The Federal Trade Commission recently announced its intention to issue broad subpoenas to almost 200 companies in the pharmaceutical industry. That industry has become a favorite target of antitrust lawsuits in recent years, but these subpoenas will not be directed at investigating possible antitrust violations. Instead they will be aimed at collecting information so that the FTC can study the “competitive effects of authorized generic drugs in the prescription drug marketplace.”

The FTC will consider both short- and long-term competitive effects: (1) how the introduction of authorized generics impacts prices in the market, and (2) to what extent their introduction may reduce the incentives for generic companies to challenge patents before they expire in order to bring new generics to market sooner.

Measuring speculative effects may be difficult. But the FTC study, if conducted in an objective manner, should provide solid data and clear the smoke created by tirades against authorized generics, such as David Balto’s March 20 Legal Times commentary (“We’ll Sell Generics, Too,” Page 39), which argues that innovator drug makers are gaming the regulatory system and harming competition.

There is little doubt that authorized generics benefit consumers by driving down prices for generic drugs. They are legal under the current regulatory scheme, and the suggestion that their introduction somehow violates antitrust law is baseless.

Generic companies, however, have a strong incentive to change the regulations and thereby limit competition. They argue that competition from authorized generics, by reducing their profits, reduces their incentive to introduce new generic drugs.

Policy-makers need to understand that any attempt to alter the current balance between generic and pioneer drug makers and to increase incentives to introduce generic drugs may reduce incentives to develop innovative drugs. Encouraging the introduction of generics by forcing consumers to pay more makes no sense whatsoever.

**AUTHORIZED GENERICS**

To understand the current debate around authorized generics, it is important to start by explaining what authorized generics are and how they are regulated by the Food and Drug Administration.

An innovator or pioneer drug company must overcome a number of obstacles before marketing a new brand-name drug, such as Lipitor or Plavix. In addition to conducting research and development, the innovator must undertake expensive, time-consuming clinical trials to establish safety and efficacy, and it must obtain FDA approval to market under a New Drug Application (NDA).

A generic manufacturer can shortcut many of these requirements. Under the 1984 Hatch-Waxman Act, a generic manufacturer need only show bioequivalence to an approved drug. The generic manufacturer can piggyback on the human trials conducted by the innovator and cite these trials in a shorter application, called an Abbreviated New Drug Application (ANDA).

So-called authorized generics do not require an ANDA. The NDA holder typically manufactures and distributes a generic version itself or authorizes a third party to distribute the drug as a generic. Since such authorized generics are identical to the brand-name drug (simply in a different package), the FDA has made clear that they can be sold under the pioneer’s NDA without any additional approval.

Most generic drugs are introduced after patents on the pioneer drug have expired. Under Hatch-Waxman, however, a generic manufacturer may seek to enter sooner if it can establish that its bioequivalent drug does not infringe the innovator’s patent or that the patent is invalid. The act provides an incentive to the first generic manufacturer to file an ANDA and challenge unexpired patents. Such first filers are insulated from competition from subsequent filers for 180 days.
Although this period is commonly called the 180-day exclusivity period, that term is a misnomer because the first filer is not protected from all competition. The generic manufacturer still faces competition from the innovator’s brand-name drug and possibly from other generic manufacturers who may have filed the first ANDAs for different dosage strengths of the same drug.

**LEGAL MARKETING**

Likewise, the first filer is not protected from competition from the innovator if the innovator decides to market an authorized generic. The Hatch-Waxman Act protects a first filer only from subsequent ANDA filers. Because authorized generics are marketed under the innovator’s NDA, the FDA cannot prevent them from being marketed during the “exclusivity” period.

The FDA and every court that has looked at this issue, including the U.S. Court of Appeals for the D.C. Circuit last year in *Teva v. Crawford*, have come to this same inexcusable conclusion. According to the FDA, it “has no legal basis on which to prevent an innovator company from marketing its approved NDA product at a price that is competitive with that charged by a first generic applicant.” The courts have agreed, finding the statute unambiguous and concluding that it would therefore be inappropriate to disturb the Hatch-Waxman balance.

Given this clear guidance, Balto’s contention that the FDA has “eschewed” its regulatory role is difficult to understand. Even if Hatch-Waxman were not clear, any attempt to prevent an innovator company from competing with generic companies—by controlling the price at which the innovator can sell or the means by which it can distribute—would be unwise. Preventing an innovator from offering products for a lower price would be inconsistent with the goals of Hatch-Waxman and the antitrust laws.

**PROMOTING COMPETITION**

Balto, a former FTC policy official, raises “antitrust concerns,” suggesting that the introduction of authorized generics is somehow harmful and that they are being used by pharmaceutical companies to eliminate generic competition, after which they will increase prices.

Fortunately, modern antitrust law recognizes that price competition is good for consumers and has severely restricted disgruntled competitors’ abilities to attack rivals for alleged predatory pricing, at least as long as the goods are sold above cost. The suggestion that the mere introduction of a product can be predatory has long been rejected.

FTC Commissioner Jon Leibowitz, who encouraged the agency to study the impact of authorized generics, has even said publicly that he is not persuaded by generic companies’ claims that authorized generics violate antitrust laws.

Indeed, if there is an antitrust risk worth evaluating, it is the agreements between pioneer manufacturers and first filers that bar the pioneer from introducing an authorized generic. While agreements between pioneer manufacturers and first filers that settle patent litigation may on balance be pro-competitive, if such agreements limit competition that would likely arise in the absence of the agreement, including competition from an authorized generic, they may be anti-competitive and illegal.

Authorized generics promote competition by lowering pharmaceutical prices. Because first filers are protected from competition from most generics (other than authorized generics) during the 180-day exclusivity period, the FDA has found that they are able to apply a “substantial markup” during this period. And this is consistent with FTC and FDA studies that have found that the prices of generic drugs decline as the number of generic rivals increases.

In fact, available data suggest consumers only receive a small discount—estimates range from as low as 5 percent to 35 percent—from the brand-name drug price if there is only one generic in the market. If there is a second generic, the data show that prices fall to around 50 percent.

These numbers are radically different from the numbers offered by Balto. He suggests that authorized generics are priced at “only a small margin below the branded drug,” as little as 5 percent, while other generics are “typically priced at about 80 percent less than the corresponding brands.” It is difficult to fathom how an authorized generic would gain any market share if that were the case.

The reality is that authorized generics are produced by pioneer companies facing drastic declines in sales, seeking to preserve revenues by matching generic competition. Pioneer manufacturers must introduce an authorized generic, rather than merely lower the price on the branded product, to retain sales, given the number of state mandatory substitution laws and formulary tiers requiring generic purchases.

**SPECULATIVE HARS**

In response to the certain benefit to consumers of lower prices from authorized generics, generic manufacturers offer a speculative argument that authorized generics may result in fewer ANDAs.

Generic manufacturers argue that they are less likely to file ANDAs and challenge patents when they lose sales to authorized generics. It is true, of course, that competition from authorized generics may have a marginal effect in discouraging the filing of some unpromising ANDAs.

Most of the evidence suggests that authorized generics will not significantly decrease the filing of ANDAs. Any reduction will likely be for generic versions of the smallest-revenue, least-profitable drugs. The cost-benefit analysis for generic companies is likely to change only in the unusual case when (1) expected profits with competition from an authorized generic are less than the costs of bringing a generic to market, but (2) expected profits in the absence of competition from an authorized generic are more than these costs.

According to the FDA, it often sees as many as five ANDAs for a single drug, even though the generic manufacturers know they will not be entitled to an exclusivity period. The FDA has noted that the willingness of multiple companies to file ANDAs and expose themselves to patent litigation—without any prospect of sharing exclusivity—is evidence that ANDAs will still be filed despite competition from authorized generics. According to the FDA, more than 85 ANDA challenges have been filed in the last two years.

All these ANDAs have been filed despite the fact that, accord-
ing to some reports, every “blockbuster” generic launched after 2003 has been met by an authorized generic.

Any change in the current Hatch-Waxman balance that helps generic manufacturers could also reduce incentives for the development of new drugs by reducing profits for pioneer manufacturers. If the potential profits for a generic version of a drug are so low that a change in regulations will discourage generic companies from entering the market, it is likely that the branded drug is not very profitable either. It’s possible that without the additional revenues from authorized generic sales, the drug innovator might not be able to incur the expense of inventing, testing, and bringing a new drug to market.

This scenario may be just as speculative as the argument that authorized generics will lead to fewer ANDA filings. But it does remind us that there are two sides to the Hatch-Waxman balancing act that must be considered before any changes are made to current law.

What is certain is that authorized generics provide consumers with lower prices. Before depriving consumers of this benefit, we hope that the FTC study will contribute to the debate by collecting real evidence, not baseless speculation, about the generic market.

M. Howard Morse is a partner in the D.C. office and co-chair of the antitrust group of Drinker Biddle & Reath. He previously served as assistant director of the FTC’s Bureau of Competition. Richard E. Coe is an associate in the firm’s Philadelphia office. They can be reached at howard.morse@dbr.com and richard.coe@dbr.com.