Brand drug manufacturers are no strangers to antitrust accusations when it comes to their complicated relationship with generic competitors — most obviously with respect to reverse payment settlements. But the massive and massively complex regulatory scheme under which drugs are regulated has provided other opportunities for regulatory legerdemain with potentially anticompetitive effect, as well.

In particular, some FTC Commissioners have raised concerns that brand drug companies have been taking advantage of an FDA drug safety program — the Risk Evaluation and Mitigation Strategies program, or “REMS” — to delay or prevent generic entry.

Drugs subject to a REMS restricted distribution program are difficult to obtain through market channels and not otherwise readily available, even for would-be generic manufacturers that need samples in order to perform the tests required to receive FDA approval to market their products. REMS allows (requires, in fact) brand manufacturers to restrict the distribution of certain drugs that present safety or abuse risks, creating an opportunity for branded drug manufacturers to take advantage of imprecise regulatory requirements by inappropriately limiting access by generic manufacturers.

The FTC has not (yet) brought an enforcement action, but it has opened several investigations, and filed an amicus brief in a private-party litigation. Generic drug companies have filed several antitrust claims against branded drug companies and raised concerns with the FDA.

The problem, however, is that even if these companies are using REMS to delay generics, such a practice makes for a terrible antitrust case. Not only does the existence of a regulatory scheme arguably set Trinko squarely in the way of a successful antitrust case, but the sort of refusal to deal claims at issue here (as in Trinko) are rightly difficult to win because, as the DOJ’s Section 2 Report notes, “there likely are few circumstances where forced sharing would help consumers in the long run.”

But just because there isn’t a viable antitrust case doesn’t mean there isn’t still a competition problem. But in this case, it’s a problem of regulatory failure. Companies rationally take advantage of poorly written federal laws and regulations in order to tilt the market to their own advantage. It’s no less problematic for the market, but its solution is much more straightforward, if politically more difficult.

Thus it’s heartening to see that Senator Mike Lee (R-UT), along with three of his colleagues
(Patrick Leahy (D-VT), Chuck Grassley (R-IA), and Amy Klobuchar (D-MN)), has proposed a novel but efficient way to correct these bureaucracy-generated distortions in the pharmaceutical market without resorting to the “blunt instrument” of antitrust law. As the bill notes:

While the antitrust laws may address actions by license holders who impede the prompt negotiation and development on commercially reasonable terms of a single, shared system of elements to assure safe use, a more tailored legal pathway would help ensure that license holders negotiate such agreements in good faith and in a timely manner, facilitating competition in the marketplace for drugs and biological products.

The legislative solution put forward by the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016 targets the right culprit: the poor regulatory drafting that permits possibly anticompetitive conduct to take place. Moreover, the bill refrains from creating a per se rule, instead implementing several features that should still enable brand manufacturers to legitimately restrict access to drug samples when appropriate.

In essence, Senator Lee’s bill introduces a third party (in this case, the Secretary of Health and Human Services) who is capable of determining whether an eligible generic manufacturer is able to comply with REMS restrictions — thus bypassing any bias on the part of the brand manufacturer. Where the Secretary determines that a generic firm meets the REMS requirements, the bill also creates a narrow cause of action for this narrow class of plaintiffs, allowing suits against certain brand manufacturers who — despite the prohibition on using REMS to delay generics — nevertheless misuse the process to delay competitive entry.

**Background on REMS**

The REMS program was introduced as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Following the withdrawal of Vioxx, an arthritis pain reliever, from the market because of a post-approval linkage of the drug to heart attacks, the FDA was under considerable fire, and there was a serious risk that fewer and fewer net beneficial drugs would be approved. The REMS program was introduced by Congress as a mechanism to ensure that society could reap the benefits from particularly risky drugs and biologics — rather than the FDA preventing them from entering the market at all. It accomplishes this by ensuring (among other things) that brands and generics adopt appropriate safety protocols for distribution and use of drugs — particularly when a drug has the potential to cause serious side effects, or has an unusually high abuse profile.

The FDA-determined REMS protocols can range from the simple (e.g., requiring a medication guide or a package insert about potential risks) to the more burdensome (including restrictions on a drug’s sale and distribution, or what the FDA calls “Elements to
Assure Safe Use” (“ETASU”). Most relevant here, the REMS process seems to allow brands considerable leeway to determine whether generic manufacturers are compliant or able to comply with ETASUs. Given this discretion, it is no surprise that brand manufacturers may be tempted to block competition by citing “safety concerns.”

Although the FDA specifically forbids the use of REMS to block lower-cost, generic alternatives from entering the market (of course), almost immediately following the law’s enactment, certain less-scrupulous branded pharmaceutical companies began using REMS for just that purpose (also, of course).

**REMS abuse**

To enter into pharmaceutical markets that no longer have any underlying IP protections, manufactures must submit to the FDA an Abbreviated New Drug Application (ANDA) for a generic, or an Abbreviated Biologic License Application (ABLA) for a biosimilar, of the brand drug. The purpose is to prove to the FDA that the competing product is as safe and effective as the branded reference product. In order to perform the testing sufficient to prove efficacy and safety, generic and biosimilar drug manufacturers must acquire a sample (many samples, in fact) of the reference product they are trying to replicate.

For the narrow class of dangerous or highly abused drugs, generic manufacturers are forced to comply with any REMS restrictions placed upon the brand manufacturer — even when the terms require the brand manufacturer to tightly control the distribution of its product.

And therein lies the problem. Because the brand manufacturer controls access to its products, it can refuse to provide the needed samples, using REMS as an excuse. In theory, it may be true in certain cases that a brand manufacturer is justified in refusing to distribute samples of its product, of course; some would-be generic manufacturers certainly may not meet the requisite standards for safety and security.

But in practice it turns out that most of the (known) examples of brands refusing to provide samples happen across the board — they preclude essentially all generic competition, not just the few firms that might have insufficient safeguards. It’s extremely difficult to justify such refusals on the basis of a generic manufacturer’s suitability when all would-be generic competitors are denied access, including well-established, high-quality manufacturers.

But, for a few brand manufacturers, at least, that seems to be how the REMS program is implemented. Thus, for example, Jon Haas, director of patient access at Turing Pharmaceuticals, referred to the practice of denying generics samples *this way*:

> Most likely I would block that purchase... We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It’s inevitable. They seem to figure out a way [to make generics], no matter what. But I’m certainly not going to make it easier for them. We’re spending millions and millions in
research to find a better Daraprim, if you will.

As currently drafted, the REMS program gives branded manufacturers the ability to limit competition by stringing along negotiations for product samples for months, if not years. Although access to a few samples for testing is seemingly such a small, trivial thing, the ability to block this access allows a brand manufacturer to limit competition (at least from bioequivalent and generic drugs; obviously competition between competing branded drugs remains).

And even if a generic competitor manages to get ahold of samples, the law creates an additional wrinkle by imposing a requirement that brand and generic manufacturers enter into a single shared REMS plan for bioequivalent and generic drugs. But negotiating the particulars of the single, shared program can drag on for years. Consequently, even when a generic manufacturer has received the necessary samples, performed the requisite testing, and been approved by the FDA to sell a competing drug, it still may effectively be barred from entering the marketplace because of REMS.

The number of drugs covered by REMS is small: fewer than 100 in a universe of several thousand FDA-approved drugs. And the number of these alleged to be subject to abuse is much smaller still. Nonetheless, abuse of this regulation by certain brand manufacturers has likely limited competition and increased prices.

**Antitrust is not the answer**

Whether the complex, underlying regulatory scheme that allocates the relative rights of brands and generics — and that balances safety against access — gets the balance correct or not is an open question, to be sure. But given the regulatory framework we have and the perceived need for some sort of safety controls around access to samples and for shared REMS plans, the law should at least work to do what it intends, without creating an opportunity for harmful manipulation. Yet it appears that the ambiguity of the current law has allowed some brand manufacturers to exploit these safety protections to limit competition.

As noted above, some are quite keen to make this an antitrust issue. But, as also noted, antitrust is a poor fit for handling such abuses.

First, antitrust law has an uneasy relationship with other regulatory schemes. Not least because of *Trinko*, it is a tough case to make that brand manufacturers are violating antitrust laws when they rely upon legal obligations under a safety program that is essentially designed to limit generic entry on safety grounds. The issue is all the more properly removed from the realm of antitrust enforcement given that the problem is actually one of regulatory failure, not market failure.

Second, antitrust law doesn’t impose a duty to deal with rivals except in very limited circumstances. In *Trinko*, for example, the Court rejected the invitation to extend a duty to
deal to situations where an existing, voluntary economic relationship wasn’t terminated. By definition this is unlikely to be the case here where the alleged refusal to deal is what prevents the generic from entering the market in the first place. The logic behind *Trinko* (and a host of other cases that have limited competitors’ obligations to assist their rivals) was to restrict duty to deal cases to those rare circumstances where it reliably leads to long-term competitive harm — not where it amounts to a perfectly legitimate effort to compete without giving rivals a leg-up.

But antitrust is such a powerful tool and such a flexible “catch-all” regulation, that there are always efforts to thwart reasonable limits on its use. As several of us at TOTM have written about at length in the past, former FTC Commissioner Rosch and former FTC Chairman Leibowitz were vocal proponents of using Section 5 of the FTC Act to circumvent sensible judicial limits on making out and winning antitrust claims, arguing that the limits were meant only for private plaintiffs — not (implicitly infallible) government enforcers. Although no one at the FTC has yet (publicly) suggested bringing a REMS case as a standalone Section 5 case, such a case would be consistent with the sorts of theories that animated past standalone Section 5 cases.

Again, this approach serves as an end-run around the reasonable judicial constraints that evolved as a result of judges actually examining the facts of individual cases over time, and is a misguided way of dealing with what is, after all, fundamentally a regulatory design problem.

**The CREATES Act**

Senator Lee’s bill, on the other hand, aims to solve the problem with a more straightforward approach by improving the existing regulatory mechanism and by adding a limited judicial remedy to incentivize compliance under the amended regulatory scheme. In summary:

- The bill creates a cause of action for a refusal to deal only where plaintiff can prove, by a preponderance of the evidence, that certain well-defined conditions are met.
- For samples, if a drug is not covered by a REMS, or if the generic manufacturer is specifically authorized, then the generic can sue if it doesn’t receive sufficient quantities of samples on commercially reasonable terms. This is not a per se offense subject to outsized antitrust damages. Instead, the remedy is a limited injunction ensuring the sale of samples on commercially reasonable terms, reasonable attorneys’ fees, and a monetary fine limited to revenue earned from sale of the drug during the refusal period.
- The bill also gives a brand manufacturer an affirmative defense if it can prove by a preponderance of the evidence that, regardless of its own refusal to supply them, samples were nevertheless available elsewhere on commercially reasonable terms, or where the brand manufacturer is unable to supply the samples because it does not actually produce or market the drug.
- In order to deal with the REMS process problems, the bill creates similar rights with similar limitations when the license holders and generics cannot come to an
agreement about a shared REMS on commercially reasonable terms within 120 days of first contact by an eligible developer.

- The bill also explicitly limits brand manufacturers’ liability for claims “arising out of the failure of an [eligible generic manufacturer] to follow adequate safeguards,” thus removing one of the (perfectly legitimate) objections to the bill pressed by brand manufacturers.

The primary remedy is limited, injunctive relief to end the delay. And brands are protected from frivolous litigation by an affirmative defense under which they need only show that the product is available for purchase on reasonable terms elsewhere. Damages are similarly limited and are awarded only if a court finds that the brand manufacturer lacked a legitimate business justification for its conduct (which, under the drug safety regime, means essentially a reasonable belief that its own REMS plan would be violated by dealing with the generic entrant). And monetary damages do not include punitive damages.

Finally, the proposed bill completely avoids the question of whether antitrust laws are applicable, leaving that possibility open to determination by courts — as is appropriate. Moreover, by establishing even more clearly the comprehensive regulatory regime governing potential generic entrants’ access to dangerous drugs, the bill would, given the holding in Trinko, probably make application of antitrust laws here considerably less likely.

Ultimately Senator Lee’s bill is a well-thought-out and targeted fix to an imperfect regulation that seems to be facilitating anticompetitive conduct by a few bad actors. It does so without trampling on the courts’ well-established antitrust jurisprudence, and without imposing excessive cost or risk on the majority of brand manufacturers that behave perfectly appropriately under the law.

Filed under: anticompetitive market distortions, antitrust, consumer protection, error costs, exclusionary conduct, ftc, health care, law and economics, regulation, regulatory reform, section 5 Tagged: antitrust, branded drugs, CREATE Act, FDA, FDAAA, generic drugs, refusals to deal, REMS, Senator Mike Lee

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