A CBO STUDY

HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY

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FDA approval before the patent on the innovator drug they were copying had expired. Those changes both increased the probability that a generic copy would become available after patent expiration and reduced the average delay between patent expiration and generic entry from more than three years to less than three months.

As generic drugs are substituted for their more expensive brand-name counterparts, the average price of a prescription falls. In CBO's retail pharmacy data set, the average retail prescription price for a brand-name drug with generic substitutes was $37 in 1994. However, including prescriptions that were filled with a generic drug, the average prescription price for a multiple-source drug was only $26. Thus, generic substitution lowered the average cost for a multiple-source prescription by $11. That result is only a rough estimate, however, since prescriptions may somewhat misrepresent the relative quantities of brand-name and generic drugs sold. For example, if generic drugs tend to have more pills dispensed per prescription than their brand-name counterparts, that estimate would understate the degree to which generic substitution reduces the average cost of a prescription. If generic drugs tend to have fewer pills dispensed, the reverse would be true.

Effect of Generic Entry on Sales

For many innovator drugs whose patents have recently expired, generic copies quickly gain a large share of the market. CBO's retail pharmacy data set includes 21 innovator drugs whose first generic competitors entered the market between 1991 and 1993. During the first full calendar year in which those 21 drugs faced generic competition, generics already accounted for an average of 44 percent of prescriptions dispensed through pharmacies.[49] Generics also cost one-fourth less than the brand-name drugs, on average, at retail prices. For seven of those drugs (Anaprox, Feldene, Lopid, Naprosyn, Pamelor, Tavist, and Xanax), generics had gained 65 percent or more of the innovator's market by 1994. For all but two of the 21 drugs, generic entry occurred within one year of patent expiration, and in many cases within three months.[50]

Other studies examining the size of the generic market after patent expiration have yielded slightly different results. Those appear to be attributable to differences in the sample of drugs studied as well as to small differences in method. A study by Grabowski and Vernon found that 11 drugs whose patents expired between 1989 and 1992 had an average generic market share (measured by quantity sold) of 50 percent in the first year after generic entry, and eight drugs whose patents expired in the 1986-1987 period had an average generic market share of 38 percent.[51] The study also found that the wholesale price of generic drugs was about half that of brand-name drugs in the first year after generic entry.

Grabowski and Vernon's average generic market share for the 1989-1992 period is higher than that measured by CBO for the 1991-1993 period in part because CBO included the quantity sold of all dosage forms of the brand-name drug, even those for which generic entry had not occurred, when calculating the percentage of total prescriptions filled with a generic drug. That method takes account of the option that brand-name manufacturers have to introduce a new dosage form (such as an extended-release capsule) just as a drug's patent is about to expire, so as to benefit from a three-year exclusivity period on that dosage form. Occasionally, manufacturers can even get a separate patent on a new dosage form. Of the 21 brand-name drugs that CBO analyzed, four had an advanced dosage form (Sinemet CR, Cardizem CD, Toprol XL, and Procardia XL) that was not yet available from generic manufacturers.

The Congress's former Office of Technology Assessment (OTA) also studied the erosion of brand-name drug sales after patent expiration.[52] In OTA's study of 35 brand-name drugs that lost patent protec-

49 The 44 percent average is weighted by sales revenues of the innovator drugs The unweighted average is 42.8 percent.

50. The two drugs for which generic entry took more than a year after patent expiration had retail pharmacy sales of about $130 million in 1991.

51. Henry Grabowski and John Vernon, "Longer Patents for Increased Generic Competition in the U.S.: The Hatch-Waxman Act After One Decade," *PharmacoEconomics* (1996).

52 Office of Technology Assessment, *Pharmaceutical R&D*, Table F-3, p. 297