



New Law
Reins in
“Authorized Generics”
Despite
Generic Industry
Court Losses,
But Leaves
Several Ambiguities

By Jeffrey N. Wasserstein and Kurt R. Karst

“Authorized generics” have increasingly been the subject of debate as brand-name firms more frequently incorporate them into lifecycle management strategies, often to dilute the effects of generic competition. The recently enacted *Deficit Reduction Act of 2005 (DEFRA)*¹ may curb the marketing of some authorized generics through changes in the treatment of authorized generic pricing under the best price requirements of the Medicaid Drug Rebate Program, but the new law leaves several unanswered questions. This article discusses recent authorized generic litigation and DEFRA’s effects and ambiguities with respect to such products.

Authorized Generics

The Food and Drug Administration (FDA) has described an authorized generic as “[a]ny marketing by an [New Drug Application (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 [Abbreviated NDA (ANDA)] for that drug.”² Thus, instead of being manufactured and marketed by a generic drug firm pursuant to FDA’s approval of an ANDA, authorized generics are manufactured by, or under a licensing agreement with, the approved NDA holder for the brand-name drug, and are marketed by the brand-name firm or an affiliate, or, alternatively, another third party (e.g., an established generic firm) that splits the sales revenue or develops other royalty arrangements with the brand-name firm.

An authorized generic is like any other generic drug marketed in the United States insofar as being equivalent to a brand-name drug (since it is, in fact, the same drug). Although authorized generics are not listed in the *Orange Book*, they are fully substitutable for the brand-name drug.³ Authorized generics have been marketed as generic drugs for purposes of selling them at a discount off the brand-name drug price, and have been subject to different rebates than ANDA-approved generics. The introduction of an authorized generic to the market typically is timed to coincide with either the end of the NDA holder’s marketing exclusivity period for the brand-name drug before there is generic competition, or with a generic applicant’s 180-day exclusivity.⁴

Authorized Generics in Court

In July 2004, FDA denied two citizen petitions submitted by Teva Pharmaceuticals USA Inc. (Teva) and Mylan Pharmaceuticals Inc. (Mylan)

challenging the marketing of authorized generics. FDA concluded, in part, that “[t]he marketing of authorized generics during the 180-day exclusivity period is a long-standing, pro-competitive practice, permissible under the [*Federal Food, Drug, and Cosmetic Act (FD&C Act)*].”⁵

Both Teva and Mylan promptly filed complaints challenging FDA’s decision. Teva’s complaint, which was filed 20 August 2004 in the United States District Court for the District of Columbia, alleged, among other things, that FDA’s petition response is irreconcilable with the fundamental premise of the *Hatch-Waxman Act* (i.e., to balance the competing interests of the brand-name and generic drug industries), and asked the court to order FDA to prohibit the sale of authorized generics prior to the expiration of 180-day exclusivity.⁶ On 23 December 2004, the court granted summary judgment to FDA and stated that the *FD&C Act* “only prohibits the FDA from approving subsequent ANDAs until after the 180-day exclusivity period has expired. Nothing in the statute provides any support for the argument that FDA can prohibit NDA holders from entering the market with a brand generic drug during the exclusivity period.”⁷ Teva appealed to the United States Court of Appeals for the District of Columbia Circuit, which affirmed the district court’s judgment on 3 June 2005.⁸

Mylan initially filed a complaint on 4 August 2004 in the United States District Court for the Northern District of West Virginia, challenging FDA’s July 2004 petition response. The complaint was voluntarily dismissed on 30 August 2004, after Mylan decided to reconsider some of its arguments, and was later refiled on 12 November 2004.⁹ The refiled complaint alleged, in part, that FDA’s petition response violated the *FD&C Act*. On 29 September 2005, after adopting the Teva holding, the court dismissed the action and concluded that FDA’s interpretation of the *FD&C Act* was permissible.¹⁰ On 13 October 2005, Mylan appealed the decision to the United States Court of Appeals for the Fourth Circuit, which currently is considering the matter.

Some generic companies also have pursued state law claims against authorized generic distributors. For example, on 23 March 2004, Mylan filed a lawsuit in Superior Court in California against Procter & Gamble Co. (P&G) and Watson Pharmaceuticals Inc. (Watson) seeking declaratory and injunctive relief, as well as restitution, for Watson’s marketing of an authorized generic of P&G’s drug Macrobid.¹¹ Mylan’s complaint alleges that the authorized generic arrangement violates



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the California Business and Professions Code, § 17200 (fraudulent business practice) and § 17500 (untrue and misleading and false advertising). The case is still pending, but P&G has requested summary judgment.

On 8 June 2005, Endo Pharmaceuticals Inc. (EPI) filed a complaint against Purdue Pharma LP (Purdue), among other companies, in Superior Court in Connecticut, alleging a violation of the Connecticut *Unfair Trade Practices Act*.¹² EPI claimed that Purdue was engaged in unfair trade practices by launching an authorized generic version of Oxycontin. On 1 July 2005, the case was removed to the United States District Court for the District of Connecticut.¹³ On 19 September 2005, after EPI's motion for remand to state court was denied, EPI voluntarily dismissed the complaint without prejudice to refile.

The Medicaid Drug Rebate Statute

Since generic companies were having no success challenging the marketing of authorized generics under the *FD&C Act*, challenges also were made to the treatment of authorized generics under the Medicaid Drug Rebate Program. Under the Medicaid Drug Rebate Statute,¹⁴ manufacturers are required to pay quarterly rebates to each state Medicaid program for all units of covered outpatient drugs reimbursed by the state Medicaid program. The Unit Rebate Amount (URA) for innovator drugs (i.e., drugs approved pursuant to NDAs) is based in large part upon the greater of the difference between the Average Manufacturer Price (AMP), which is a weighted average price to wholesalers selling to the retail class of trade, and the best price to any commercial customer, or 15.1% of the AMP.¹⁵ Authorized generics, like the brand-name drug, are considered innovator drugs because they are marketed under NDAs, not ANDAs.¹⁶

Although the statute and Medicaid Rebate Agreement are ambiguous on the question of whether a brand manufacturer must include sales to an authorized generic distributor or the authorized generic distributor's sales to its customers in the brand manufacturer's best price, the Centers for Medicare & Medicaid Services (CMS) has historically tacitly acquiesced to the practice of drug manufacturers excluding authorized generics from the best price or AMP of the branded version. During the last year, CMS came under pressure from Congress to reexamine this policy. In February 2005, Health and Human Services (HHS) Secretary Michael Leavitt testified during a Senate Finance Committee hearing that CMS

could not administratively dictate that prices for an authorized generic affect the brand name drug's best price.¹⁷ The following day, HHS issued a clarification saying that CMS could revise the definition of best price to account for the price of an authorized generic if it did so through notice-and-comment rulemaking.¹⁸ On 18 March 2005, CMS Administrator Mark McClellan sent a letter to the Generic Pharmaceutical Association (GPhA) stating that "CMS is reviewing its policy on the calculation of prices for these drugs."¹⁹ GPhA had been urging CMS to require that an NDA drug's best price include the authorized generic price.

DEFRA

With the enactment of *DEFRA*, signed into law on 8 February 2006, generic manufacturers got much of what they were demanding.²⁰ Although *DEFRA* does not specifically refer to authorized generics, the bill requires a manufacturer that "approves, allows, or otherwise permits any drug of the manufacturer to be sold under [an NDA] approved under [FD&C Act § 505(c)]," to include "all such drugs that are sold under [an NDA] approved under [FD&C Act § 505(c)]" in the manufacturer's AMP and best price reports.²¹ Authorized generics (as with all NDA drugs) are drugs marketed pursuant to an application approved under *FD&C Act* § 505(c).

DEFRA is somewhat ambiguous as to what the manufacturer's best price report is required to include. The revised "best price" definition states:

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under [an NDA] approved under [FD&C Act § 505(c)]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States . . .²²

The bill also states that the best price of a brand manufacturer that "approves, allows, or otherwise permits any other drug of the manufacturer to be sold under [an NDA] approved under [FD&C Act § 505(c)], shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer . . ."²³ In other words, the brand manufacturer would have to

include all prices at which it sells the products, including prices to an authorized generic distributor. This will change the current treatment of sales to authorized generic distributors, which currently are excluded from best price.²⁴

There is some ambiguity, however, as to whether Congress intended to have the brand manufacturer include only the sale price to the authorized generic distributor or whether the brand manufacturer's best price should also include prices from the authorized generic distributor to its own customers.²⁵ Other *DEFRA* language requires a brand manufacturer to include in its best price reports "all such drugs that are sold under [an NDA] approved under [FD&C Act § 505(c)] . . ."²⁶ This seems to include the lowest price available to an entity that would otherwise be included in the best price, regardless of whether the lowest price was for the brand or the authorized generic; although the same provision then refers to the definition of best price discussed immediately above.²⁷ Perhaps the best reading of this provision is that a brand manufacturer must include only the sale price to the authorized generic distributor; however, CMS might interpret these provisions more broadly to include subsequent sales by the distributor. In either case, including the sales prices to authorized generic distributors is likely to increase the brand manufacturer's URA by lowering the best price.

Similarly, there is some ambiguity about what the brand manufacturer is required to include in the AMP. The current AMP definition is "the average price *paid to the manufacturer* for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."²⁸ This seems to suggest that a brand manufacturer would only be responsible for including its own sales. However, *DEFRA* also added a new section to the AMP definition:

In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under [an NDA] approved under [FD&C Act § 505(c), the definition of AMP] shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.²⁹

This new section suggests that a brand manufacturer's AMP may include the authorized generic distributor's prices as well, since it seems to be a separate, complete definition applicable to manufacturers described in it, and does not

specify that it is limited to prices paid to the brand manufacturer. Moreover, the redundancy in the two provisions seems to suggest that the latter is intended to add the requirement to include the prices at which the authorized generic distributor sells the drug. It is also possible to read the new provision as describing a special case of the current definition, which does limit AMP-includible sales to those "paid to the manufacturer" and not to a manufacturer's distributor. This reading would avoid the problem of including two sales of the same unit in AMP—the first from the manufacturer to the authorized generic distributor and the second from the distributor to its customer. Such "double counting" of a relatively low price could substantially reduce the brand manufacturer's AMP, to the detriment of the government. In any event, the new changes will most likely reduce the brand manufacturer's AMP.

Conclusion

Thus far, recent litigation surrounding authorized generics thus far has affirmed FDA's position that the marketing of such products does not violate the *FD&C Act*; however, generic companies may yet prevail in state courts. On the legislative front, although the authorized generic provision in *DEFRA* has revised the treatment of such products under the Medicaid Rebate Statute, which will negatively affect the continued viability of authorized generic arrangements, it also leaves several unanswered questions that will cause continued uncertainty in the treatment of authorized generic agreements under the Medicaid Rebate Program.

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REFERENCES

- 1 Pub. L. No. 109-171, 120 Stat. 4 (2006).
FDA Response, Docket Nos. 2004P-0075 & 2004P-0261, at 2 n. 2 (2 July 2004).
- 2 See e.g., *Orange Book* Preface, at xvi.
- 3 In certain circumstances, a generic applicant whose ANDA contains a Paragraph IV certification (i.e., a certification that a patent listed in the *Orange Book* for the reference listed NDA drug is invalid or will not be infringed by the manufacture, use, or sale of the generic drug) is protected from competition from subsequent generic versions of the same drug product for 180 days. This marketing protection is commonly referred to as "180-day exclusivity." On 4 April 2006, the Federal Trade Commission (FTC) announced that it is considering a study on authorized generics and their potential effect on 180-day exclusivity.
- 4 FDA Response, Docket Nos. 2004P-0075 & 2004P-0261, at 13. FDA has not yet responded to a third petition, which was sub-



mitted on behalf of Andrx Pharmaceuticals, Inc. on 23 December 2004. See Andrx Citizen Petition, Docket No. 2004P-0563 (23 December 2004). In that petition, Andrx argues that “the labeling and marketing of name brand drugs as generic versions is fundamentally misleading and therefore subject to FDA’s authority to prevent misbranding under section 502(a) of the Act.” *Id.* at 2. Congress addressed the issue of authorized generics, indirectly and on a limited basis, in § 1102(a)(1) of the *Medicare Prescription Drug, Improvement, and Modernization Act* of 2003 (*MMA*), Pub. L. No. 108-173, 117 Stat. 2066 (2003), which amended the *FD&C Act* to create § 505(j)(5)(B)(iv)(I). This section provides that an ANDA applicant who is a “first applicant” (as defined in § 505(j)(5)(B)(iv)(II) of the *FD&C Act*, and therefore eligible for 180-day exclusivity) who enters into an agreement to market an authorized generic and markets that drug cannot indefinitely “park” its exclusivity and delay generic competition while it markets the authorized generic.

6 See *Teva Pharma. v. Crawford*, 355 F.Supp.2d 111 (D.D.C. 2004).

7 *Id.* at 117 (emphasis in original).

8 See *Teva Pharma. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

9 In a letter to the court explaining the voluntary dismissal, Mylan’s counsel cited facts disclosed at the preliminary injunction hearing “that have a significant bearing on related aspects of the ‘authorized generic’ question and the considerable anti-competitive effects of authorized generics on the industry. The importance of these issues to Mylan and the entire generic pharmaceutical industry has led Mylan to conclude that all potential claims and aspects . . . should be presented for review

together in one action.” Letter from William Rakoczy (Counsel to Mylan) to The Honorable Irene Keeley, United States District Court for the Northern District of West Virginia, 30 August 2004, at 1.

- 10 See *Mylan Pharma. Inc. v. Thompson*, Case No. 1:04CV242 (N.D. W. Va. 2004).
- 11 See *Mylan Pharma. v. The Proctor & Gamble Corp.*, Case No. CGC-04-429860 (Cal. Super. Ct. 2004).
- 12 See *Endo Pharma., Inc. v. Purdue Pharma.*, Case No. CV-05-4005300-S (Ct. Super. Ct. 2005).
- 13 See *Endo Pharma., Inc. v. Purdue Pharma.*, Case No. 3:05CV1059 (D. Ct. 2005).
- 14 42 USC § 1396r-8.
- 15 *Id.* § 1396r-8(c).
- 16 See *id.* § 1396r-8(k)(7)(A).
- 17 See *Pink Sheet Daily*, CMS Lacks Authority To Include “Authorized” Generic In A Brand’s “Best Price” (16 February 2005).
- 18 See *Pink Sheet Daily*, “Authorized” Generic Could Be Added To Brand’s “Best Price,” HHS Clarifies (17 February 2005).
- 19 Letter from Mark B. McClellan, M.D., Ph.D., Administrator, CMS, to Kathleen Jaeger, President & CEO, GPhA (18 March 2005).
- 20 The version of *DEFRA* passed by the House of Representatives was not identical to the version passed by the Senate and signed by the President. Complaints have been filed in courts seeking a declaration that *DEFRA* is unconstitutional on the ground that the act is invalid because it failed to comply with the Bicameral Clause of the United States Constitution. See *The Washington Post*, Spending Measure Not a Law, Suit Says Senate, House Versions Are Different, (22 March 2006) A04.
- 21 *DEFRA* Conference Report § 6003. ANDA products, which are approved under *FD&C Act* § 505(j), not § 505(c) like NDAs, will presumably continue to be treated by CMS as non-innovator drugs that are separate from the reference listed NDA drug, with separate AMPs and with no effect on the best price of the NDA drug.
- 22 42 USC § 1396r-8(c)(1)(C)(i), as amended by Conference Report § 6003(b)(1)(A) (emphasis added).
- 23 *DEFRA* Conference Report § 6003(b)(1)(B)(iii) (emphasis added).
- 24 The effective date of these changes is 1 January 2007. *DEFRA* Conference Report § 6003(c). Taken literally, the first report submitted in 2007 covering the fourth quarter of 2006 would be required to include pricing for authorized generics. However, it is possible that CMS will determine to implement the new provisions beginning with the report for first quarter of 2007. There is not a “grandfather” provision to protect authorized generic arrangements entered into before 1 January 2007.
- 25 Presumably, the sale price from the brand manufacturer to the authorized generic distributor would most often be the lowest price, because the distributor would likely sell at some mark-up to make a profit, but it is conceivable that certain arrangements could result in the distributor selling to certain customers at a price lower than the price it paid the brand manufacturer.
- 26 *DEFRA* Conference Report § 6003(a)(1).
- 27 *Id.* § 6003(b)(1).
- 28 42 USC § 1396r-8(k)(1)(A), as amended by Conference Report § 6001(c) (emphasis added).
- 29 *DEFRA* Conference Report § 6003(b)(2).


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