gains from the 180-day marketing exclusivity period for these large revenue drugs are likely substantial. Even when anticipated authorized generic entry negatively impacts these expected gains, it is unlikely that it would do so to the extent necessary to deter all generic manufacturers from filing paragraph IV certifications. As a result, there is no evidence that the increasing prevalence of authorized generic drugs has harmed consumers through delayed generic entry.

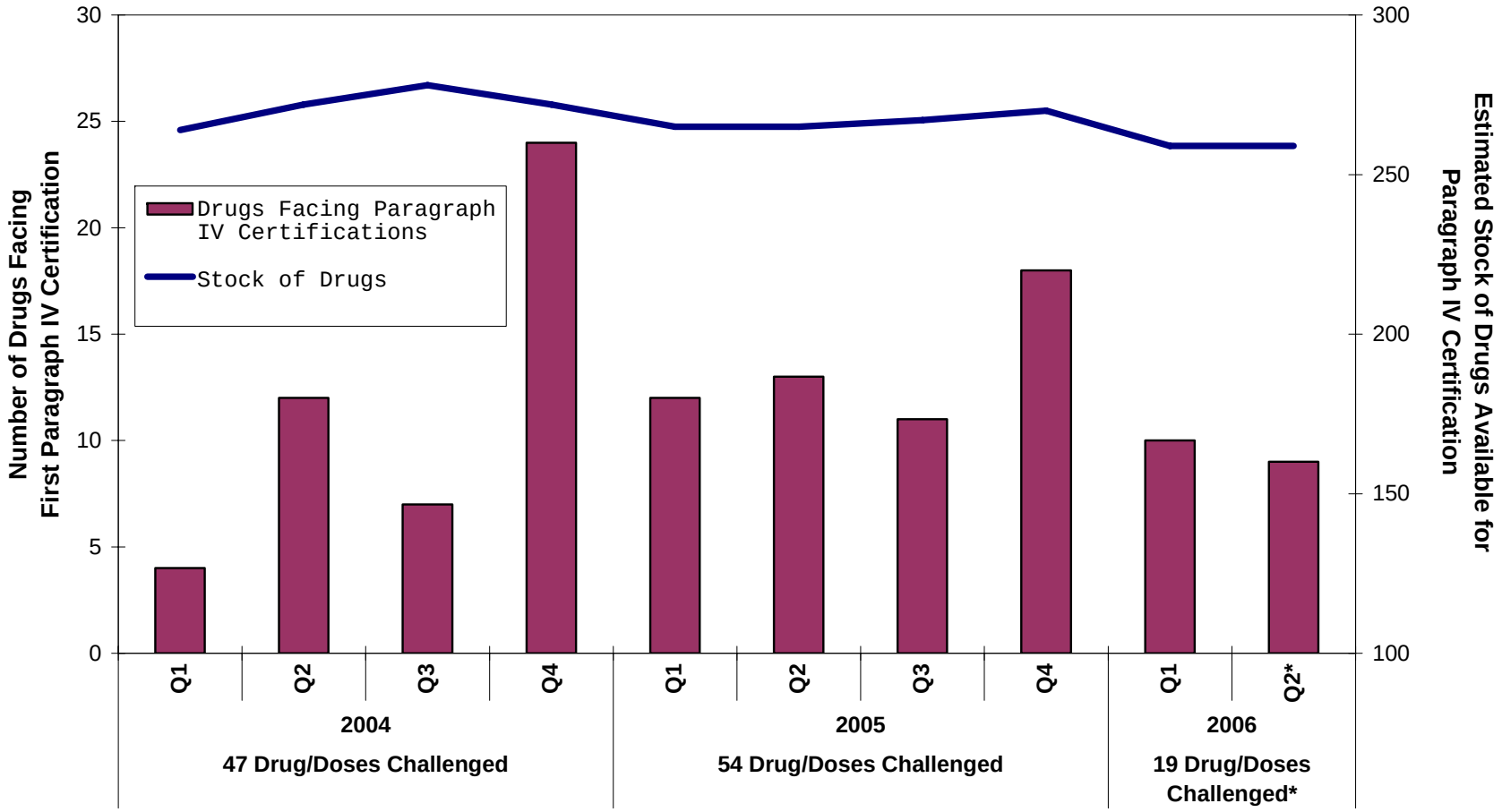
In earlier research, Berndt et al. (2007), we find that consumers are likely to benefit from authorized generic entry due to lower generic prices during the 180-day marketing exclusivity period. Taken together these analyses suggest that the recent increase in authorized generic drugs has benefited consumers.

Exhibit 1
Prevalence of Authorized Generic Entry by Year



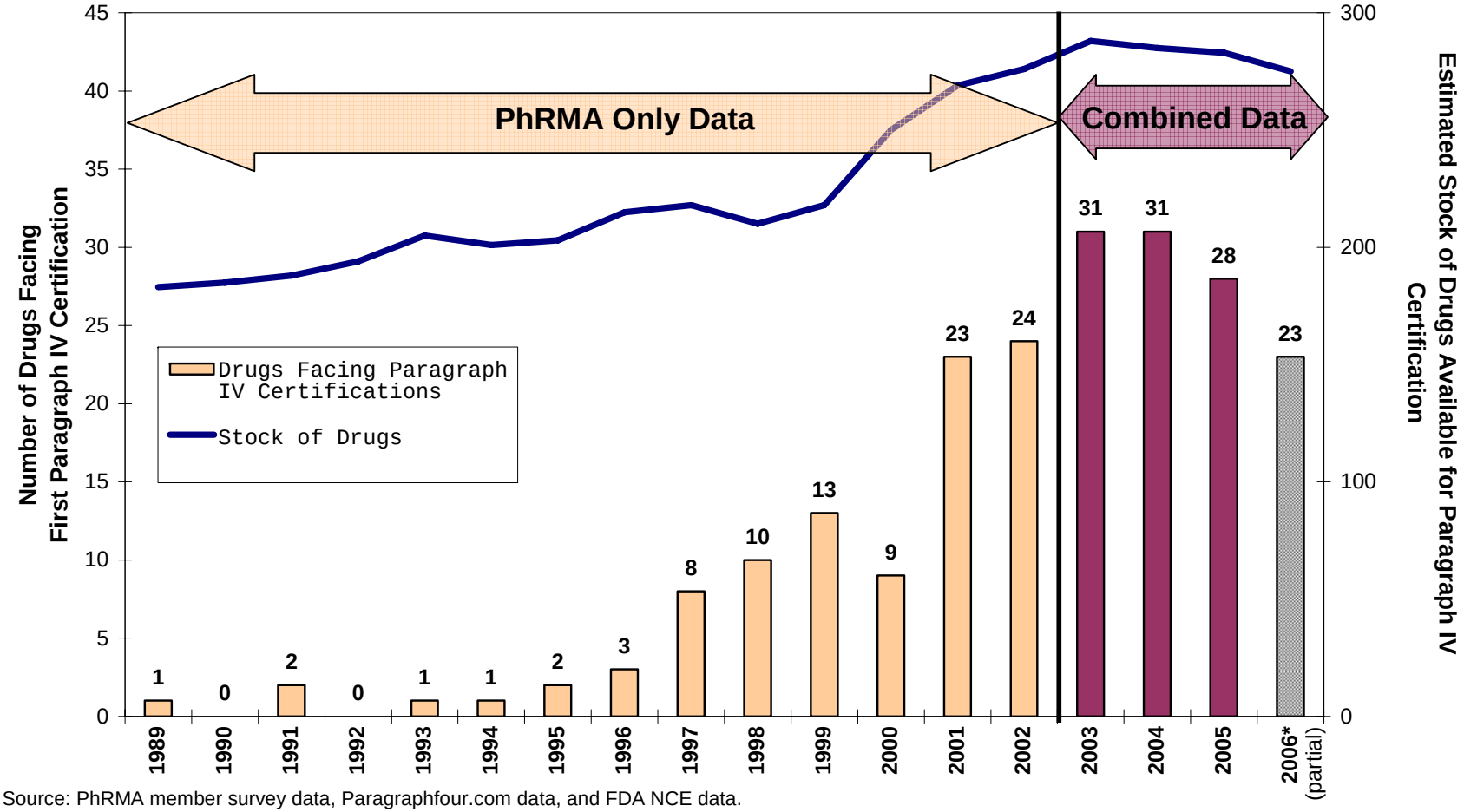
Source: Publicly source data on authorized generic entry (1992 through June 2006).
Note: 2006 reflects partial year data through June 2006.

Exhibit 2
FDA Data: Drugs Facing and Available for First Paragraph IV Certification



Source: http://www.fda.gov/cder/ogd/ppiv.htm (visited on 18 August 2006) and FDA NCE data.
Note: Some drugs facing paragraph IV certifications may be counted more than once if the ANDAs containing paragraph IV certifications for different doses of the drug are filed in separate submissions. Stock of drugs available for paragraph IV certifications is the sum of drug approvals between the previous four and 12 years.

Exhibit 3
PhRMA and Paragraphfour.com Data: Drugs Facing First Paragraph IV Certification



Source: PhRMA member survey data, Paragraphfour.com data, and FDA NCE data.
Note: If a drug has more than one dosage strength, the date of the first paragraph IV certification across all of the doses is used. Only partial year data are available for 2006 (through 4/06 for PhRMA and 9/1/06 for ParagraphIV.com). Stock of drugs available for paragraph IV certifications is the sum of drug approvals between the previous four and 12 years.

Exhibit 4
PhRMA Data: Summary of Paragraph IV Filings at the Drug Level By Year

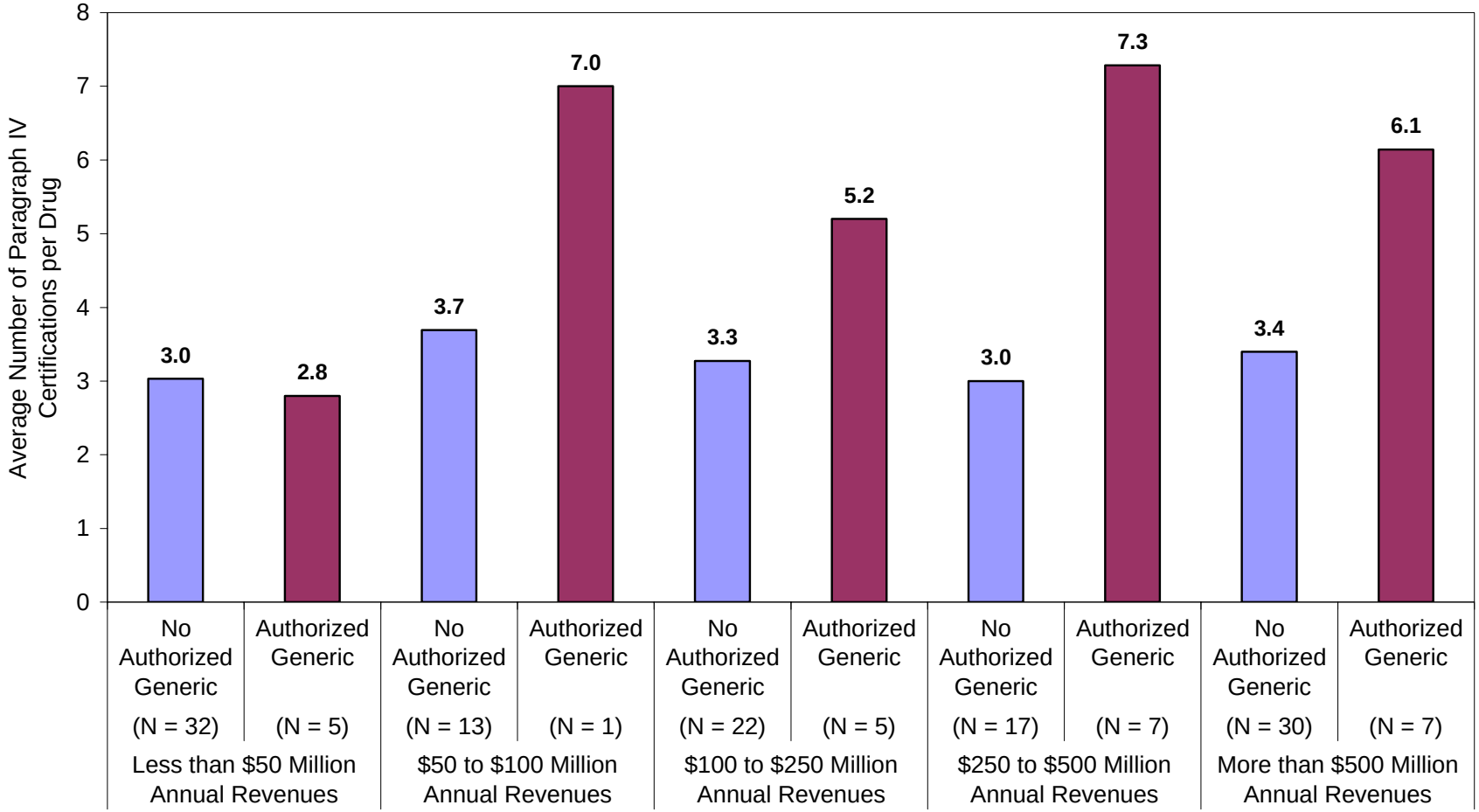
Year	Number of Drugs Facing First Paragraph IV Certification[1]	Average Number of Paragraph IV Certifications per Drug within Six Months of First Certification[2]
1989	1	1.0
1990	0	
1991	2	1.0
1992	0	
1993	1	1.0
1994	1	1.0
1995	2	1.0
1996	3	1.0
1997	8	2.3
1998	10	1.6
1999	13	1.5
2000	9	1.3
2001	23	1.4
2002	24	1.6
2003	19	1.5
2004	23	1.9
2005	13	1.8
2006 (partial)	4	1.3

Source: PhRMA member survey data. 2006 reflects partial year data through 4/06.
Notes:

[1] Total number of drugs facing their first Paragraph IV filing.

[2] Average number of unique generic manufacturers filing a paragraph IV certification against a drug within six months of the first filing and whose first filing was in the given year (e.g., if a drug had two paragraph IV certifications, one in November 1998 and one in January 1999, this would be counted as 2 challenges for a drug first challenged in 1998). The average is taken across all drugs facing their first certification in that year.

Exhibit 5
Authorized Generic Entry, Paragraph IV Certifications, and Drug Size



Source: PhRMA member survey data, public source data on authorized generic entry, and Verispan data on revenues.
Notes: Annual revenues are calculated for the year during which the drug received its first paragraph IV certification.

Table 1: Description of Paragraph IV Datasets

	FDA	PhRMA	Paragraphfour.com
Drugs Included	All drug/doses facing a paragraph IV certification	Drug/doses of PhRMA survey respondents facing a paragraph IV certification	All drug/doses facing a court challenged paragraph IV certification
Dates Covered	March 2, 2004 to May 2006	1989 to April 2006	2003 to September 1, 2006
Paragraph IV Certification Date Reported	Date of first ANDA filing with a paragraph IV certification against a drug/dose	Date notice of ANDA filing with a paragraph IV certification was received by the brand manufacturer. For all ANDA filings against a drug/dose	Date brand manufacturer files suit against an ANDA filer with a paragraph IV certification
Other Comments	Contains the universe of drugs with paragraph IV certifications since 2004 No information other than the date of the first paragraph IV certification	Based on drugs from a sample of brand manufacturers Contains information on each paragraph IV certification filed against a drug	Contains the universe of drugs with paragraph IV certifications subject to litigation since 2003 Information limited to drugs subject to patent litigation and defendants in those challenges