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July 10, 2017

Hon. Tom Marino
Chair, Regulatory Reform,

Commercial & Antitrust Law Subcommittee

House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Building
Washington, D.C. 20515

Hon. David Cicilline
Ranking Member, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office

Washington, D.C. 20515

Dear Chairman Marino and Ranking Member Cicilline:

On behalf of Momenta Pharmaceuticals, Inc. a biotechnology company in Cambridge, and our almost 300 employees, I am writing to you today to request your consideration and support of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212). CREATES is bipartisan legislation that is urgently needed to address drug pricing by increasing competition and patient access to safe and affordable generic and biosimilar medicines. I commend you for holding a hearing on this important bill and urge the Committee to mark-up the bill and move it to the House floor promptly.

I testified in March in my capacity as Chair of the Biosimilars Council before a Subcommittee of the House Oversight Committee on this the anticompetitive impact of restricted access to comparative products. There was strong support for finding a solution to problem of assuring access to comparative sample products needed for development of affordable medicine. (A copy of my testimony is attached.)

Certain brand pharmaceutical companies are currently preventing competition by blocking biosimilar and generic drug manufacturers' ability to purchase samples, which are used to conduct the bioequivalent testing necessary to bring safe and affordable medicines to market at the earliest possible date. None of the same barriers exist when comparative samples are purchased for novel medicine development. The Food and Drug Administration (FDA) has stated that this anti-competitive practice – known as restricted access abuse – is "a problem" that "delays the availability of generics."[1] A

[1] Food & Drug Administration (FDA), Dr. Janet Woodcock, Congressional Testimony before House Committee on Oversight & Investigations, March 22, 2017.

recent study by Michael Carrier demonstrates the need to act and the harm to competition caused by these practices.[2]

More than 150 complaints have been sent to the FDA and a significant majority of these brand drug products are quite expensive, costing patients thousands of dollars per month. Recent research estimates the potential scope of the current brand revenue where a brand company could use Risk Evaluation and Mitigation Strategy (REMS) and Non-REMS restricted access to block generic competition at more than $22 billion.[3] This problem is growing and patient access to safe and affordable generic and biosimilar medication is being delayed. With the shift in the market to higher priced biologics, this problem is particularly acute for the newly emerging biosimilars industry, of which Momenta Pharmaceuticals is a leading participant.

Unfortunately, the FDA does not have the authority to prevent the abuse of REMS and restricted access programs. REMS put in place important safety protocols, but are explicitly prohibited from being used to delay or prevent generic competition. It should be noted that generic drug developers are required to adhere to safe handling and other structures that protect patient safety, and this is done every time brand companies permit the sale of samples for generic drug development.

To ensure that generic drug developers are not prevented, by a small handful of brand companies, from obtaining samples necessary to bring new accessible generic and biosimilar drugs to patients and payers, Congressional action is necessary. The bipartisan CREATES Act (H.R. 2212) would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics. The FDA is well-known for its "gold standard" in protecting the safety of patients and in the Agency's review of the CREATES Act has stated that current FDA guidance on the provision of samples protects patients.

With nearly nine out of ten (87%) in favor of "making it easier for generic drugs to come to marker in order to increase competition and reduce costs"[4] and over 18 health care stakeholders calling for Congressional action to provide "generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors," support for the bipartisan CREATES Act (H.R. 2212) is broad and well-founded. We would greatly appreciate your support and co-sponsorship of the CREATES Act.

This is one step that has broad support that can make a difference in assuring affordable, competitive access to medicine today and in the years to come.

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[2] Carrier, Michael A., *Sharing, Samples, and Generics: An Antitrust Framework, 3 CORNELL L. REV. __ (forthcoming Sept. 2017),* https://ssrn.com/abstract=2979565. (copy attached.)
[3] Matrix Global Advisors, Alex Brill, "REMS and Restricted Distribution Programs: An Estimate of the Market," June 2017.
[4] Kaiser Family Foundation, "Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs," May 2017.

Thank you for the consideration of our views. Please do not hesitate to contact me at 617.395.2786 or bleicher@momentapharma.com .

Sincerely,

Bruce A. Leicher
Senior Vice President and General Counsel

Cc: Ryan Dattilo, Counsel (ryan.dattilo@mail.house.gov
Slade Bond, Counsel (slade.bond@mail.house.gov)

TESTIMONY OF BRUCE A. LEICHER

SENIOR VICE PRESIDENT AND GENERAL COUNSEL

MOMENTA PHARMACEUTICALS, INC.

BOARD CHAIR, BIOSIMILARS COUNCIL, A DIVISION OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES

SUBCOMMITTEE ON HEALTH CARE, BENEFITS, AND ADMINISTRATIVE RULES OF THE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

MARCH 22, 2017

Good morning Chairman Chaffetz, Chairman Jordan, Ranking Member Cummings, Ranking Member Krishnamoorthi and Members of the Subcommittee. Thank you for the opportunity to participate in this timely and important hearing.

I am Bruce Leicher, Senior Vice President and General Counsel at Momenta Pharmaceuticals, and Chair of the Biosimilars Council Board of Directors. The Council is a division of the Association for Accessible Medicines (AAM), formerly GPhA.

AAM and the Biosimilars Council commend you for holding today's hearing to discuss a problem that limits patient access to affordable medicines: certain brand pharmaceutical manufacturers' use of restricted distribution programs, including Food and Drug Administration (FDA)-mandated Risk Evaluation and Mitigation Strategies (REMS), to limit market access and generic development of their product.

Having worked in the biotechnology industry for over 25 years and in the biosimilars industry since its inception, I've seen firsthand how these strategies prevent or delay competition. Congress has encouraged generic and biosimilar competition through a delicate balance between innovation and competition established by The Drug Price Competition and Patent Term Restoration Act (P.L. 98-417; 21 U.S.C. §355,) commonly referred to as Hatch-Waxman, and the Biologics Price Competition and Innovation Act (BPCIA) (P.L. 114-38, 42 U.S.C. § 262). Alarmingly, anticompetitive practices threaten to undermine the success achieved through generic competition and to strangle an emerging biosimilars market.

For over 30 years, generic companies have safely and effectively purchased branded drugs on the free market so that they could conduct the testing necessary to file applications for marketing approval at the FDA. But in recent years, certain brand pharmaceuticals have used restricted distribution schemes, including REMS, to block such purchase and testing. If brand products cannot be purchased, then generic drugs and biosimilars cannot be developed. Without such development, the competition envisioned by Hatch-Waxman and the BPCIA will not occur and patients will not have access to safe, effective and more affordable life-saving medicines.

Momenta, and the larger generic and biosimilar industry, are committed to ensuring that all Americans have access to safe, effective and affordable drugs. We have supported the proper use of FDA REMS programs since their inception nearly a decade ago. These programs allow for the safe distribution and use of certain pharmaceuticals that have a higher risk profile. This industry does not support any policies that would endanger patients. Nor do we want to contribute to drug shortages or add unnecessary overhead costs to already low-margin products. Our members comply with the same rules and regulations administered by the FDA for testing of medicine. Any discussion or insinuation to the contrary is simply an effort to distract from the real issue at hand: addressing the use of REMS or other non-FDA mandated restrictions on drug supply to block or delay lower cost generics and biosimilars from coming to market.

I. COMPETITION WORKS

Hatch-Waxman is the foundation on which the nation's generic drug industry was built. For more than 32 years, it has proven to be a tremendous success. Generic medicines are almost 90% of the prescriptions dispensed in this country, yet account for less than 30% of drug spending[1]. On average, generics are 80-85% less expensive than brand drugs[2]. By bringing drugs to the market at a lower price point, generics help drive down costs to patients, as well as the greater U.S. healthcare system, including private health insurance plans and public programs. Generic drug savings provide the healthcare system with the ability to invest in new medications and save hundreds of billions of dollars annually. In fact, generic competition has expanded patient choice and lowered healthcare costs, saving $1.46 trillion in the last decade alone[3]. To underscore the success of our sector, consider that while generic drug utilization continues to

[1] *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

[2] *Understanding Recent Trends in Generic Drug Prices.* HHS Office of the Assistant Secretary for Planning and Evaluation. January 2016. https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices

[3] *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

increase, the share of pharmaceutical spending attributed to generics is decreasing[4]. More prescription drugs are being dispensed to patients, while the cost of generic medicines declines.

Looking forward, biosimilars present the same opportunity – competition for high-cost specialty biologic medicines. To contextualize the promise of biosimilars, consider that branded specialty medicines are only 1% of all prescriptions, but account for more than 30% of total pharmaceutical spending[5]. Utilization of these costly drugs is only expected to increase in the coming years. Experts anticipate that specialty products will account for nearly half of all pharmaceutical costs in the next three to five years[6]. As more conditions are treated with these more effective but higher cost biologics instead of traditional small molecule drugs, total spending is expected to increase. This is why the competition promised by biosimilars is so important to patients and taxpayers.

Thanks to the bipartisan work of Congress to enact the BPCIA, opportunities for greater access to lower-cost and high-quality biosimilar medicines are on the horizon. Today we have a growing and thriving biosimilars industry – creating good jobs and leading the world with our innovative science – particularly in the science of more fully understanding our biologic products. In fact, the FDA reported that over 64 biosimilar programs were under review for development of 23 different biologic products.[7] Momenta alone has seven biosimilar development programs which has required us to more than double the size of our workforce. These are American jobs, paying good wages that enhance the economic and innovative dynamism of the U.S economy. Various economic impact studies estimate projected savings for American taxpayers and patients between $42 billion[8] to as much as $250 billion[9] over the first 10 years of biosimilar market formation. But if we are not able to access comparator brand product to conduct development in a timely and routine manner, this will not happen.

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[4] *Understanding Recent Trends in Generic Drug Prices.* HHS Office of the Assistant Secretary for Planning and Evaluation. January 2016. https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices

[5] *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

[6] 2015 ExpressScripts Drug Trend Report, available at https://lab.express-scripts.com/lab/~/media/e2c9d19240e94fcf893b706e13068750.ashx

[7] Testimony of Dr. Janet Woodcock Testimony "Examining FDA's Generic Drug and Biosimilar User Fee Programs." House Energy and Commerce Committee. March 2, 2017. https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-generic-drug-and-biosimilar-user-fee-programs

[8] "*The Cost Savings Potential of Biosimilar Drugs in the United States"* RAND Corporation. 2014. https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf

[9] *"The $250 Billion Potential of Biosimilars"* Express Scripts. April 2013. http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars

Generics, and the patient access and savings they produce, are an American success story. A robust biosimilar market is becoming more of a reality every day. However, we are leaving savings on the table. We need to boost competition and reduce regulatory burdens to ensure this dynamic thrives. One of the surest ways to accomplish that goal is to address restricted distribution schemes and abuses of FDA REMS programs that limit generic and biosimilar development and competition.

II. RESTRICTED DISTRIBUTION ABUSES BLOCK GENERIC DRUG ENTRY

Our efforts to lower costs and improve access to medicines are often frustrated by brand tactics designed to block or delay the generic and biosimilar drug development process. These tactics take the form of novel self-imposed restricted distribution schemes with wholesalers or specialty pharmacies that mimic FDA REMS programs, or hide behind the veneer of patient safety and FDA mandates.

This refusal to sell samples may be direct, or may take the form of the brand restricting the supplier from selling the product for research purposes or through unreasonable contract terms. In any case, it has nothing to do with safety and they are rarely designed to manage costs or prevent a shortage. These samples are used solely for FDA-required testing, following FDA's review and approval of the competitor's safety protocols. Ultimately, the brand's actions to keep generic and biosimilar firms from receiving samples makes it impossible for prospective competitors even to submit an application for FDA approval – indefinitely preventing patients from accessing affordable treatment options.

For instance, in the past few years, when we have sought to purchase brand products from customary wholesalers in the supply chain, we are now asked if we are conducting generic or biosimilar studies. On multiple occasions, they inform us that their contract prohibits them from selling the brand product for that purpose. No REMS program was involved; it was simply a self-justified refusal to sell to a generic or biosimilar competitor.

On another occasion, we were told we could not purchase a product because it was subject to a REMS program that restricted distribution to patients only on a named basis. We looked up the product and it was not subject to a REMS. We then informed the wholesaler, who then informed us they could not sell the product to us for biosimilar development.

Ironically, when we attempt to purchase the same product for use in comparative novel development programs that are not designed to develop competitive products, we do not encounter these refusals. It is clear that this dichotomy has nothing to do with safety but everything to do with preventing lower-cost generic or biosimilar competition.

As a result, we are now forced to consider how difficult it will be to obtain the brand product when selecting generic or biosimilar development programs. In cases where access is restricted, we have not initiated some programs. Uncertain litigation is often the only option to gain access, and that is too costly and time-consuming for companies like Momenta. Some of the larger companies that have the resources to sustain such litigation have been suing over access to individual products for years.

Other AAM members report similar experiences: a REMS or self-imposed restricted distribution program limits sale of a drug and acts to preclude timely development of follow-on products. The bottom line is simple: a generic or biosimilar manufacturer is prevented from obtaining the brand drug, is unable to perform the testing required for FDA review and approval, and patients miss out on the savings that would be available through generic competition. These barriers need to be removed and customary access restored.

III. FEDERAL REGULATORS HAVE RECOGNIZED THESE ABUSES

These abuses have real costs: a 2014 study concluded the abuse of REMS and REMS-like limited distribution strategies cost the U.S. healthcare system $5.4 billion annually - $1.8 billion to the federal government[10]. But these abuses affect more than just payers – they have a direct impact on the costs borne by patients. The Federal Trade Commission (FTC) has weighed in on cases currently pending in federal court. In one, the FTC noted "a troubling phenomenon: the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition.[11]"

In a 2010 presentation to ACI's REMS Conference, a prominent Washington, D.C. law firm highlighted how REMS programs could be used as a "tool for profitability.[12]" They went on to make a nod to Stanley Kubrick's 1964 film *Dr. Strangelove*, subheading the title of their presentation, "How to learn to stop worrying and love REMS" because of the potential the program had to forestall competition[13].

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[10] Brill, Alex, Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry, Matrix Global Advisors, July, 2014.

[11] Brief for the Federal Trade Commission as Amici Curiae, Mylan Pharmaceuticals, Inc. v. Celgene Corporation, (No. 2:14-CV-2094-ES-MAH) Available: https://www.ftc.gov/policy/advocacy/amicus-briefs/2014/06/mylan-pharmaceuticals-inc-v-celgene-corporation

[12] Powerpoint Presentation contained in Congressional Record of Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights hearing titled, "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition" https://www.judiciary.senate.gov/meetings/the-creates-act-ending-regulatory-abuse-protecting-consumers-and-ensuring-drug-price-competition

[13] *Id.*

In addition to the FTC's activity, senior officials at the FDA have repeatedly spoken of the challenge. Dr. John Jenkins, M.D., then Director of the FDA's Office of New Drugs previously stated that, "the problem is the use of REMS blocking generic competition. [14]" He went on to say that "innovators have really become very aggressive in using that strategy [and] hiring the best lawyers to back up that strategy.[15]" The Director of the FDA Center of Drug Evaluation and Research, Janet Woodcock, M.D., testified only a few weeks ago that these abuses are "a problem we struggle with a lot[16]" and went on to note that they have "delayed [the] availability of generics.[17]"

But access to the brand drug is only part of the problem. Another common ploy is to use the law's shared-REMS requirement to prevent launch of a filed and otherwise ready to be approved generic competitor. This involves the statutory requirement that, unless waived, the brand and follow-on products must enter into a single, shared safety protocol[18]. It has become yet another opportunity for brands to game the system.

For example, a product to treat irritable bowel syndrome was able to continue to repeatedly increase prices through abuse of the FDA administered shared REMS system since 2008[19]. While a generic competitor ultimately entered the market, this occurred only after prolonged refusal by the brand to negotiate a shared-REMS which FDA noted took more than three years to conclude. The Agency characterized the brand's repeated delays as "pre-textual appeals to safety as a means to delay that competition.[20]" Unfortunately, FDA has only limited authority to allow generic manufacturers to implement their own REMS programs, even when the agency has confirmed the generic company's ability to satisfactorily implement the necessary precautions.

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[14] Gingery, Derrick. REMS That Block Generics Are 'Major' Problem For FDA, Jenkins Says. "The Pink Sheet" Daily. January 8, 2015.

[15] *Id.*

[16] Testimony of Dr. Janet Woodcock Testimony "Examining FDA's Generic Drug and Biosimilar User Fee Programs." House Energy and Commerce Committee. March 2, 2017. https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-generic-drug-and-biosimilar-user-fee-programs

[17] *Id.*

[18] Federal Food, Drug and Cosmetic Act § 505-1(i)(1)(B), 21 U.S.C. 355–1 (i)(1)(B)

[19] AAM Analysis of AWP Data from Truven Health Analytics, Micromedex Solutions. RED BOOK Online. Alosetron. Oral. 0.5 mg. 30s ea.

[20] Brief of Defendant Sylvia Matthews Burwell, et al. on Plaintiff's motion for a Temporary Restraining Order, Prometheus Laboratories, Inc. v. Sylvia Matthews Burwell, et al. (2015) (No. 1:15-CV-00742 (JEB)). Available at: http://www.fdalawblog.net/LOTRONEX%20-%20Roxane%20TRO-PI%20Opp.pdf

Even after FDA provided a waiver for the generic manufacturers to operate an equivalent REMS program, the brand sued the Agency in an attempt to force the generics back into the stalled negotiations. In the time period between expiration of the brand exclusivity and the FDA waiver, the brand raised its price over 50%, much more rapidly than it had prior to the threat of generic competition[21].

These abuses keep important products off the market indefinitely, even after the FDA has determined that the company's follow-on product is just as safe and just as effective as the brand product, and even when the brand product's patent protection has expired. The FDA needs more explicit authority to authorize generic and biosimilar companies to implement safe REMS programs of their own under FDA regulation.

IV. THESE ABUSES ARE NOT NEW AND SHOW NO SIGNS OF SLOWING

This is not a new problem. Almost five years ago, the Senate passed legislation that included language – at FDA's request – to address it. In 2012, the Senate passed that language as part of the prescription drug user fee reauthorization[22]. Unfortunately, the language fell out when the bill went to conference with the House of Representatives. Since then, FDA has frequently called for legislation to address REMS abuse. Dr. Woodcock has repeatedly addressed the point head-on in testimony to Congress, calling for a legislative fix. Last year, when asked why brand companies are abusing the REMS program she stated, "innovator companies feel it is their duty to their stockholders to delay completion as long as possible.[23]" These products bring in billions of dollars in revenue to the brand so, as Dr. Woodcock noted, market manipulations are viewed merely as a cost of doing business.

There were further legislative discussions last year, as legislation was introduced in the House and Senate, and as part of the 21st Century Cures process. We are encouraged by the continued attention, and hope that Congress will complete work on a solution to this issue this year.

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[21] AAM Analysis of AWP Data from Truven Health Analytics, Micromedex Solutions. RED BOOK Online. Alosetron. Oral. 0.5 mg. 30s ea.

[22] Food and Drug Administration Safety and Innovation Act, S. 3187, 112th Congress (As passed by Senate May 24, 2012)

[23] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs. Before S. Comm. on Health, Education, Labor and Pensions*, 114th Congress (2016) (Comments by Janet Woodcock, MD, Director of Center for Drug Evaluation and Research at FDA). Available at: http://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs

The potential for abuses is only growing. Increasingly, new FDA approvals are subject to REMS, and the percentage of REMS programs that require distribution restrictions referred to as Elements to Assure Safe Use (ETASU) has increased dramatically in the last several years. In 2009, roughly 75% of REMS programs only required medication guides – but now over 50% of REMS programs include limits on distribution[24]. Some manufacturers have even requested FDA to impose these restrictions despite FDA's conclusion that they are not necessary to protect patient safety[25]. In the context of biologic products – drugs that tend to have extremely high list prices – 34% of all biologics approved are subject to a REMS program[26]. As more biologics lose underlying patents and market exclusivities, the profit incentives for brand manufacturers to delay biosimilar development will become even more pronounced than they already are.

V. RESTRICTED DISTRIBUTION ABUSES ARE NOT LIMITED TO PRODUCTS WITH REMS

There is also growing use of self-imposed restricted distribution programs. While most attention has focused on high-profile examples, these are by no means outliers. AAM has surveyed their membership about products they have encountered where restricted distribution agreements prevent a generic or biosimilar drug developer from purchasing samples. There are dozens of products on that list in addition to the 78 FDA REMS programs. Many self-imposed restricted-distribution programs are designed – often explicitly – to block generic entry.

For example, in an investor presentation, the pharmaceutical manufacturer Retrophin discussed how limiting distribution of the drugs Thiola® and Chenodal® to a single specialty pharmacy would block a lower-cost alternative from coming to market and serve to protect their product from competition[27]. I'll also note this Committee's previous investigation of Turing Pharmaceuticals' pricing practices around the drug Daraprim®. Turing used a closed distribution system as an effective block on generic competition. John Hass, the company's director of patient access, said so explicitly, noting that generics wishing to buy samples of the drug would not be welcome. Hass said:

[24] Individual REMS programs listed at: https://www.accessdata.fda.gov/scripts/cder/rems/

[25] Letter from FDA to Jennifer Ekelund at pg 3. February 2015. http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021196Orig1s015ltr.pdf

[26] Individual REMS programs listed at: https://www.accessdata.fda.gov/scripts/cder/rems/

[27] Retrophin: Manchester Pharmaceuticals Acquisition February 13, 2014. Available at: https://web.archive.org/web/20150226002409/http://www.retrophin.com/pdf/ManchesterAcquisitionAgreementConferenceCall.pdf

> *"Most likely I would block [a generic 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 manufacture a generic alternative] no matter what. But I'm certainly not going to make it easier for them*[28]*."*

These programs do not stand on any FDA safety requirements. Rather, the manufacturers choose to adopt REMS-like protocols because they know how effective a tool they can be in blocking lower-cost alternatives from coming to market.

Your colleagues on the Senate Aging Committee have also examined market restrictions absent any FDA-mandate. Summarizing their investigations of abuses by drug companies like Turing, Retrophin, and Valeant, they noted that:

> *"In the cases of Turing and Retrophin, placing the drug into restricted distribution was a way for the companies to control who could buy their drugs. Mr. Shkreli blocked any purchase that looked like an attempt by a potential generic entrant to obtain the [brand product]. To the extent that drugs travelled through less-typical channels (such as 340B institutional distribution), the same rules applied—sales via that channel were carefully regulated and quantity limited to ensure that drugs were not sold to a potential generic entrant.* [29]*"*

The Committee also noted testimony from Dr. Woodcock on the challenge posed by non-FDA-mandated restricted distribution schemes. She explained:

> *"[T]he companies on their own behalf have restricted programs that we do not really understand, but they are not related to REMS. We have had over 100 inquiries from generic companies who cannot get a hold of the innovator drug to compare their drug to. We have done everything we can to—we have written a letter saying, you know, that REMS does not require this, you can give it out for this purpose, and so forth, and we also refer these to [the Federal Trade Commission], okay? But we still continue to get*

[28] Ed Silverman, *How Martin Shkreli prevents generic versions of his pricey pill*, Pharmalot, October 5, 2015. Available: http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/

[29] Special Committee on Aging United States Senate, *Sudden Price Spikes in Off-Patent Prescription Drugs:*

The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System. December 2016.

complaints from generic companies that they cannot get a hold of the drug to make the comparison they need to do.[30]"

So while many opponents of reform have argued that there are only a small number of products that are subject to REMS with ETASU, they ignore two very important facts: first, more and more products approved are subject to a REMS requirement, just setting the system up for further abuse; second, there is no public record of what companies are already using restricted distribution networks to restrict access to specific drug samples. Most troubling, the FDA cannot prevent those contractual arrangements and the FTC has yet to bring an enforcement action against one.

VI. RESTRICTED DISTRIBUTION ABUSES POSE A PARTICULARLY GRAVE THREAT TO THE DEVELOPMENT OF BIOSIMILARS

I have made clear the harm that these abuses are already causing today. But the danger is even more pronounced as we look to the future. As the biosimilars market develops, the high price of many new biologics will only incentivize further abuse of these types of arrangements, and create incredibly excessive spending for the healthcare system through the loss of potential savings.

As we increasingly shift from use of small-molecule drugs to biologic products, the development of biosimilar medicines will be critical to reducing the cost of prescription drugs. But such products are much more complex and difficult to develop. The foundation of biosimilar development is demonstrating that a biosimilar is highly similar to the brand product. This requires thorough characterization of multiple lots of the brand product over time. If access to brand lot variability is blocked by restricted access to brand product, then biosimilar development will be blocked.

In addition, unlike most small molecule generic drugs, the development of biosimilars is more likely to involve clinical trials and require far greater quantities of samples of the original product. For instance, clinical studies blind the medicine from the physician to avoid bias and ensure the validity of the data. This requires the purchase and re-labeling of the product to conduct the study. Moreover, the quantities are large and require purchases over a longer period

[30] Testimony of Dr. Janet Woodcock, "Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs" January 28, 2016 HELP Hearing, Trans. at 51:4–14 https://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs

of time than generic development. Restricted access at any point in the development cycle could cause a study to fail, thereby slowing or preventing the entry of lower-cost biosimilar medicines.

Perhaps what is most interesting is a review of ClinicalTrials.gov – the website listing clinical studies in the United States – showing over 90 comparative clinical trials underway by brand companies that use comparative or combined use of brand products that appear to be freely purchased without any of these restrictions[31]. This makes clear that the motivation of the restrictions is to protect profits, not patients.

To be clear, the use of restricted distribution schemes, whether tied to a REMS or self-imposed, poses a severe threat to the billions in savings expected in the next ten years through biosimilar competition.

Some may tell you that this is "too small" of a problem to address legislatively. But the numbers say otherwise. The Congressional Budget Office has estimated various reform proposals as saving billions of dollars for taxpayers. Experts at the FDA and FTC have called for fixes to these abuses. Anything less merely continues the opportunity for further abuse.

I would be happy to address any questions from the Subcommittee.

[31] Individual studies available at https://clinicaltrials.gov/.

Sharing, Samples, and Generics: An Antitrust Framework

103 CORNELL L. REV. __ (forthcoming 2017)

Michael A. Carrier[†]

Rising drug prices are in the news. By increasing price, drug companies have placed vital, even life-saving, medicines out of the reach of consumers. In a recent development, brand firms have prevented generics even from entering the market. The ruse for this strategy involves risk-management programs known as Risk Evaluation and Mitigation Strategies ("REMS"). Pursuant to legislation enacted in 2007, the FDA requires REMS when a drug's risks (such as death or injury) outweigh its rewards. Brands have used this regime, intended to bring drugs to the market, to block generic competition. Regulations such as the federal Hatch-Waxman Act and state substitution laws foster widespread generic competition. But these regimes can only be effectuated through generic entry. And that entry can take place only if a generic can use a brand's sample to show that its product is equivalent.

More than 100 generic firms have complained that they have not been able to access needed samples. One study of 40 drugs subject to restricted access programs found that generics' inability to enter cost more than $5 billion a year. Brand firms have contended that antitrust law does not compel them to deal with their competitors and have highlighted concerns related to safety and product liability in justifying their refusals. This Article rebuts these claims. It highlights the importance of samples in the regulatory regime and the FDA's inability to address the issue. It shows how a sharing requirement in this setting is consistent with Supreme Court caselaw. And it demonstrates that the brands' behavior fails the defendant-friendly "no economic sense" test because the conduct literally makes no sense other than by harming generics.

Brands' denial of samples offers a textbook case of monopolization. In the universe of pharmaceutical antitrust behavior, other conduct—such as "pay for delay" settlements between brands and generics and "product hopping" from one drug to a slightly modified version—has received the lion's share of attention. But sample denials are overdue for antitrust scrutiny. This Article fills this gap. Given the failure of Congress and the FDA to remedy the issue, antitrust can play a crucial role in ensuring generic access to samples, affirming a linchpin of the pharmaceutical regime.

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INTRODUCTION

Rising drug prices are in the news. By increasing price, drug companies have placed vital, sometimes life-saving, medicines out of the reach of consumers. In a recent development, brand firms have prevented generics even from entering the market. The ruse for this strategy involves risk-management programs known as Risk Evaluation and Mitigation Strategies ("REMS"). Pursuant to legislation enacted in 2007, the FDA requires REMS when a drug's risks (such as death or injury) outweigh its rewards. Brands have used this regime, intended to bring drugs to the market, to block generic competition. Regulations such as the federal Hatch-Waxman Act[1] and state substitution laws foster widespread generic competition. But these regimes can only be effectuated through generic entry.

[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

And that entry can take place only if a generic can use a brand's sample to show that its product is equivalent.

More than 100 generic firms have complained that they have not been able to access needed samples.[2] One study of 40 drugs subject to restricted access programs found that generics' inability to enter cost more than *$5 billion* a year.[3] As a leading FDA official lamented, brands "feel it's their duty to their stockholders to delay competition as long as possible."[4]

Brand firms have contended that antitrust law does not compel them to deal with their competitors and have highlighted concerns related to safety and product liability in justifying their refusals. This Article rebuts these claims. It highlights the importance of samples in the regulatory regime and the FDA's inability to address the issue. It shows how a sharing requirement in this setting is consistent with Supreme Court caselaw. And it demonstrates that the brands' behavior fails the defendant-friendly "no economic sense" test because the conduct literally makes no sense other than by harming generics.

Part I provides a background on REMS, offering a history and overview before examining the concern of blocked generic entry. Part II presents the caselaw, which is still developing, with opinions issued primarily in the setting of motions to dismiss. Part III outlines the relevant antitrust framework for the most appropriate case: a monopolization claim under Section 2 of the Sherman Act. It addresses monopoly power, the regulatory regime, and exclusionary conduct, the latter in the setting of refusals to deal and through a lens that analyzes whether the conduct makes economic sense.

Part IV then applies this new antitrust framework, showing how the denial of samples and failure to participate in shared REMS programs each can violate antitrust law because they tend to lack economic sense other than by harming generic competition. Part V concludes by rebutting the four justifications on which brand firms have most frequently relied. It first addresses arguments, based on the caselaw, that deny a duty to deal and reject liability where there is no previous course of dealing between the parties. And it then addresses two excuses based on business concerns about the safety of generic drugs and

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[2] *The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016*, https://www.leahy.senate.gov/download/creates-act-one-pager (last visited Jan. 16, 2017). [https://perma.cc/JJ2Z-EW3W].

[3] *See* Alex Brill, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*, MATRIX GLOBAL ADVISORS, at 1, July 2014.

[4] David Gaugh, *Strengthening REMS for Patient Safety and Faster Access to Generics*, CONGRESS BLOG, Apr. 18, 2016. [https://perma.cc/2TKL-T9SM]. *See also* SEN. JUD. SUBCOMM. ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS, at 1:00 (June 21, 2016) https://www.lee.senate.gov/public/index.cfm/press-releases?ID=22C9F4E4-899A-475F-BE52-4FB7DC6ADA11 [https://perma.cc/6MJL-G9AL] (rejecting claim that REMS denials are merely an example of "lifecycle management," contending instead that they show "blatantly anti-competitive conduct" (statement of Sen. Lee (R-UT)).

increased exposure to product liability claims.

Brands' denial of samples offers a textbook case of monopolization. In the universe of pharmaceutical antitrust behavior, other conduct—such as "pay for delay" settlements between brands and generics[5] and "product hopping" from one drug to a slightly modified version[6]—has received the lion's share of attention. But sample denials are overdue for antitrust scrutiny. This Article fills this gap. Given the failure of Congress and the FDA to remedy the issue, antitrust can play a crucial role in ensuring generic access to samples, affirming a linchpin of the pharmaceutical regime.

I. REMS

Courts are beginning to address the antitrust implications of brand companies' refusals to share samples of drugs that are subject to REMS programs. This Part examines REMS, tracing its history and requirements, and offering examples. It then provides an overview of generic competition. Finally, it highlights the anticompetitive concern with REMS, which can prevent generic drugs from reaching the market.

A. Background

Beginning with the passage of the Food Drug and Cosmetic Act in 1938, the U.S. Food and Drug Administration ("FDA") has required drug manufacturers to prove safety before entering the market.[7] In the following several decades, the agency imposed more rigorous requirements for demonstrating safety and effectiveness.[8]

In the mid-2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs"), a voluntary system by which drug sponsors implemented risk-minimizing plans to address known risks.[9] A RiskMAP is "a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits."[10] These were developed for

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[5] *E.g.*, FTC v. Actavis, 133 S. Ct. 2223 (2013).

[6] *E.g.*, New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638 (2d Cir. 2015).

[7] Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 et seq.).

[8] *See* Shashank Upadhye & Braden Lang, *The FDA and Patent, Antitrust, and Property Takings Laws: Strange Bedfellows Useful to Unblock Access to Blocked Drugs*, 20 B.U. J. SCI. & TECH. L. 84, 91–-92 (2014).

[9] FDA, Center for Drug Evaluation and Research (CDER) & Center for Biologics Evaluation and Research (CBER), *Guidance for Industry, Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications* 3, Sept. 2009, http://www.fda.gov/downloads/Drugs/.../Guidances/UCM184128.pdf. [https://perma.cc/NT3N-QPGP].

[10] *Id.*

products requiring strategies "beyond describing the risks and benefits of the product in labeling and performing required safety reporting"[11] and formed the precursor to REMS.[12]

In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA").[13] Section 505-1(a)(1) of the Act authorizes the FDA to require sponsors of drug applications[14] to submit a proposed REMS if the agency determines that it is needed to ensure that a drug's benefits outweigh its risks.[15] By September 2008, holders of drug applications that the FDA selected for REMS were required to submit a proposed REMS program.[16] The transition to mandatory REMS was not intended to significantly change the voluntary programs in place at the time.[17]

The FDA has defined REMS as "required risk management plans that use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks."[18] Examples of REMS requirements include education addressing the risk of serious infection, certification of healthcare professionals targeting severe allergic reactions, the monitoring of liver damage, and negative pregnancy tests to address severe birth defects.[19]

In determining the need for REMS, the FDA considers factors including (1) the population size likely to use the drug; (2) the seriousness of the disease; (3) the drug's expected benefit; (4) the expected duration of treatment; (5) the seriousness of adverse effects; and (6) the drug's novelty.[20] The FDA can require a REMS before a drug enters the market based on known risks or after the drug has been approved based on new evidence of risk.[21]

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[11] *Id.* (explaining that "[f]or the majority of approved products, labeling and routine reporting requirements are sufficient to mitigate risks and preserve benefits" but that "[i]n a small number of cases, when additional measures were needed to ensure that the benefits of a drug outweigh the risks of the drug, FDA approved the drug with a RiskMAP").

[12] FDA, STANDARDIZING AND EVALUATING RISK EVALUATION AND MITIGATION STRATEGIES (REMS) 9, Sept. 2014.

[13] 21 U.S.C. § 355-1(a)(1).

[14] The requirements apply to brand firms filing new drug applications ("NDAs"), generics filing abbreviated new drug applications ("ANDAs"), and biologic manufacturers filing biologics license applications ("BLAs"). FDA, STANDARDIZING REMS, *supra* note 12, at 9.

[15] 21 U.S.C. § 355-1(a)(1).

[16] *Guidance for Industry*, *supra* note 9, at 5.

[17] *Id.*

[18] FDA, *A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS)*, at 2, http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf [https://perma.cc/CY7S-PRY4] (last visited Dec. 21, 2016).

[19] *Id.* at 3, 13.

[20] *Id.* at 6.

[21] FDAAA, 21 U.S.C. § 355-1(a)(2)(A).

All REMS must include a timetable for submission of periodic reports to the FDA regarding the REMS program.[22] Other requirements vary depending on the risk profile of the drug and the need to inform doctors or patients of safety concerns.[23] REMS programs differ in their level of restriction. The "least restrictive" program includes medication guides for patients and communication plans for healthcare practitioners.[24]

More restrictive REMS programs have "Elements To Assure Safe Use (ETASU)," which can include prescriber experience requirements, certification systems, patient monitoring or registration, or controlled distribution.[25] These requirements can restrict a drug's distribution and affect how it can be sold to consumers. ETASU measures are "designed to be compatible with established distribution, procurement, and dispensing systems for drugs."[26] Even though the requirements affect distribution, the FDA has sought to ensure that they do not burden patients who "have difficulty accessing health care (such as patients in rural or medically underserved areas)" or those with "serious or life-threatening diseases or conditions."[27]

Since their enactment in 2007, REMS programs—in particular, ETASU requirements—have become an increasingly prevalent part of the FDA approval process. 40 percent of new drugs have REMS programs.[28] There are currently 76 approved REMS programs, with 42 of these requiring ETASU measures.[29] The prevalence of ETASU requirements marks a shift from early REMS programs, which tended to cover less restrictive medication guides.[30] Despite their increasing frequency, a report from the U.S. Department of Health and Human Services' Office of Inspector General questioned "the overall effectiveness of the REMS program," with just 7 of 49 REMS meeting all of their goals.[31] An understanding of the competitive effects of REMS-related behavior requires a brief overview of generic competition.

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[22] FDA, STANDARDIZING REMS, *supra* note 12, at 9; FDA, *Brief Overview*, *supra* note 18, at 17 (noting that timetable "must be at least by 18 months, 3 years, and in the 7th year after the REMS is approved" and "[c]an be eliminated after 3 years").

[23] *See* Upadhye & Lang, *supra* note 8, at 92.

[24] *Id.* at 93.

[25] FDA, *Brief Overview*, *supra* note 18, at 13; Upadhye & Lang, *supra* note 8, at 94.

[26] FDAAA, 21 U.S.C. § 355-1(f)(2)(D)(ii).

[27] FDAAA, 21 U.S.C. § 355-1(f)(2)(C).

[28] Brill, *supra* note 3, at 2.

[29] FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17 (last visited Jan. 18, 2017). [https://perma.cc/SNH2-EACQ].

[30] Brill, *supra* note 3, at 3.

[31] HHS OFFICE OF INSPECTOR GENERAL, FDA LACKS COMPREHENSIVE DATA TO DETERMINE WHETHER RISK EVALUATION AND MITIGATION STRATEGIES IMPROVE DRUG SAFETY 16 (Feb. 2013).

B. Generic Competition

Generic competition is an indispensable foundation of the pharmaceutical industry. Congress enacted the Hatch Waxman Act in 1984 to ensure the provision of "low-cost, generic drugs for millions of Americans."[32] Generic competition would save consumers, as well as the federal and state governments, millions of dollars each year. And it would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed."[33]

The competition policies underlying the Hatch Waxman Act were strengthened by state drug product selection ("DPS") laws, in effect in all 50 states today, which reduce prices for consumers.[34] These laws allow (and often require) pharmacists, absent a doctor's contrary instructions, to substitute generic versions of brand-name prescriptions. The laws are designed to address the disconnect in the industry between prescribing doctors, who are not directly responsive to drug pricing, and paying insurers and consumers, who do not directly select the prescribed drug.[35] In particular, DPS laws carve out a role for pharmacists, who are much more sensitive to prices than doctors.[36]

In the past three decades, the size of the generics market has burgeoned.[37] Making up 19% of the prescription drug market in 1984, they now constitute 89%.[38] Generics enter the market at significantly lower prices, with an average cost 80 to 85 percent lower than that of a brand drug.[39] As a result, brand drugs, which make up only 11% of prescriptions today, are responsible for 73% of drug spending.[40] Between 2006 and 2015, the ten-year savings from generic drugs was nearly *$1.5 trillion*.[41]

Generics can offer substantial savings because they do not need to replicate

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[32] 130 CONG. REC. 24427 (1984) (statement of Rep. Waxman).

[33] *Id.*

[34] Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

[35] *See* BUREAU OF CONSUMER PROTECTION, DRUG PRODUCT SELECTION: STAFF REPORT TO THE FTC 2–3 (1979).

[36] ALISON MASSON & ROBERT L. STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 7 (1985).

[37] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

[38] *See* GPHA, 2016 GENERIC DRUG SAVINGS & ACCESS IN THE UNITED STATES REPORT 5 (2016).

[39] FDA, *Facts about Generic Drugs*, June 28, 2016, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm. [https://perma.cc/NK9P-TL7Q].

[40] GPHA REPORT, *supra* note 39, at 5.

[41] *Id.* at 6.

brand firms' expensive and lengthy clinical trials.[42] As the Supreme Court has confirmed, a central purpose of the Hatch Waxman Act was to "allow a generic competitor to file an abbreviated new drug application ("ANDA") piggy-backing on the brand's [new drug application] ("NDA")."[43] Instead of "providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug," with such piggybacking "designed to speed the introduction of low-cost generic drugs to market."[44]

C. Concern: Blocking Generics

The competition between brands and generics at the heart of the Hatch Waxman Act is subject to a prerequisite: the use of a brand's sample.[45] Generic firms must have access[46] to samples of reference listed drugs[47] (which, for ease of reference, I refer to as brand drugs) to engage in bioequivalence testing, ensuring that its drug is absorbed into the body at the same rate as the brand's drug.[48] Such testing requires the generic applicant to have "access to a sufficient quantity" of the brand drug "to conduct the necessary comparisons" between the two.[49] Brand firms can stifle generic entry by invoking their REMS programs to refuse to sell samples of their drugs.

Typically, generics can acquire samples from distributors or wholesalers.[50]

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[42] *See* FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 5 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. [https://perma.cc/EY4H-UWXT]. State substitution laws also allow generics to avoid marketing and promotion costs.

[43] Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012).

[44] *Id.*

[45] *E.g.*, FDA, Center for Drug Evaluation and Research (CDER), *Guidance for Industry, Handling and Retention of BA and BE Testing Samples* 3 (May 2004).

[46] *See The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition Before the S. Judiciary Comm.*, 114th Cong. 2 (2016) (statement of Beth Zelnick Kaufman).

[47] FDA, Center for Drug Evaluation and Research (CDER), *How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD Guidance for Industry*, at 4, Dec. 2014, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425662.pdf. [https://perma.cc/YE9D-WZAR].

[48] FTC, GENERIC DRUG STUDY, *supra* note 43, at 5.

[49] FDA, *How to Obtain a Letter*, *supra* note 31, at 2.

[50] Lauren Battaglia, *Risky Conduct with Risk Mitigation Strategies? The Potential Antitrust Issues Associated with REMS*, ANTITRUST HEALTH CARE CHRONICLE 28 (Mar. 2013); Transcript of Motions Hearing, Actelion Pharm. Ltd. v. Apotex, Inc., 1:12-cv-05743, at 52 (D.N.J. Oct. 17, 2013) (generic would "vastly prefer[]" buying from "wholesaler, . . . distributor, or specialty pharmacy" than brand); José P. Sierra, *Generics Demand Brand Drug Samples for ANDA Filings*, PHARMARISC.COM, Apr. 11, 2013, http://www.pharmarisc.com/2013/04/generics-demand-brand-drug-samples-for-anda-filings/ [https://perma.cc/F8B8-HW7P] (generic firms "[o]rdinarily . . . purchase" samples "from wholesalers on the open market").

But REMS often include "provisions barring distributors and wholesalers from selling the drug to entities without approval under the REMS,"[51] which result in generics "turn[ing] to the branded manufacturers themselves to supply the drug samples directly."[52] When the brands then deny samples, the generics have no recourse.[53] A generic company cannot use a foreign sample as a substitute because the FDA does not consider this to be the same drug product for bioequivalence testing purposes.[54] And even if a generic has "the exact recipe of a brand formulation," it "cannot manufacture its own version" because only the brand version constitutes the "reference listed drug" under the Hatch Waxman Act.[55] Absent access to the brand sample, the generic company cannot demonstrate bioequivalence and thus can enter the market only by replicating all of the safety and efficacy evidence for the drug product, directly contravening the Hatch-Waxman Act's objectives.

Congress was keenly aware of the importance of generic competition when it passed the FDAAA. In doing so, it included a provision that made clear that ETASU measures should not be used to prevent generic firms from accessing samples of drugs covered by REMS.[56] In particular, the statute explicitly states that "[n]o holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application."[57] Such language provides not only that brands shall not use REMS to *block* generics but also that they shall not use them to *delay* generics.[58]

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[51] Battaglia, *supra* note 49, at 28. For an example, see *infra* note 88.

[52] Battaglia, *supra* note 49, at 28.

[53] *See, e.g.*, *Actelion v. Apotex* transcript, *supra* note 48, at 80 (FDA denied generic's attempt to address brand's refusal to provide sample by acquiring samples of Canadian drug).

[54] *See* Upadhye & Lang, *supra* note 8, at 112 n.129 ("reference product is defined in § 355(j)(7)," which, in referring to "drug products approved under § 355(b) and (c)," allows reference only to U.S. products since "foreign approved products are approved under that country's law" rather than sections 355(b) and (c)).

[55] *Id.* at 112. *See id.* at 111-12 ("FDA-approved brand product must be accessed and studied" and "[f]oreign reference product is not allowed").

[56] 21 U.S.C. § 355-1(f)(8).

[57] Food and Drug Administration Amendments Act of 2007 (FDAAA), 21 U.S.C. § 355-1(f)(8). The full text reads: "No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 505(b)(2) or (j) [21 U.S.C. § 355(b)(2) or (j)] or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application."

[58] Earlier legislation would have been even more explicit in clarifying brand obligations to provide samples to generics for bioequivalence testing. *See* Food and Drug Administration Amendments Act of 2007, H.R. 2900, 110th Cong. (1st Sess. 2007) (brand must provide "a sufficient amount of drug to conduct bioequivalence testing" if generic agrees to distribution restrictions assuring safe use and pays fair market value); S. 3187, 112th Cong. § 1131(k) (as passed by Senate, May 24, 2012) (providing that "no elements to ensure safe use shall prohibit

Congress was concerned that restrictions meant to prevent risky drugs from reaching consumers could prevent generic firms from buying samples and bringing those drugs to the market.[59] Senators have criticized brands' uses of access to samples to block and delay generics. In a recent hearing, Senator Charles Grassley (R-IA) lamented "tactics that appeared to frustrate the intent of the Hatch-Waxman Act," as brand firms "were misusing their . . . REMS to withhold access to drug samples for bioequivalence testing and generic drug development in violation of FDA regulations and the Hatch Waxman Act."[60] Similarly, Senator Patrick Leahy (D-VT) explained that "[t]his simple delay tactic uses regulatory safeguards as a weapon to block competition."[61] Brands need not even refuse to deal with a generic, instead "simply engag[ing] in never-ending negotiations that have the effect of delaying entry."[62]

In addition to the brand providing samples, Congress anticipated that generics and brands would need to cooperate. The 2007 legislation creating the regime required brands and generics to work together to create shared REMS known as a Single Shared REMS program ("SSRS").[63] With the exception of instances in which the burden of such a single, shared system outweighed the benefit[64] or an aspect of the elements to assure the drug's safe use is covered by a patent or trade secret,[65] the brand and generic must work together in creating a

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. . . supply of a [needed] drug . . . for the purpose of conducting [necessary] testing"). The failure to include such language must be viewed in the context of the FDAAA, "vast" legislation that "altered a significant portion of the FDA's powers," Christopher Megaw, *Reviving Essential Facilities to Prevent REMS Abuses*, 47 COLUM. J. L. SOC. PROBS. 103, 116 (2013), and in which other provisions were deemed more important. *See* Upadhye & Lang, *supra* note 8, at 99 (deeming the "drug-user fee reauthorization" to be "the most important provision"). Even more significant, the Supreme Court has made clear that "it is at best treacherous to find in congressional silence alone the adoption of a controlling rule of law." United States v. Wells, 519 U.S. 482, 496 (1997) (citation omitted); *see also* Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2053–54 (2014) ("legislative inaction is usually indeterminate" and "[a]llowing legislative inaction to guide common-law decisionmaking is not deference, but abdication"); Johnson v. Transp. Agency, 480 U.S. 616, 672 (1987) (Scalia, J., dissenting) (relying on "congressional inaction" to signal acquiescence to a prior judicial opinion is "a canard").

[59] *See supra* note 58.

[60] *CREATES Act Hearing*, *supra* note 31 (statement of Senator Chuck Grassley (R-IA)).

[61] *Id.* (statement of Senator Patrick Leahy (D-VT)).

[62] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, SEN. SPECIAL COMM. ON AGING, 114TH CONG. 2, 115 (2016). *See also* Katie Thomas, *Drug Makers Use Safety Rule to Block Generics*, N.Y. TIMES, Apr. 16, 2013, at B1 (quoting Rep. Henry Waxman: "The purpose of these postmarket safety plans was to protect consumers from risky drugs, not to allow brand companies to thwart generic competition.").

[63] *See* 21 U.S.C. 355–1(i)(1)(B).

[64] Federal Food, Drug, and Cosmetic Act § 505-1(i)(1)(B), 21 U.S.C. 355–1(i)(1)(B)(i).

[65] 21 U.S.C. 355–1(i)(1)(B)(ii).

shared REMS program.

Finally, it is not just Congress that has lamented brands' denials of needed samples. The FDA has demonstrated similar concern. Testifying at a Senate hearing, a leading agency official worried that REMS elements to ensure safe use "may restrict who gets the drug," with this power "used as an excuse . . . to not give the drug to the generics so they can compare it to their drug."[66] Such behavior causes "barriers and delays in getting generics on the market."[67]

II. REMS CASELAW

Courts have addressed the issue of brand firms using REMS to block or delay generic entry. But this is a nascent issue, analyzed in only seven cases to date, none past the motion-to-dismiss stage. Part II introduces the cases, most of which occurred in the setting of brands' refusals to provide samples to generics, and two of which arose in the shared REMS setting.

A. Lannett v. Celgene

In the first case, *Lannett v. Celgene*, Lannett sued Celgene, the manufacturer of thalidomide (Thalomid), which originally was used as a sleeping pill to treat morning sickness during pregnancy and has been used to treat patients with multiple myeloma and leprosy complications.[68] Because the drug was notoriously linked to severe birth defects and fetal deaths, the FDA in 1998 approved it with strict safety protocols called a System for Thalidomide Education and Prescribing Safety ("STEPS") that restricted the drug's distribution.[69]

Lannett sought FDA approval to market a generic version of Thalomid. It alleged that the agency approved its request to obtain samples from Celgene but that Celgene refused to sell samples.[70] At the same time, the STEPS program prevented Lannett from obtaining samples through other channels.[71] The generic alleged that it agreed to all the "health and safety restrictions set forth by the FDA" to acquire Thalomid.[72] And it contended that Celgene's refusal to provide samples prevented it from introducing a generic version and harmed consumers

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[66] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs*, HEARING BEFORE S. COMM. ON HEALTH, EDUCATION, LABOR AND PENSIONS, 114th Cong., 2d Sess., Trans. at 50:24-51:2 (Jan. 28, 2016) (testimony of Janet Woodcock).

[67] *Id.*, trans. at 51:2-3.

[68] Complaint, Lannett Co. v. Celgene Corp., 2:08-cv-03920-TJS, at 1, 5 (E.D. Pa. Aug. 15, 2008); U.S. Food & Drug Administration, *Thalidomide (marketed as Thalomid) Information* (last updated July 24, 2015), https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm107296.htm.

[69] *Id.* at 2, 4–5.

[70] *Id.* at 2.

[71] *Id.*

[72] *Id.* at 18.

who were forced to pay monopoly prices.[73]

Without offering a substantive opinion, the district court denied defendants' motion to dismiss.[74] Shortly afterwards, the case settled.[75]

B. Actelion v. Apotex

The second case involved bosentan (Tracleer), a drug used to treat pulmonary arterial hypertension.[74a] Brand firm Actelion sought a declaratory judgment that it did not have a duty to sell samples to Apotex, Roxane, and Actavis, justifying its refusal based on "government mandated safety concerns."[76] The generics, on the other hand, alleged that Actelion refused to sell samples in order to maintain a monopoly.[77]

In ruling from the bench that it would deny defendant's motion to dismiss, the court noted that the Supreme Court's refusal-to-deal decisions were "fact-specific" and "industry-specific."[78] In particular, it observed that "[t]he FDA is not the [Federal Communications Commission]" but is "a different environment," which made "clear" that the agency "does not have the regulatory power to compel samples" and that "there is no other potential remedy to a defendant suffering anticompetitive conduct in that regulatory scheme."[79] The court was "mindful of what Justice Scalia said" in the important case of *Verizon v. Trinko*[80] that "it's not the role of this Court or any Court to impose its own sense of competition or fairness or to become a super-regulatory agency."[81] But "[t]hat having been said," the court continued, "*Trinko* can't repeal Section 2," which "survives," and is "available, if the facts allow it, to prevent the improper maintenance and extension of a monopoly through improperly motivated conduct."[82]

Turning to the facts of the case, the generics "alleged a profit motive which did not exist in *Trinko*."[83] And the court found that the generics could successfully prove monopolization if they could show that defendants were

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[73] *Id.* at 16, 18.

[74] Order Upon Consideration of Defendant Celgene Corp.'s Renewed Motion to Dismiss, No. 08-3920 (Mar. 30, 2011); Battaglia, *supra* note 48, at 28 n.14.

[75] Erin Coe, *Lannett Cuts Deal with Celgene in Thalomid Antitrust Case*, LAW360 (Dec. 7, 2011).

[74a] *See Actelion v. Apotex* transcript, *supra* note 48, at 16.

[76] *See id.* at 116.

[77] *Id.*

[78] *Id.* at 115.

[79] *Id.* at 115–16.

[80] 540 U.S. 398 (2004).

[81] *Actelion v. Apotex* transcript, *supra* note 48, at 116.

[82] *Id.*

[83] *Id.* at 115.

"motivated not so much by safety concerns but instead [] by the desire to use the REMS or REMS equivalent . . . to maintain and extend a monopoly."[84] Shortly after the court denied the motion to dismiss, the case settled.[85]

C. Mylan v. Celgene

In the third case, *Mylan Pharmaceuticals v. Celgene*, Mylan sued Celgene, alleging that Celgene misused its REMS program to prevent Mylan from obtaining samples of Thalomid and Revlimid, treatments for, among other conditions, cancers and bone marrow disorders.[86] In 1998, the FDA approved Thalomid with the STEPS program described above.[87] Revlimid also had an approved REMS program.

Mylan first attempted to obtain samples from Celgene in October 2004 and continued to negotiate, unsuccessfully, for five years.[88] The Thalomid STEPS program also prevented Mylan from obtaining samples of the drug through wholesale distributors. [89] Mylan similarly alleged that it unsuccessfully negotiated for Revlimid samples from 2009 until 2012.[90] Mylan claimed that Celgene violated antitrust law because it sold samples at retail prices to research organizations and lacked a legitimate business reason for refusing to sell to Mylan.[91]

The district court denied Celgene's motion to dismiss, finding that Mylan sufficiently pled a monopolization claim.[92] It found that Third Circuit cases that had analyzed duties to deal found a "prior course of dealing" to be "relevant but not dispositive in determining whether such a duty applies."[93] It also noted that in *Trinko*, the Supreme Court considered facts like selling at retail and a prior course of dealing "not for their independent significance, but rather for what they *suggest*: [a] willingness to engage in irrational, anticompetitive conduct."[94] The court concluded that Mylan's pleadings were "sufficient to allow the case to proceed to discovery," in part because Celgene pled "no legitimate business

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[84] *Id.* at 117.

[85] Kat Greene, *Actelion Settles Row Over Giving Drugs To Generics Makers*, LAW360, Feb. 28, 2014.

[86] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 3–4 (D.N.J. Dec. 22, 2014).

[87] *Id.* at 3–4. *See supra* text accompanying note 68.

[88] *Id.* at 4–5.

[89] *Id.* at 4.

[90] *Id.* at 7–9 ("Mylan alleges that Celgene followed a 'nearly identical path of delay' for Revlimid, and that it worked to obtain samples from August 2009 to May 2012.").

[91] *Id.* at 17–18.

[92] *Id.* at 9.

[93] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 12-13 (D.N.J. Dec. 22, 2014).

[94] *Id.* at 9 (emphasis in original).

reason" for the behavior.[95] Celgene filed an interlocutory appeal, which the Third Circuit denied.[96] The case is scheduled for trial in 2017.[97]

D. In re Suboxone

In the fourth case, *In re Suboxone*, direct purchasers and end payors of Suboxone, a drug used to treat opioid addiction, filed multi-district litigation against Reckitt Benckiser.[98] Plaintiffs alleged multiple antitrust violations, including a claim that Reckitt manipulated the requirement of an SSRS.[99]

In December 2011, the FDA approved Reckitt's Suboxone REMS program to decrease the risk of pediatric exposure.[100] The next month, the FDA informed sponsors of pending generic applications that brand and generic versions would be subject to an SSRS, and the FDA anticipated that this requirement would be completed by May 2012.[101]

Seeking to undercut the requirement of working together, Reckitt "reportedly turned down numerous invitations to participate in meetings with the [g]enerics, and refused to engage in substantive discussions until the [g]enerics agreed to a number of conditions the[y] found unfavorable," including "an upfront agreement that all manufacturers would share the costs of product liability for future potential lawsuits."[102] The plaintiffs also alleged that Reckitt "refused to share non-public information from its REMS program until its demands were met."[103]

Plaintiffs notified the FDA of Reckitt's refusal, but the agency acknowledged that it could not compel the firm to share its non-public REMS

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[95] *Id.* at 17–18. The court dismissed a Section 1 claim targeting the brand manufacturer and distributors, finding that there was no showing that they had a "common anticompetitive goal." *Id.* at 24.

[96] Vin Gurrieri, *3rd Circuit Declines To Hear Mylan, Celgene Antitrust Fight*, LAW360, (Mar. 6, 2015).

[97] Brian Malkin, *NYSBA's REMS and Other Drug Distribution Restrictions Program Provide an Excellent and Informative Discussion*, FDALIFE, Nov. 4, 2016, http://www.fdalife.com/2016/11/04/nysbas-rems-and-other-drug-distribution-restrictions-program-provided-an-excellent-and-informative-discussion/ [https://perma.cc/4H4D-VUBS].

[98] 64 F. Supp. 3d 665 (E.D. Pa. 2014).

[99] *Id.* at 674–77; Federal Food, Drug, and Cosmetic Act § 505-1(i)(1)(B), 21 U.S.C. 355–1 (i)(1)(B) ("A drug that is the subject of an abbreviated new drug application and the listed drug shall use a single, shared system under subsection (f).").

[100] *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d at 675.

[101] *Id.* Plaintiffs explained that the agency gave a short turnaround time because Reckitt's recently approved REMS only needed to be amended slightly to incorporate the bioequivalent generics. *Id.*

[102] *Id.*

[103] *Id.*

program.[104] Although the FDA implored Reckitt to work with the generics in good faith and to not block or delay them, the brand allegedly refused to cooperate unless the generics granted it veto authority or a super-majority vote on all issues relating to the SSRS. With Reckitt taking "unreasonable positions" and using "delay tactics to keep [g]enerics off of the market for as long as possible,"[105] the generics sought and received a waiver from the FDA to submit their own separate REMS program.[106]

The court granted Reckitt's motion to dismiss, concluding that its refusal to cooperate did not violate the antitrust laws.[107] It stated that, even though "[i]t would have been easier to have Reckitt provide its REMS to its competitors with no strings attached, and participation on Reckitt's part would have allowed the process to move more quickly," a monopolist "certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous."[108]

The court reasoned that the generics could apply for a waiver and create their own program.[109] The case thus differed from the denial-of-samples cases, where the generic was not able to receive a sample in the first place. And the court found that even though there could be liability "where the SSRS process is manipulated to completely preclude a generic from filing an [application]," that was "not the situation" in this case.[110]

E. Natco v. Gilead Sciences

In the fifth case, *Natco Pharma v. Gilead Sciences*, generic firm Natco sued Gilead, the manufacturer of ambrisentan (Letairis), a drug used for the treatment of pulmonary arterial hypertension.[111] Letairis can cause serious birth defects and is subject to a REMS program limiting its distribution to specialty pharmacies, dispensed by specially certified pharmacists. Natco alleged that Gilead refused to sell Letairis samples, thereby preventing its generic drug from receiving FDA approval.[112] And it claimed that it offered to pay a market rate for samples and to buy the samples from Express Scripts, one of the specialty pharmacies dispensing Letairis.

The court granted Gilead's motion to dismiss on the grounds that Natco could have received the drug through a REMS-certified physician.[113] The court

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[104] *Id.*

[105] *Id.* at 675, 687.

[106] *Id.* at 676.

[107] *Id.* at 688.

[108] *Id.* (citation omitted).

[109] *Id.*

[110] *Id.*

[111] 2015 WL 5718398, at *1 (D. Minn. Sept. 29, 2015).

[112] *Id.* at *2.

[113] *Id.* at *5.

also was persuaded by another company's ability to obtain the drug for bioequivalence.[114] The court found that complying with REMS was a legitimate business reason not to sell the samples.[115] And it dismissed Natco's Section 1 claim on the grounds that it did not specify particularized facts alleging an anticompetitive conspiracy.[116]

F. In re Thalomid and Revlimid

In *In re Thalomid and Revlimid Antitrust Litigation*, the court denied a motion to dismiss in a third case challenging Celgene's denial of samples of Thalomid and Revlimid.[117] The plaintiffs challenged Celgene's refusal to provide samples, which was "contrary to FDA communications with the generic manufacturers, which they forwarded to Celgene, and which stated that the agency would not take action if Celgene provided the samples."[118]

Celgene argued that a termination of a prior course of dealing was a necessary element of a refusal-to-deal claim. The court rejected this argument, explaining that the termination of dealing in the classic case of *Aspen Skiing v. Aspen Highlands Skiing*[119] was "used as circumstantial evidence" of the defendants' "anti-competitive motivation" and "lack of legitimate business justifications."[120] The court found that "motivation is central" and that it was "too soon" to determine that issue because Celgene "provided samples to researchers who were not seeking to enter the market, but not to competitors who were."[121] The court found a "plausible inference" that defendant's reliance on its distribution programs was "pretextual" since it "continued to refuse to deal" even after the generics provided letters from the FDA indicating that the agency would not take action if Celgene provided samples.[122] Finally, the court denied a motion to dismiss on the grounds of an overall anticompetitive scheme that included obtaining patents by fraud, engaging in sham litigation, filing a sham citizen petition with the FDA, and entering into "pay for delay" settlements.[123]

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[114] *Id.* at *5–*6.

[115] *Id.* at *5.

[116] *Id.* at *7.

[117] 2015 WL 9589217 (D.N.J. Oct. 29, 2015).

[118] *Id.* at *5.

[119] 472 U.S. 585 (1985).

[120] *In re Thalomid and Revlimid Antitrust Litig.*, 2015 WL 9589217, at *15.

[121] *Id.*

[122] *Id.* The court also dismissed the defendant's justification based on product-liability concerns. *Id.* at *16.

[123] *Id.* at **5–7, *16.

G. In re Suboxone II

In a second *Suboxone* decision,[124] generic Amneal Pharmaceuticals sued Indivior (the successor company to Reckitt), the manufacturer of suboxone.[125] Amneal alleged that Indivior delayed generic entry by preventing the development of an SSRS and filing a sham citizen petition, thereby engaging in monopolization, attempted monopolization, and false advertising.[126]

As discussed above,[127] in January 2012, the FDA directed all generic filers to contact Indivior to develop an SSRS, expecting that the process would be completed by May 2012. But the brand refused to participate in weekly meetings, demanded that generics share product-liability costs, and refused to engage in substantive conversations or describe its REMS program at an initial meeting.

In June 2012, the FDA allowed the companies to create a new REMS that did not use Indivior's allegedly propriety information, expecting the SSRS to be "up and running" by August 2012.[128] But Indivior came up with "new excuses" to delay the SSRS, refusing to sign an agreement unless the generics "agree[d] to share a pre-specified percentage of all future product liability claims, regardless of fault."[129] Generics instead requested a waiver of the shared program, which the FDA granted in February 2013.[130]

Amneal challenged Indivior's conduct in relation to the SSRS, claiming that the actions amounted to anticompetitive deception.[131] The court found that such a claim did not apply because the ruling on which Amneal relied, *Broadcom Corp. v. Qualcomm Inc.*,[132] was "decidedly narrow" and "confined to its unique factual circumstances" of promises made to standard-setting organizations.[133] The court dismissed the plaintiffs' claims, finding that they merely "recast[]" their duty-to-deal allegation as a deception claim.[134]

In contrast, the court found that "a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable."[135] Because "there has been no determination . . . that every aspect of the conduct alleged by Amneal fails under the antitrust laws[,] . . . Indivior's conduct during

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[124] *See supra* Section II.D.

[125] *In re* Suboxone Antitrust Litig., 2017 WL 36371, at *1 (E.D. Pa. Jan. 4, 2017).

[126] *Id.* at *1, *3.

[127] *See supra* notes 100-101 and accompanying text.

[128] *Id.* at *3–*4.

[129] *Id.*

[130] *Id.* at *5.

[131] *Id.* at *7.

[132] 501 F.3d 297 (3d Cir. 2007).

[133] *Suboxone*, 2017 WL 36371, at *7–*8.

[134] *Id.*

[135] *Id.*

the SSRS process may be considered as one aspect of the overarching scheme claim."[136]

In short, courts in four of the five cases addressing a refusal to provide samples for generic testing denied motions to dismiss, allowing the case to proceed. In contrast, the two cases involving a shared REMS program rejected antitrust liability for standalone claims, with one acknowledging potential liability as part of an overall course of conduct. Given the fledgling state of analysis, this Article next articulates an antitrust framework for courts to apply.

III. ANTITRUST FRAMEWORK

The most typical antitrust case against brands for denying samples to generics is a monopolization claim under Section 2 of the Sherman Act.[137] To be liable for illegal monopolization, a company not only must have monopoly power but also must engage in exclusionary conduct.[138] This Part examines these issues. It first addresses monopoly power before analyzing refusals to deal with rivals. It then focuses on the existence and effectiveness of a regulatory regime. And it concludes with a discussion of the "no economic sense" test that can be discerned in not only refusal-to-deal cases but also more general monopolization jurisprudence and antitrust scholarship.

A Section 1 claim targeting agreements between brands and other firms has received less attention.[139] It is unlikely that a brand and generic would enter into an arrangement violating Section 1 because a denial of a sample does not result in the requisite agreement,[140] and the shared REMS setting (where the parties' continuing interactions lead to a greater opportunity for coordination) is marked by divergent incentives, with generics seeking to enter the market quickly and brands seeking to delay entry.[141] But it is conceivable that a brand could enter into an agreement with distributors to withhold samples. And in this scenario, it is no defense that, as one court asserted, there is no "common anticompetitive

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[136] *Id.* at *9.

[137] *See* 15 U.S.C. § 2.

[138] *See* United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

[139] The absence of mergers and acquisitions precludes reliance on Section 7 of the Clayton Act. *See* 15 U.S.C. § 18.

[140] 15 U.S.C. § 1.

[141] In contrast, aligned incentives are present in other pharmaceutical behavior, most notably "pay for delay" (sometimes called "reverse payment" or "exclusion payment") settlements in which brands pay generics (initially in cash, now in in-kind transactions) to delay entry. *E.g.*, FTC v. Actavis, 133 S. Ct. 2223, 2227 (2013). This raises antitrust concern because the brand gets more exclusion than is warranted by the patent alone. *See* Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 9–10 (2014). Because the brand makes more by keeping the generic out of the market than the two parties would receive by competing in the market, the parties have an incentive to split the monopoly profits, making each better off than if the generic had entered. In many cases, the generic even gains more through settlement than through successful litigation. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 73 (2009).

goal"[142] since a plaintiff challenging an agreement under Section 1 only needs to show anticompetitive effects that outweigh procompetitive justifications under the Rule of Reason.[143]

A. Monopoly Power

A monopolization case consists of monopoly power and exclusionary conduct.[144] The first element, which has not been the focus of the REMS cases to date, is monopoly power, which has been defined as "the power to control prices or exclude competition."[145] Monopoly power can be shown in one of two ways. First, it can be proved indirectly by examining a defendant's market share along with barriers to entry that could entrench that market position.[146] Courts regularly hold that a 90 percent market share supports market power, with some courts finding a 75 percent share to be sufficient.[147]

Monopoly power also can be proved directly,[148] such as when a brand firm is able to "maintain the price of [a drug] at supracompetitive levels without losing substantial sales . . . ."[149] Direct proof of monopoly power also can consist of observable effects on the market such as a price increase or output reduction.[150]

The Supreme Court has held that a market can consist of a single product[151] and courts have held that a single brand drug can constitute its own relevant market, which has led naturally to the conclusion of monopoly power.[152] As

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[142] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 24 (D.N.J. Dec. 22, 2014).

[143] *See, e.g.*, Michael A. Carrier, *The Rule of Reason: An Empirical Update for the 21st Century*, 16 GEO. MASON L. REV. 827 (2009) (surveying Rule-of-Reason cases between 1999 and 2009); Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 B.Y.U. L. REV. 1265 (1999) (surveying Rule-of-Reason cases between 1977 and 1999).

[144] *E.g.*, United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

[145] United States v. E.I. duPont de Nemours & Co., 351 U.S. 377, 391 (1956).

[146] *See* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE, ¶ 6.2b, at 359–60 (5th ed. 2016).

[147] *Id.* ¶ 6.2a, at 357.

[148] ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 69-70 (7th ed. 2012) (noting that "direct proof has provided the basis for findings of substantial anticompetitive effects in some prominent cases").

[149] *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 388 n.19 (D. Mass. 2013); *see also In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 246 (D. Conn. 2015).

[150] Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007).

[151] Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 481–82 (1992).

[152] *E.g.*, *In re* Aggrenox Antitrust Litig., 2015 WL 1311352, at *11 (D. Conn. Mar. 23, 2015) (if the brand was not "able to charge supracompetitive prices," it "is not clear why [it] would have sued to prevent entry" of the generic); *In re Cipro Cases I & II*, 2015 WL 2125291, at *22 (Cal. May 7, 2015) (plaintiff's prima facie case "will suffice, without more, to raise a presumption of the patentee's market power" since "[l]ogically, a patentee would not pay others to stay out of the market unless it had sufficient market power to recoup its payments through supracompetitive pricing"); *In re* Nexium Antitrust Litig., 968 F. Supp. 2d 367, 388

discussed below, where potential purchasers have no alternative to using a particular drug, as is typically the case in the REMS setting, monopoly power is likely.[153]

B. Refusals to Deal

The caselaw on exclusionary conduct is less clear than that on monopoly power. Courts often distinguish between the "willful acquisition or maintenance of [monopoly] power" and "growth or development as a consequence of a superior product, business acumen, or historic accident."[154] This Article focuses on a monopolization claim based on a refusal to deal with potential rivals.[155]

Courts have explained that generally, monopolists do not have a duty to deal with competitors.[156] A century ago, the Supreme Court famously declared that "as a general matter, the Sherman Act 'does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal.'"[157] But the Court later explained that this right is not "unqualified"[158] and that "[u]nder certain circumstances, a refusal to cooperate with rivals can constitute anticompetitive conduct and violate [Section] 2."[159] In the context of sample denials, this Article uncovers a combination of regulatory ineffectiveness and

(D. Mass. 2013) (rejecting defendants' claim that "other drugs may be used to treat heartburn"); *In re* Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005) (relevant market composed of brand and generic terazosin hydrochloride); *In re* Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 680-81 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003) (brand and generic versions of heart medication with chemical compound diltiazem hydrochloride constitute single market); *but see, e.g.*, Meijer, Inc. v. Warner Chilcott Holdings Co., 245 F.R.D. 26, 32–33 (D.D.C. 2007) (ordering discovery on oral contraceptives beyond brand and related generic version); *In re* Remeron Direct Purchaser Antitrust Litig., 367 F. Supp. 2d 675, 683 (D.N.J. 2005) (rejecting market definition limited to brand and generic versions because "[g]enerics normally enter the market with prices significantly lower than that of the first brand name manufacturers").

[153] *See infra* notes 225–228 and accompanying text.

[154] United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

[155] Another somewhat-related antitrust claim treats the sample as an "essential facility" that a monopolist cannot deny to rivals seeking to compete in a market. A plaintiff relying on such a theory must show "(1) control of the essential facility by a monopolist; (2) a competitor's inability . . . to duplicate the essential facility; (3) the denial of the use of the facility[;] . . . and (4) the feasibility of providing the facility." MCI Commc'ns Corp. v. AT&T, 708 F.2d 1081, 1132–33 (7th Cir. 1983). This Article does not focus on essential-facilities claims, which are more narrowly targeted to natural monopolies and conduct in downstream markets and less likely to be consistent with the conservatism of the no-economic-sense test and the factual setting of brands' denial of samples.

[156] Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 600 (1985).

[157] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) (quoting United States v. Colgate & Co., 250 U.S. 300, 307 (1919)).

[158] *Aspen Skiing Co.*, 472 U.S. at 601.

[159] *Trinko*, 540 U.S. at 408.

conduct lacking economic sense that triggers such an obligation. The facts of the leading refusal-to-deal cases offer necessary guidance.

Several monopolization cases have served as landmarks guiding refusal-to-deal analysis.[160] For example, in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, the owner of three downhill skiing facilities in Aspen, Colorado failed to offer a justification for withdrawing from a joint ticketing arrangement with the owner of the only other facility in the area.[167a] The Supreme Court defined exclusionary conduct as that which "tends to impair the opportunities of rivals" and which "either does not further competition on the merits or does so in an unnecessarily restrictive way."[161] The Court found that the monopolist was liable for anticompetitive conduct because it was willing to forego ticket sales and sacrifice profits to harm its smaller competitor.[162]

In a second classic case, *Otter Tail Power Co. v. United States*, the Supreme Court required a company to share electric power transmission with rivals.[163] The company "was already in the business of providing a service to certain customers," and thus could not "refuse[] to provide the same service to certain other customers."[164] In particular, there were "no engineering factors that prevented Otter Tail from selling power at wholesale to those towns that wanted municipal plants or [transferring] the power."[165] Rather, its "refusals to sell at wholesale or to [transfer] were solely to prevent municipal power systems from eroding its monopolistic position."[166] And as discussed in the next Section, additional monopolization cases highlight the importance of an effective regulatory regime covering the conduct.

C. Regulatory Regime

One of the most important developments in antitrust law in the past generation has been the Supreme Court's attention to regulatory regimes. In recent years, the Court has pointed to these regimes in the telecommunications

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[160] *See generally* Michael A. Carrier, Nicole Levidow, & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERK. TECH. L. J. __ (forthcoming 2017), https://papers.ssrn.com/sol3/Papers.cfm?abstract_id=2724604. [https://perma.cc/KC6P-MWJ4] (analyzing whether, by altering distribution scheme, Turing violated antitrust laws).

[167a] *See* 472 U.S. 585, 605–11 (1985).

[161] *Id.* at 605 n.32

[162] *Id.* at 608.

[163] *See generally* 410 U.S. 366, 377–82 (1973) (affirming lower court's monopolization finding).

[164] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 410 (2004).

[165] *Otter Tail*, 410 U.S. at 378.

[166] *Id.*

and securities contexts in downplaying the need for antitrust enforcement.[167]

The Supreme Court in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*[168] considered the effect of a telecommunications regime on the application of antitrust law. The Telecommunications Act of 1996 sought to break up local monopolies by requiring incumbent local exchange carriers ("ILECs"), which had state-provided monopolies in the provision of local phone service, to share their networks with competitors. The *Trinko* case arose when an AT&T customer alleged that Verizon discriminated against new entrants in the local market.[169]

The Court found that the statute "deter[red] and remed[ied] anticompetitive harm" and thus rejected the plaintiff's refusal-to-deal claim.[170] The presence of a regime that included penalties and reporting requirements[171] significantly reduced "the additional benefit to competition provided by antitrust enforcement."[172] In contrast, the Court continued, where "nothing built into the regulatory scheme . . . performs the antitrust function, the benefits of antitrust are worth its sometimes considerable disadvantages."[173]

The Court distinguished the *Aspen Skiing* and *Otter Tail* cases by noting that the defendants in those cases offered ski lift tickets and power transmission, respectively, which were services already available to the public.[174] By contrast, Verizon was required to share unbundled network elements, a "brand new" type of service that "exist[ed] only deep within the bowels" of the company.[175] These network elements were "offered not to consumers but to rivals, and at considerable expense and effort," which played a role in the dismissal of Trinko's claim.[176] The Court also worried about requiring a firm to share with its rivals, as such a remedy would "require[] antitrust courts to act as central planners" and could "facilitate the supreme evil of antitrust: collusion."[177]

In addition to considering the role of the telecommunications regime in fostering competition, the Court more generally described the relationship between antitrust and regulation. It explained that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at

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[167] This section is adapted from Carrier, *Unsettling Settlements*, *supra* note 148.

[168] 540 U.S. 398 (2004).

[169] For a detailed overview and analysis of *Trinko*, see generally Michael A. Carrier, *Of* Trinko, *Tea Leaves, and Intellectual Property*, 31 J. CORP. L. 357 (2006).

[170] *Trinko*, 540 U.S. at 412.

[171] *Id.* at 413.

[172] *Id.* at 412.

[173] *Id.* (citation omitted).

[174] *Id.* at 409–10.

[175] *Id.* at 410.

[176] *Id.*

[177] *Id.* at 408.

issue."[178] In particular, courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry."[179] And the analysis needs to "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."[180]

Consistent with this approach, the Court in *Credit Suisse Securities v. Billing*[181] concluded that the securities law regime "implicitly preclud[ed]" the application of the antitrust laws. In *Billing*, securities buyers challenged practices by which underwriting firms forced them to buy additional shares, pay high commissions, and purchase less desirable securities. The Court explained that the conduct fell "squarely within the heartland of securities regulations"[182] and that the Securities and Exchange Commission ("SEC") had authority to supervise the activities and "continuously exercised" such authority.[183] It also pointed to the "complex, detailed line" separating permitted from forbidden activity and the existence of activity that could be punished under the antitrust laws but upheld under the securities laws.[184]

Before minimizing the need for antitrust scrutiny, courts must find not only that a regulatory regime exists but also that it functions effectively. In *Trinko*, Justice Scalia explained that phone companies that provided local service were required to "be on good behavior" and not to discriminate in providing access to certain facilities before they could enter the long-distance market.[185] In addition, firms that did not satisfy these conditions were subject to financial penalties, daily or weekly reporting requirements, and the suspension or revocation of long-distance approval.[186] The Court concluded that "the regime was an effective steward of the antitrust function."[187] In *Credit Suisse*, the Court noted the SEC's active enforcement, pointing as one example to its detailed definitions of "what underwriters may and may not do and say during their road shows" and bringing actions against underwriters who violated the regulations.[188] In short, it is not just the existence of a regulatory regime that is important for antitrust analysis but also its effectiveness.

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[178] *Id.* at 411.

[179] *Id.* (quoting United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 91 (1975)).

[180] *Id.* (quoting Concord v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990)).

[181] 551 U.S. 264, 267 (2007).

[182] *Id.* at 285.

[183] *Id.* at 277.

[184] *Id.* at 279.

[185] 540 U.S. 398, 412 (2004).

[186] *See id.* at 412–13. Even if the effectiveness of the telecommunications regime was weaker than the Court anticipated, at least the regulators were engaging in actions that promoted competition. *See* Carrier, *supra* note 148, at 69–70.

[187] *Trinko*, 540 U.S. at 413.

[188] *Billing*, 551 U.S. at 277.

D. No-Economic-Sense Test

In contemplating tests for exclusionary conduct, one conservative approach that has been employed is the "no economic sense test."[189] This framework determines if the exclusion of rivals "likely would have been profitable if the nascent competition flourished and the monopoly was not maintained."[190] Applying the test requires an evaluation of the conduct's gains (not including those from eliminating competition) and costs to the monopolist.[191] The test focuses on the "reasonably anticipated impact" (according to "objective economic considerations for a reasonable person") rather than its actual impact.[192]

The no-economic-sense inquiry offers an economic test to determine whether the monopolist's sole motive is to impair competition. If a firm undertakes conduct that makes no economic sense, its "anticompetitive intent" can be "unambiguously . . . inferred."[193] As one commentator has explained, the test's application "could not be simpler if . . . the conduct cannot possibly confer an economic benefit on the defendant other than by eliminating competition."[194] Even in more nuanced settings than sample denials or shared REMS settings, the "technological superiority" of a new product should not prevent a finding of exclusionary conduct since the "value to consumers of the new system relative to the preexisting system" may not be "greater than the required development costs."[195] In short, if a brand acquires or maintains monopoly power by engaging

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[189] This section is adapted from Michael A. Carrier & Steve Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 117 (2016).

[190] Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 ANTITRUST L.J. 413, 415 (2006). For conduct allegedly creating a monopoly, the test asks "whether the conduct likely would have been profitable if the existing competitors were not excluded and monopoly was not created." *Id.*

[191] *Id.* at 416.

[192] *Id.*

[193] A. Douglas Melamed, *Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles?*, 73 ANTITRUST L.J. 375, 393 (2006). *See also id.* at 391–92 (employing the term "sacrifice test" because it is "widely used," but recognizing that both this test and the no-economic-sense test depend "not on the timeline, but rather on the nature of the conduct—on whether it would make no business or economic sense but for its likelihood of harming competition"); Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 76 (2009) (conduct that is economically irrational absent reduced competition leads to the natural inference that the actor "was aware of and motivated solely to achieve that reduction").

[194] Werden, *supra* note 197, at 415.

[195] Janusz A. Ordover & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation*, 91 YALE L.J. 8, 49 (1981). *See also* Spirit Airlines v. Nw. Airlines, 431 F.3d 917, 953 (6th Cir. 2005) (Moore, J., concurring) (stating that viable predation claims are based on theory that "an incumbent seeks to retain monopolist control in the future by ceasing to engage in economically rational behavior in the present in an effort to drive potential rivals from the market"); ROBERT H. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF 144 (1978) (suggesting test to identify business practices that "would not be considered

in sample denials or shared REMS behavior that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.[196]

Many courts, most notably the Supreme Court, have endorsed and applied a framework based on this analysis.[197] In *Aspen Skiing*, the Court found that the defendant "was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival."[198] And in *Trinko*, the Court highlighted "a willingness to forsake short-term profits to achieve an anticompetitive end."[199] Lower courts have offered similar approaches.[200]

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profit maximizing except for the expectation either that (1) rivals will be driven from the market, leaving the predator with a market share sufficient to command monopoly profits, or (2) rivals will be chastened sufficiently to abandon competitive behavior the predator finds inconvenient or threatening").

[196] Application of the no-economic-sense test would reach an outcome similar to (or even more deferential than) tests courts have used to analyze refusals to deal outside the pharmaceutical context. Two of the three approaches apply a "presumptively valid business justification" that can be rebutted, sometimes on grounds of pretext. Data General v. Grumman Systems Support Corp., 36 F.3d 1147 (1st Cir. 1994); Image Technical Services, Inc. v. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1997). If conduct satisfies this presumptively valid justification, it will clear the easier-to-satisfy threshold that accepts all justifications other than those harming competitors. The other test, articulated in *In re Independent Service Organizations Antitrust Litigation* ("*Xerox*"), 203 F.3d 1322 (Fed. Cir. 2000), provides three categories in which patent holders could be liable: tying, obtaining a patent through fraud, and sham litigation. The first category could reach more aggressively than the no-economic-sense test to ensnare a patentholder even if it had a justification for tying. And the categories addressing fraud and sham litigation present behavior that would tend not to satisfy the no-economic-sense test.

[197] Many of the courts' versions apply the related profit-sacrifice test, which offers an even more aggressive test that may not credit short-term profit sacrifice even for long-term economic gain. *See infra* notes 217–20 and accompanying text.

[198] Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 610–11 (1985).

[199] 540 U.S. 398, 409 (2004).

[200] *See, e.g.*, Novell, Inc. v. Microsoft Corp., 731 F.3d 1064, 1075 (10th Cir. 2013) (test satisfied when "monopolist's conduct [is] irrational but for its anticompetitive effects" (citing *Aspen Skiing*, 472 U.S. at 597; *Trinko*, 540 U.S. at 407)); Covad Commc'ns Co. v. Bell Atl. Corp., 398 F.3d 666, 676 (D.C. Cir. 2005) (considering predatory practice to be "one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor" (citing Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 222–23 (1993))); Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp., 910 F.2d 139, 148 (4th Cir. 1990) (conduct exclusionary if monopolist made "a short-term sacrifice in order to further its exclusive, anticompetitive objectives" (citing Smithkline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1065 (3d Cir. 1978))); Ne. Tel. Co. v. AT&T, 651 F.2d 76, 94–95 (2d Cir. 1981) (properly instructed jury could reasonably find that monopolist designed product to impede competition); Response of Carolina, Inc. v. Leasco Response, Inc., 537 F.2d 1307, 1330 (5th Cir. 1976) (technological tying cases "limited to those instances where the technological factor tying the hardware to the software has been designed for the purpose of tying the products, rather than to achieve some technologically beneficial result"); ILC Peripherals Leasing Corp. v. IBM, 458 F. Supp. 423, 439 (N.D. Cal. 1978) (no liability where

Commentators have advocated the test.[201] So have the leading antitrust treatises.[202] And the Department of Justice ("DOJ") has advanced it in several important cases. For example, in *Trinko*, the agency asserted that "conduct is not exclusionary or predatory unless it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition."[203] In *United States v. Microsoft Corp.*,[204] the DOJ contended that Microsoft's protection of its operating system monopoly was exclusionary because it "would not make economic sense unless it eliminated or softened competition."[205] In *American Airlines*,[206] the agency asserted that the defendant excluded rivals by adding "money-losing capacity" and that "distinguishing legitimate competition from unlawful predation requires a common-sense business inquiry" based on "whether the conduct would be profitable, apart from any exclusionary

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"there was no evidence that IBM was sacrificing present profits with the expectation of recouping its losses with subsequent price increases").

[201] *See, e.g.*, Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50, 54 (noting that, as applied to rival's access demands, rule "runs the least risk of reducing investment incentives while maintaining society's critical interest in preserving consumer welfare through competition"); Melamed, *supra* note 200, at 389 (offering test providing that "conduct is anticompetitive if, but only if, it makes no business sense or is unprofitable for the defendant but for the exclusion of rivals and resulting supracompetitive recoupment"); Werden, *supra* note 197, at 422–25 (articulating "no economic sense" framework); *cf.* Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential Generic Competitors*, 67 FLA. L. REV. 977, 1023 (2015) ("[U]nder the profit-sacrifice test, conduct is anticompetitive only if the defendant has no legitimate business purpose for the conduct or it is unprofitable in the short run and makes business sense only if a rival is excluded, leaving the defendant with a supracompetitive recoupment in the long run."); *see generally* Steve D. Shadowen et al., *supra* note 200, at 75–77.

[202] *See generally* IIIA PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 773e, at 209–13 (2d ed. 2002) (refusal to deal unlawful if irrational in sense that defendant sacrificed opportunity to make profitable sale only because of adverse impact refusal would have on rival); HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE, & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 12.3, at 13 (3d ed. 2017) ("If a design change makes no economic sense unless the exclusion of rivals is taken into account, it is reasonable to infer both that the purpose behind the design change was anticompetitive and, more importantly, that the anticompetitive effects of the design change predominated over any technological benefits.").

[203] Brief for the United States and the FTC as Amici Curiae Supporting Petitioner at 15, Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004) (No. 02-682) (emphasis omitted).

[204] 253 F.3d 34 (D.C. Cir. 2001).

[205] Brief for Appellees United States and the State Plaintiffs at 48, United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001) (Nos. 00-5212, 00-5213).

[206] United States v. AMR Corp. (*American Airlines*), 335 F.3d 1109 (10th Cir. 2003).

effects."[207] And in *United States v. Dentsply Int'l*,[208] the DOJ argued that "Dentsply's exclusionary policies made no economic sense but for their tendency to harm rivals, and so were predatory."[209]

The test also avoids some of the recognized shortcomings of the "profit sacrifice" test, which assesses whether conduct would be "unprofitable for the defendant but for the exclusion of rivals and resulting supra-competitive recoupment."[210] In particular, the profit-sacrifice test, unlike the no-economic-sense test, could punish short-term sacrifices such as investments in R&D or capital equipment even though they would lead to a higher profit in the long term.[211] The no-economic-sense test does not punish such investments, which "make economic sense apart from any tendency to eliminate competition."[212] And the test avoids disputes about whether the manufacturer anticipated that it would recoup its sacrificed profits sometime in the future.[213] Having introduced the no-economic-sense test, the next Part articulates an antitrust framework that applies the test to sample denials and shared REMS conduct in the pharmaceutical industry.

IV. THE ANTITRUST CASE AGAINST REMS PROGRAMS

In applying the antitrust framework articulated in Part III to REMS programs, this Part first addresses monopoly power. It then highlights the regulatory regime's existence and effectiveness. And it then turns to exclusionary conduct, focusing first on sample denials before concluding with

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[207] Brief for Appellant United States of America at 2, 30, United States v. AMR Corp. (*American Airlines*), 335 F.3d 1109 (10th Cir. 2003) (No. 01-3202) (public redacted version).

[208] 399 F.3d 181 (3d Cir. 2005).

[209] Brief for the United States at 28, United States v. Dentsply Int'l, Inc., 399 F.3d 181 (3d Cir. 2005) (No. 03-4097) (public redacted version).

[210] Melamed, *supra* note 200, at 389; *see also* Ordover & Willig, *supra* note 203, at 9–10 ("[P]redatory behavior is a response to a rival that sacrifices part of the profit that could be earned under competitive circumstances, were the rival to remain viable, in order to induce exit and gain consequent additional monopoly profit." (footnotes omitted)).

[211] *See* Werden, *supra* note 197, at 424. *See also* Herbert Hovenkamp, *The Harvard and Chicago Schools and the Dominant Firm* 115 (2008) (noting that profit-sacrifice test "does not adequately distinguish anticompetitive 'sacrifice' from procompetitive 'investment'").

[212] Werden, *supra* note 197, at 424.

[213] *See* Christopher R. Leslie, *Predatory Pricing and Recoupment*, 113 COLUM. L. REV. 1695, 1699 (2013) (describing "unnecessary and counterproductive" recoupment analysis); Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 319–20 (2006) (noting that no-economic-sense test "is primarily different from the conventional profit-sacrifice standard because it does not require a showing that there is a period of time in which the defendant's profits are lower than they were before the exclusionary conduct was undertaken" and that "[t]he reduction in profits can be conceptual rather than temporal").

shared REMS programs.[214]

A. Monopoly Power

In the REMS cases to date, the courts have focused their attention on the issue of exclusionary conduct. For example, after articulating the elements of the monopolization offense, the court in *In re Suboxone* asserted that "[s]imple possession of monopoly power is not enough" and that "a defendant must also engage in exclusionary conduct to run afoul of [Section 2]," after which it proceeded directly to examine the issue of the defendant's duty to deal.[215] In *Mylan v. Celgene*, the court indicated (at the motion-to-dismiss stage) that the parties solely disputed the conduct element.[216] And in *Actelion v. Apotex*, the court ruled that it would proceed to discovery without examining the issue of monopoly power.[217]

In the cases litigated to date, proving monopoly power has not been a hurdle. One reason is the procedural setting, with courts crediting plaintiffs' allegations related to the factually-intensive determination of monopoly power in the context of a motion to dismiss. But as the cases proceed to later stages, analysis could very well reveal monopoly power, reflecting the control that brands typically have over markets consisting of REMS drugs. The factors, for example, that the FDA evaluates[218] in requiring REMS "imply a cost-benefit analysis"[219] that considers whether other drugs treat the same disease. Where there is a less dangerous alternative on the market, the FDA would not be likely to approve a new, more dangerous product.[220] Instead, the agency is more likely to approve a risky REMS product only where there is no safer, effective alternative on the market. In other words, the REMS product is likely to fill an unmet medical need, lack close substitutes, and reflect monopoly power. Regardless of the factual setting relevant to monopoly power, the vast majority of the antitrust analysis to date has emphasized the second element: exclusionary conduct.[221]

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[214] Another anticompetitive concern, which lies outside the scope of this Article, arises from brands' blocking of generics through patents on REMS.

[215] *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 678–79 (E.D. Pa. 2014).

[216] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 9 (D.N.J. Dec. 22, 2014).

[217] *See Actelion v. Apotex* transcript, *supra* note 49, at 117.

[218] FDA, *Brief Overview*, *supra* note 18, at 6 (factors include the population size likely to use the drug, seriousness of the disease, drug's expected benefit, expected duration of treatment, seriousness of adverse effects, and drug's novelty).

[219] Megaw, *supra* note 57, at 132.

[220] *Id.*

[221] Another issue is whether the plaintiff can demonstrate antitrust injury. *See In re* Warfarin Sodium Antitrust Litig., 214 F.3d 395, 401 (3d Cir. 2000) (noting that "[i]t is difficult to imagine a more formidable demonstration of antitrust injury" than higher drug prices); Anna Fabish, *REMS Abuse and Antitrust Injury: Round Peg, Square Hole*, LAW360, Nov. 4, 2015 https://www.law360.com/articles/723053%20/rems-abuse-and-antitrust-injury-round-peg-

B. Existing Regulations

Central to the antitrust analysis of exclusionary conduct is an understanding of the regulatory regime. As the *Trinko* Court explained, "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."[222] Courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry,"[223] and the analysis must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."[224]

Just as the telecommunications regime in *Trinko* and securities regime in *Billing* presented comprehensive frameworks, the Hatch-Waxman Act and FDAAA offer exhaustive schemes that prescribed Congress's desired balance between competition and innovation in the pharmaceutical industry. The drafters of the Hatch-Waxman Act used patent-term extensions, market exclusivity, and 30-month stays to foster innovation.[225] And they introduced several mechanisms to increase generic competition.

Even though generic drugs have the same active ingredients, dosage, administration, performance, and safety as patented brand drugs, generic manufacturers were required, at the time of the Act, to engage in lengthy and expensive trials to demonstrate safety and effectiveness.[226] The FDA approval process took several years, and because the required tests constituted infringement, generics could not begin the process during the patent term.[227] They therefore waited until the end of the term to commence these activities, which prevented them from entering the market until two or three years after the patent's expiration. At the time Congress enacted Hatch-Waxman, there was no generic equivalent for roughly 150 drugs whose patent terms had lapsed.[228]

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square-hole [https://perma.cc/JTK4-UX6U] (raising concerns with antitrust-injury showing); Darren S. Tucker, Gregory F. Wells, & Margaret E. Sheer, *REMS: The Next Pharmaceutical Enforcement Priority?*, 28 ANTITRUST 74, 78 (2014) (discussing elements of injury and causation).

[222] Verizon Commc'ns. Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004).

[223] *Id.* (quoting United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 91 (1975)).

[224] *Id.*

[225] *See* Carrier, *supra* note 148, at 43–45.

[226] FDA, *Generic Drugs: Questions and Answers*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last visited Jan. 12, 2017).

[227] CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 3, 38 (1998).

[228] H.R. REP. NO. 98-857, pt. 2, at 11 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650. This paragraph is adapted from Carrier, *supra* note 148, at 42.

The drafters of the Hatch-Waxman Act[229] encouraged challenges to invalid or noninfringed patents, believing that such challenges would lead to earlier market entry and lower prices.[230] They exempted from infringement the manufacture, use, or sale of a patented invention for uses "reasonably related to the development and submission of information" under a federal law regulating the manufacture, use, or sale of drugs.[231] In addition to allowing the testing of the product before patent expiration, the drafters allowed generics to avoid the filing of a New Drug Application ("NDA") by submitting an Abbreviated New Drug Application ("ANDA").[232] To do this, the generic must show that its drug possesses the same active ingredient, route of administration, bioequivalence, and other characteristics of the brand.[233] If it can make this showing, it can rely on the brand's safety and effectiveness studies, dispensing with the need for independent preclinical or clinical studies.[234]

In fact, generic competition was an explicit goal of the Hatch-Waxman Act. Looking at the marketplace in 1984, the drafters sought to ensure the provision of "low-cost, generic drugs for millions of Americans."[235] And it believed the legislation would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed."[236] A crucial centerpiece of the Act, in short, involved a reduction in drug prices by facilitating generic entry.

The importance of generic competition is crucial not only for the Hatch-Waxman Act but also for other elements of the pharmaceutical regime. The drafters of the FDAAA included a provision that made clear that ETASU measures should not be used to prevent generic firms from accessing samples of drugs covered by REMS.[237] In particular, it made clear that "[n]o holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application."[238] Congress also provided that brand firms would not use REMS

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[229] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 335).

[230] *See* 130 CONG. REC. 24427 (1984) (statement of Rep. Waxman).

[231] 35 U.S.C. § 271(e)(1).

[232] *See* FTC, GENERIC DRUG STUDY, *supra* note 43, at 5.

[233] *Id.*

[234] *See id.*; *see, e.g.*, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012) (Hatch Waxman Act "allow[s] a generic competitor to file an [ANDA] piggy-backing on the brand's NDA").

[235] 130 CONG. REC. 24427 (1984) (statement of Rep. Waxman).

[236] *Id.*

[237] 21 U.S.C. § 355-1(f)(8) ("No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) or (j) [21 U.S.C. § 355(b)(2) or (j)] or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.").

[238] *Id.*

programs to burden patients who had serious medical conditions or difficulty accessing health care.[239] Such direction has been undermined by the drugs at issue in the cases, which involved treatments for pulmonary arterial hypertension (Tracleer), cancers and bone marrow disorders (Thalomid and Revlimid), and opioid addiction (Suboxone).[240]

Nor is the goal of fostering generic competition restricted to federal regulations. State drug product selection ("DPS") laws, in effect in all 50 states today, are designed to lower prices for consumers.[241] These laws allow—and in many cases require—pharmacists, absent a doctor's contrary instructions, to substitute generic versions of brand-name prescriptions.[242]

DPS laws are designed to address the disconnect in the industry between prescribing doctors, who are not directly responsive to drug pricing, and paying insurers and consumers, who do not directly select the prescribed drug.[243] In particular, DPS laws carve out a role for pharmacists, who are much more sensitive to prices than doctors.[244] The laws typically allow pharmacists to substitute generic versions of brand drugs only if they are "AB-rated" by the FDA. To receive an AB rating, a generic drug must be therapeutically equivalent to the brand drug, which means that the generic has the same active ingredient, form, dosage, strength, and safety and efficacy profile.[245] The drug also must be bioequivalent, which signifies that the rate and extent of absorption in the body is roughly equivalent to the brand drug.[246] Without access to samples, the generic is not able to show equivalence, thus blocking the crucial substitution at pharmacy counters throughout the country.

C. Ineffective Regulations

The regulatory context discussed in the previous section showed the vital significance of samples. The Hatch-Waxman Act and 50 state substitution laws are explicitly centered on early generic entry to the market.

Price falls dramatically from entry because generics do not need to replicate

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[239] FDAAA, 21 U.S.C. § 355-1(f)(2)(C). *See supra* note 27 and accompanying text.

[240] *See supra* Part II.

[241] Carrier, *supra* note 54, at 1017–18. *See supra* notes 35–37 and accompanying text.

[242] *Id.*

[243] *See* BUREAU OF CONSUMER PROTECTION, DRUG PRODUCT SELECTION: STAFF REPORT TO THE FTC 2–3 (1979).

[244] ALISON MASSON & ROBERT L. STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 7 (1985).

[245] *See generally* FDA Center For Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations* (36th ed. June 10, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. [https://perma.cc/VQ8Y-75dd].

[246] *Id.*

brand firms' expensive and lengthy clinical trials.[247] But the prerequisite to entering the market at a low price by demonstrating bioequivalence is the ability to access a brand's sample.[248] This entire regime comes crashing to a halt without this access. For without the sample, the generic cannot engage in the required testing and must replicate all of this work, in direct contravention of the Hatch-Waxman Act. One commentator has explained that "[i]f the brand company could limit access to its drug and be immune from any liability for doing so, the deprivation would essentially gut the purpose of the Hatch Waxman Act," which Congress would not have done in such a "back-handed manner."[249]

Congress was keenly aware of the importance of generic competition when it passed the FDAAA, which made clear that brands could not use ETASU restrictions to "block or delay" generic applications.[250] Despite the statute's prohibition on blocking or delaying generic competition, more than 100 generic firms have complained that they have not been able to access samples they need for testing to reach the market.[251] As discussed above,[252] Senators have lamented that the refusal to share samples is a "simple delay tactic [that] uses regulatory safeguards as a weapon to block competition" and that brands have "misus[ed]" REMS "in violation of FDA regulations and the Hatch Waxman Act."[253] Even though the drafters of REMS believed that the programs would not be used to block or delay generic entry, they have in fact been used in such a manner.[254]

Not only is the regime not working as intended, but the FDA is unable to fix the problem. A Senate committee concluded that the agency "has attempted to stymie [brands'] obstruction" by providing letters to generic entrants indicating that "they . . . see no safety risk," but its "actions have been largely ineffective."[255] While the statute "provide[s] the basis for the FDA to take

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[247] *See supra* notes 43–47 and accompanying text. The lack of promotion and marketing is another factor lowering generic costs.

[248] *See supra* note 46 and accompanying text.

[249] Upadhye & Lang, *supra* note 8, at 97.

[250] 21 U.S.C. § 355-1(f)(8).

[251] *CREATES Act*, *supra* note 2.

[252] *Id.* (statement of Senator Patrick Leahy (D-VT)); *see supra* notes 58–66 and accompanying text.

[253] *Id.* (statement of Senator Patrick Leahy (D-VT)); *CREATES Act Hearing*, *supra* note 32 (statement of Senator Chuck Grassley (R-IA)).

[254] Congress has recently considered legislation that would address the concerns of REMS programs. The CREATES Act provides a cause of action to a generic if the brand "decline[s] to provide sufficient quantities" of a drug "on commercially reasonable, market-based terms." CREATES Act, *supra* note 2, sec. 3(b)(1)(A). It also provides a cause of action if the brand "fail[s] to reach agreement with respect to a single, shared system" after 120 days. *Id.* sec. 3(b)(2). In addition to ordering (either) sufficient quantities of the drug or negotiation, the legislation provides for remedies that include attorneys' fees, costs, and an amount sufficient for deterrence. *Id.* secs. 3(b)(1)(D), 3(b)(2)(C).

[255] *Sudden Price Spikes*, *supra* note 61, at 115.

action" against brand firms, "the lack of a remedial scheme leaves much to debate about the FDA's authority to enforce and consequently little incentive for the FDA to do so."[256]

Nor has the agency had more success in relation to shared REMS, as "get[ting] competitors to work together so that [they] can get a market share from the [brand] has proven very challenging for the FDA to get . . . done," which "has delayed access."[257] Other than cases involving intellectual property, the agency has concluded that it "only has the power to authorize separate REMS systems if the delay in generic entry" has resulted in a drug's cost "affect[ing] patient access," which means that it "only act[s] after substantial delay."[258] The director of the FDA's Center for Drug Evaluation and Research (which is responsible for drug safety[259]) has concluded that the agency "ha[s] to try and try and try and try, and then finally, . . . declare defeat and . . . go ahead and let the generics have their own system that is separate but equal."[260]

It thus is not a surprise that the FDA has conceded that "issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by the Federal Trade Commission ("FTC"), which is the Federal entity most expert in investigating and addressing anticompetitive business practices."[261] To similar effect, the FDA responded to a citizen petition by Prometheus Laboratories by explaining that "[t]o the extent that . . . there may be antitrust issues associated with establishing single, shared systems," the party should "consult with the FTC."[262] And the court in *Actelion v. Apotex* found it *"*clear . . . that the FDA does not have the regulatory power to compel samples and that there is no other potential remedy to a defendant suffering anticompetitive conduct in that regulatory scheme."[263]

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[256] *Id.* at 117 n.733. The FDA does not even "have the authority to take enforcement actions against sponsors that do not include all information requested in FDA assessment plans." HHS REPORT, *supra* note 30, at 22.

[257] *Sudden Price Spikes*, *supra* note 61, at 115.

[258] *Id.* at 116.

[259] FDA, *About the Center for Drug Evaluation and Research*, Dec. 9, 2014, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ [https://perma.cc/5FN7-LJWU].

[260] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs*, HEARING BEFORE S. COMM. ON HEALTH, EDUCATION, LABOR AND PENSIONS, 114th Cong., 2d Sess., Trans. at 57:40 (Jan. 28, 2016) (testimony of Janet Woodcock).

[261] Partial Petition Approval & Denial to Dr. Reddy's Laboratories Petition at 7, No. FDA-2009-P-0266-0006 (Aug. 7, 2013).

[262] Grant in Part and Denial in Part at 6, No. FDA-2013-P-0572 (Oct. 7, 2013).

[263] *Actelion v. Apotex* transcript, *supra* note 49, at 115–16. *See also* Matthew Perrone, *Drug Distribution Becomes Weapon to Block Competition*, DETROIT NEWS, Mar. 3, 2016, http://www.detroitnews.com/story/business/2016/03/03/drug-distribution-competition-prices/81286042/ [https://perma.cc/297V-TD7T] (leading FDA attorney asserts that the agency "is hesitant to make a call on whether a manufacturer is actually intending to delay

Because the FDA has no power to compel a sale, the regulatory regime is not able to address competitive effects in the industry, ensuring an opportunity for antitrust enforcement.[264] As it turns out, antitrust can play a uniquely effective role in addressing the anticompetitive harms unleashed by the REMS regime. Absent a showing, not revealed to date, of below-market-rate offers, the denial of samples, as shown in the next Section, makes no economic sense other than by harming generic competition.[265]

D. Sample Denials

The regulatory regime, ineffectively enforced, opens the door for antitrust. And that regime is well-equipped to analyze behavior so extreme that it fails even the conservative, defendant-friendly, no-economic-sense test.

Most fundamentally, the refusal to provide REMS samples to generics makes no economic sense other than by harming generics. Generics have been willing to pay a high price for samples, with one even stating that it pays "ridiculous amounts of money" for "a commercially immaterial quantity of drug."[266] The case law provides examples of generics' willingness to purchase samples at a rate that would be profitable to the brand.[267] In *Actelion v. Apotex*, generic firm Apotex was willing to "pay market prices for the samples."[268] And in *Natco Pharma v. Gilead Sciences*, generic Natco "offered to pay the market

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generic competition"); Anna M. Fabish, *Why REMS Abuse Doesn't Belong in Antitrust Litigation*, LAW360 (Apr. 23, 2015), https://www.law360.com/articles/645875/why-rems-abuse-doesn-t-belong-in-antitrust-litigation [https://perma.cc/7LZE-MWPY] ("The FDA would certainly need to expand its existing review and enforcement tools . . . to determine . . . how to remedy a refusal" to provide samples).

[264] The court in *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665 (E.D. Pa. 2014), asserted that the statute prohibits brands from "manipulating the process to cause delay," which apparently "provides for increased FDA oversight and diminishes the need for antitrust scrutiny." *Id.* at 688. But such a holding fails to consider the effectiveness of the regulatory regime, in particular the FDA's inability and unwillingness to address competition concerns.

[265] The Federal Trade Commission has filed two amicus briefs that have contended that refusals to provide samples can constitute exclusionary conduct under Supreme Court case law and undermine the goals of the Hatch Waxman Act; that distribution agreements are not immune from antitrust scrutiny; and that bioequivalence testing is exempt from patent infringement. *See generally* Federal Trade Commission's Brief as *Amicus Curiae*, Mylan Pharms. v. Celgene Corp., Case No. 2:14-CV-2094-ES-MAH (D.N.J. June 17, 2014); Federal Trade Commission's Brief as *Amicus Curiae*, Actelion Pharms. v. Apotex Inc., Case No. 1:12-cv-05743-NLH-AMD (D.N.J. Mar. 11, 2013).

[266] *CREATES Act Hearing*, *supra* note 31 (statement of Beth Zelnick Kaufman at 2:11).

[267] Generics that lack access to a sample are not able to use a foreign sample as a substitute. *See supra* note 54 and accompanying text.

[268] Memorandum of Law In Support of Defendants'/Counterclaim Plaintiffs' Opposition to Plaintiffs'/Counterclaim Defendants' Motion for Judgment on the Pleadings and to Dismiss Counterclaims, Actelion Pharm. Ltd. v. Apotex, Inc., 2013 U.S. Dist. Ct. Briefs LEXIS 27858, at *22; *see also Actelion v. Apotex* transcript, *supra* note 48, at 49 (Roxane's counsel states that "[t]he generics have offered to pay retail published price or, frankly . . . any price that was within the realm of reasonableness").

rate and shipping" for more than 500 tablets.[269]

This willingness to pay the market rate has been combined with brands' seemingly irrational responses in refusing to provide samples. In *Mylan v. Celgene*, for example, Mylan alleged that it "requested the purchase of limited Revlimid samples for bioequivalence testing, offering to pay market value" as well as its willingness to "enter into an indemnification agreement" that included nearly every concession to terms Celgene requested" during earlier negotiations.[270] Celgene, however, responded by rejecting Mylan's offer.[271] In fact, after negotiating for the sale of Thalomid samples for five years, and reaching an indemnification agreement in 2009, as of the date of this Article, nearly *eight years later*, Mylan *still* has not been able to obtain access to samples.[272] Another example is provided by generic firm Amneal, which explained to a Senate committee that it requested samples in December 2013, signed an agreement in February 2016, but (as of the date of this Article) still did not have samples.[273] These examples of a lack of economic sense are confirmed when, at the same time brands deny samples to generics, they make sales to other entities including research organizations, distributors, and specialty pharmacies.[274]

In short, it is clear that generics are willing to buy samples from brands and, in every reported instance, pay at least a profitable market rate. This situates the denials comfortably in the range of facts in which courts have found liability because of a refusal to accept a retail price.

In *Aspen Skiing*, the Court found that the defendant "was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival."[275] In discussing the decision, the *Trinko* Court emphasized "[t]he unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing," which "suggested a willingness to forsake short-

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[269] 2015 WL 5718398, at *2 (D. Minn. Sept. 29, 2015). The regulatory regime and legislative history make clear that, in calculating the cost of a sample, brands cannot include future effects from product-liability lawsuits or safety concerns. *See infra* notes 385-399 and accompanying text.

[270] Plaintiff Mylan Pharmaceuticals' Brief in Opposition to Celgene's Motion to Dismiss, Civ. Action No. 2:14-cv-02094-ES-MAH, 2014 U.S. Dist. Ct. Briefs LEXIS 1435, at *13–14 (D.N.J. June 16, 2014).

[271] *Id.*

[272] *See* Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 4–7 (Dec. 22, 2014).

[273] *CREATES Act Hearing*, *supra* note 32, at 2–3 (statement of Beth Zelnick Kaufman).

[274] *Actelion v. Apotex* transcript, *supra* note 49, at 49–50; *see also In re* Thalomid and Revlimid Antitrust Litig., 2015 WL 9589217, at *15 (D.N.J. Oct. 29, 2015) ("motivation is central" when brand "provided samples to researchers who were not seeking to enter the market, but not to competitors who were").

[275] Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 610–11 (1985).

term profits to achieve an anticompetitive end."[276] And it observed that an "unwillingness to renew the ticket *even if compensated at retail price* revealed a distinctly anticompetitive bent."[277]

To similar effect was *Otter Tail Power Co. v. United States*,[278] in which the Court required a company to share electric power transmission with rivals. The firm was already providing the service, and the only reason it refused to provide it to competitors was "to prevent municipal power systems from eroding its monopolistic position."[279] Like the ski lift tickets in *Aspen Skiing*, the defendant was "already in the business of providing" power transmission services to other customers.[280]

In contrast, the *Trinko* Court distinguished between refusing to sell a product at the "retail price," an indicator of anticompetitive behavior in implying "a calculation" of a "future monopoly retail price [that] would be higher,"[281] and Verizon's ability only to obtain a "cost-based rate of compensation" under the relevant statute.[282]

Refusing to make a sale at the market price (or even higher) does not make sense absent harm to the generic. It is consistent with the monopolist's conduct in *Aspen Skiing* (sacrificing profits) and *Otter Tail* (harming competitors) and readily distinguishable from *Trinko* (unprofitable price).

Drug samples also are far closer to the services available to the public under *Aspen Skiing* and *Otter Tail* than the "brand new" type of service in *Trinko* that "exist[ed] only deep within the bowels" of Verizon.[283] For REMS programs that the FDA requires after the drug is already on the market, by definition the product is available. Even when a sample is requested before a drug is approved, the brand firm is in the business of producing drugs. And once it has manufactured the drug, providing a sample involves no additional effort. It is not as if the brand needs to embark on a separate process of creating a new product just to provide to the generics. The ready availability of samples offers additional evidence that the refusal to provide them to generics constitutes behavior that makes sense only by harming rivals.

In short, the denial of samples falls comfortably within the factual setting of cases in which courts have found liability. As the *Actelion* court recognized: "[I]f

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[276] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 409 (2004).

[277] *Id.*

[278] 410 U.S. 366 (1973).

[279] *Id.* at 378.

[280] *Trinko*, 540 U.S. at 410.

[281] *Id.* at 409.

[282] *Id.*

[283] *Id.* at 410.

the defendants can prove that the plaintiffs are motivated not so much by safety concerns but instead . . . by the desire to use the REMS or REMS equivalents, to use exclusive distribution agreements and to use a[n] otherwise legitimate refusal to deal together to maintain and extend a monopoly, then they may very well make out a Section 2 claim."[284]

E. Shared REMS

The other setting in which REMS issues have arisen involves Single Shared REMS Programs, known as SSRS.[285] By offering a shared system, SSRS programs reduce the burdens on healthcare providers and manufacturers. For example, the REMS program covering opioids involves multiple companies.[286] Such a joint effort against a public health problem would be much more difficult without coordination. As a result of the shared REMS program, more prescribers have received training on pain management and on the safe prescription of opioids.[287]

Another example is provided by the SSRS for mycophenolate-containing prescription medicines, which "weaken[] the body's immune system so it will not attack and reject a transplanted organ."[288] The FDA required the shared program because the products were marketed by different sponsors, and a single REMS program that could be "used and shared by all of these sponsors" would "reduce the burden on the health care system."[289] A single, shared system for the products would "make it easier for prescribers to participate in the REMS program" because there would "only be one education program for prescribers."[290] And it would be easier for manufacturers, who could "maintain a single call center to support health care professionals and the REMS

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[284] *Actelion v. Apotex* transcript, *supra* note 52, at 117.

[285] Federal Food, Drug and Cosmetic Act § 505-1(i)(1)(B), 21 U.S.C. 355–1 (i)(1)(B).

[286] *See* FDA, *Approved REMS*, *supra* note 29.

[287] FDA, *Fact Sheet – FDA Opioids Action Plan*, Sept. 13, 2016, http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm. [https://perma.cc/VW5F-U5UX] *See also* FDA, *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioid Analgesics*, Jan. 9, 2017; http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm163647.htm [https://perma.cc/T4P7-NBEV] (noting that REMS is "one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics").

[288] *Questions and Answers: FDA Approves a Single Shared Risk Evaluation and Mitigation Strategy (REMS) for Mycophenolate-containing Medicines*, http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm318880.htm. [https://perma.cc/MW8T-TPQW].

[289] *Id.*

[290] *Id.*

program."[291]

In short, shared REMS programs serve important public health purposes. And central to the programs is the alignment of brand and generic REMS. As an FDA official explained: "If we are approving a generic drug and there is a REMS in place for the innovator drug, the requirements are the same for the [generic] product."[292]

Despite this need for coordination, on several occasions brands have delayed generic entry by failing to negotiate in good faith, claiming that generics "remain free at all times to develop their own REMS program."[293] One technique involves a claimed "absolute right to keep its REMS confidential,"[294] which purportedly means that the FDA is unable to "compel [the brand] to share its proprietary REMS program."[295] To the contrary, the REMS program is not confidential, appearing with full details including the program's elements, sample letters, patient guides, enrollment forms, and screenshots, on the FDA's website.[296] Even if information subject to discussion between the FDA and brand before final approval is generally not available, the final implemented REMS program is public.[297]

Brands also have delayed approval by employing IP.[298] The statute provides that the SSRS requirement can be waived if "an aspect of the elements to assure

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[291] *Id.* Another example is provided by the SSRS for transmucosal immediate-release fentanyl ("TIRF"), which relieves sudden and short-term pain in cancer patients. FDA, *Questions and Answers: FDA Approves a Class Risk Evaluation and Mitigation Strategy (REMS) for Transmucosal Immediate-Release Fentanyl (TIRF) Medicines*, July 9, 2015, http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm284717.htm [https://perma.cc/EGB9-FTR9]. The FDA approved this shared program even though the TIRF medicines "already had individual REMS in place" to "reduce the burden on the healthcare system of having separate REMS programs in place for individual TIRF medicines." The benefit of a single shared program is that "prescribers, pharmacies, distributors, and outpatients will only need to enroll in one REMS program" in order "to prescribe, dispense, or receive all drugs in the TIRF medicines class."

[292] Terry Toigo, FDA, *A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS)* (42:00), https://collaboration.fda.gov/p97727926/?launcher=false&fcsContent=true&pbMode=normal (last visited Jan. 20, 2017).

[293] Reply in Support of Defendants' Motion to Dismiss, *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665, at *8–*11 (E.D. Pa. 2014).

[294] *Id.* at 7.

[295] *Id.* at 6.

[296] FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)*: *Tracleer*, http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=61 (last visited Jan. 16, 2017) [https://perma.cc/G6LH-WV2U].

[297] *See* FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last visited Jan. 16, 2017) [https://perma.cc/4KLQ-DQTA].

[298] *Sudden Price Spikes*, *supra* note 61, at 116.

safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that, as a trade secret, is entitled to protection."[299] The burden is on the generic to show that "it has sought a license for use of an aspect of the elements to assure safe use for the applicable listed drug" and that it "was unable to obtain a license."[300] An FDA official confirmed that brands use "dilatory assertions that portions of the REMS are protected by . . . 'IP' rights or constitute trade secrets" to delay generic access.[301] In every one of its attempts to mediate a joint SSRS program, the FDA was not successful, ultimately allowing the generic to create its own REMS.

The FDA has allowed a generic to create its own REMS program on 13 occasions.[302] Even though the agency has the power to release these parties from the SSRS requirement, it can only do so after showing that the burden of the program outweighs the benefit or that there is protected IP as part of the REMS program.[303] The FDA's power, in short, does not prevent prolonged negotiations that could delay generic approval. When a brand manipulates the process to cause delay, the agency is not able to remedy the issue. As discussed above,[304] the FDA "only act[s] after substantial delay,"[305] and even then, "ha[s] to try and try and try and try, and then finally . . . declare defeat and . . . go ahead and let the generics have their own system that is separate but equal."[306] A leading FDA official stated simply that brands often use shared REMS programs to "block[] generic competition."[307]

The FDA's inability to act carves out a potential role for antitrust law. How should antitrust law be applied? The answer is more nuanced than the case of sample denials. For negotiation is not an on/off switch that automatically triggers (or fails to trigger) antitrust scrutiny. But in certain cases, the brand's refusal to negotiate in good faith will run afoul of the no-economic-sense test. Factors for a court to consider include how long the parties have been negotiating, how different the shared program is from the brand's already-existing REMS program, evidence of the brand firm's bad faith, evidence of the generic firm's

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[299] 21 U.S.C. § 355-1(i)(1)(B)(ii) (2016). For the other exception, see 21 U.S.C. § 355–1(i)(1)(B)(i) ("[T]he burden of creating a single, shared system outweighs the benefit of a single, system.").

[300] 21 U.S.C. § 355-1(i)(1)(B)(ii).

[301] *Sudden Price Spikes*, *supra* note 61, at 116.

[302] *Id.*

[303] *See* 21 U.S.C. § 355–1 (i)(1)(B).

[304] *See supra* notes 251–67 and accompanying text.

[305] *Sudden Price Spikes*, *supra* note 61, at 116.

[306] *Id.*

[307] *Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA): Testimony of Janet Woodcock* before SEN. COMM. ON HEALTH, EDUCATION, LABOR AND PENSIONS, at 19 (Jan. 28, 2016).

good faith, and additional alleged anticompetitive behavior.[308]

One example that would appear to fail the no-economic-sense test is provided by *In re Suboxone Antitrust Litigation*.[309] In that case, the plaintiffs alleged that in a setting in which the FDA "contemplated rapid development of a shared REMS"[310] since the brand's "own previously-approved Suboxone REMS could be amended to add generic manufacturers in a relatively short time,"[311] the brand (1) "turned down numerous invitations to participate in meetings" and "refused to engage in substantive discussions until the [g]enerics agreed to a number of [allegedly unfavorable] conditions"; (2) "refused to share non-public information from its REMS program until its demands were met"; (3) "refused to cooperate unless the [g]enerics agreed to provide Reckitt veto authority or a super-majority vote on all issues relating to the SSRS"; and (4) "[took] unreasonable positions and utilized delay tactics to keep [g]enerics off of the market for as long as possible."[312] Another example is provided by the negotiation between Jazz Pharmaceuticals and generics concerning the narcolepsy drug Xyrem, for which the FDA waived the requirement of an SSRS given the parties' inability to agree to terms, which was "likely to further delay the approval" of a generic version of the drug.[313] The FDA also has waived shared REMS after an unsuccessful three-year negotiation.[314]

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[308] Evidence relevant to these factors appears in examples offered in this section. For an argument that shared REMS do not require significant changes from brand REMS, see *CREATES Act Hearing*, *supra* note 32 (statement of Beth Zelnick Kaufman at 2:17) ("[O]nce a REMS is in place, that means the FDA and the innovator have already decided the details" of the program, with "[t]he mystery . . . gone" and "[a]ll of the secrets are out" and "on a piece of paper," which leaves only the task of "find[ing] a way to change that program . . . from a single-source supply to a multi-source supply," which generic firms have been doing "for 32 years since Hatch-Waxman").

[309] 64 F. Supp. 3d 665 (E.D. Pa. 2014).

[310] End Payor Plaintiffs' Consolidated Amended Class Action Complaint, *In re* Suboxone Antitrust Litig., 2013 WL 5467390 ¶ 51 (Aug. 15, 2013).

[311] *Id.* ¶ 53 (noting that FDA had recently approved brand REMS).

[312] *In re* Suboxone, 64 F. Supp. 3d at 675, 687. *See also Memorandum re: Decision To Waive the Requirement for a Single, Shared System REMS for Buprenorphine-Containing Transmucosal Products* (submitted to ANDA 090819 et al., Feb. 22, 2013) (referencing Subutex (buprenorphine) and Suboxone (buprenorphine and naloxone)).

[313] Memorandum from Trueman W. Sharp, *Abbreviated New Drug Applications (ANDAs) for sodium oxybate oral solution products*, at 13, Jan. 17, 2017.

[314] Memorandum re: Decision to Waive the Requirement for a Single, Shared System REMS for Alosetron Products at 12 n.41 (submitted to ANDA 200652 on May 4, 2015). Guidance also could come from legislation such as the Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act") of 2016, S. 3056 (114th Cong.) (introduced June 21, 2016), which provides that negotiations for shared REMS must occur within 120 days. Section 3(b)(2)(B). *See also id.* § 3(b)(1)(D) (providing that if brands do not provide samples on "commercially reasonable, market-based terms," the generic could, in addition to obtaining the sample, receive attorneys' fees and other damages). *Id.* For a critique of the CREATES

Conduct similar to that in *Suboxone* and *Jazz* most likely would fail the no-economic-sense test. In particular, conduct could lack economic sense for reasons relating to safety, cost-sharing, and IP licensing. First, brands have highlighted safety concerns arising from generics' creation of their own REMS programs.[315] For example, Jazz argued against a waiver of a shared system on the grounds that such a waiver would "impact patient safety" since "'without access to all of the data, Jazz would lose the ability to ensure that the pharmacy has all of the data necessary to monitor for overlapping prescriptions, review for potentially interacting agents that are unknown to the prescriber, and review [indicators] regarding potential misuse, abuse, or diversion.'"[316] Brands wishing to exercise more control and oversight over generic REMS programs naturally would find it in their interest to negotiate in good faith to expeditiously complete a shared REMS. For brand firms that have voiced safety concerns, a failure to do so makes no economic sense other than by delaying generic entry.

Second is the potential for cost-sharing. When multiple sponsors are involved, the FDA requires the parties to negotiate for shared REMS programs, which promise to "[r]educe [the] burden for different stakeholders" by allowing a "single portal to access materials and other documentation and information about the program" and allow "prescribers, pharmacies, and healthcare settings [to] complete certification and other administrative requirements once rather than for each individual drug."[317] As a benefit of a shared REMS system, the FDA also has pointed to the "[p]otential for cost sharing among all sponsors."[318] To the extent, then, that the brand delays negotiating the SSRS, it could increase its costs in a way that makes sense only because of delayed generic competition.

Third, similar to its denial of sales of samples in a manner that makes no economic sense,[319] brands could be leaving money on the table by not entering into profitable licensing arrangements with generics. One of the grounds on which the FDA can waive the requirement of a shared REMS is that the generic shows that "it has sought a license for use of an aspect of the elements to assure safe use for the applicable listed drug" but "was unable to obtain a license."[320] If that attempt includes at least a reasonable royalty, a brand could be refusing to negotiate in good faith. This would not make sense if not for its effect in impairing generic competition.

Act, see Erika Lietzan, *A Second Look at the CREATES Act: What's Not Being Said*, 17 FED. SOC'Y REV. 38, 48–50 (Oct. 2016).

[315] For a critical analysis of brands' safety-based claims, see *infra* Section V.C.

[316] Sharp Memorandum, *supra* note 316, at 18.

[317] Elaine Lippmann, FDA, *Development of Single, Shared System REMS*, GPHA FALL TECHNICAL CONFERENCE 6, Oct. 26, 2016.

[318] *Id.*

[319] *See supra* notes 268–75 and accompanying text.

[320] 21 U.S.C. § 355–1(i)(1)(B)(ii).

A lack of good-faith negotiation also could form part of a larger scheme of anticompetitive behavior.[321] Such behavior, together with some combination of patent-related fraud, sham litigation, settlements, "product hopping," and "citizen petitions," could increase the likelihood of an antitrust violation.[322] In settings in which evidence relating to a shared REMS alone is ambiguous, consideration of a more expansive array of the brand's behavior could provide useful guidance.

In short, brand conduct in the shared REMS setting can violate the antitrust laws just as can the denial of samples. This conclusion on antitrust liability in both settings is strengthened by the consideration, and rebuttal, of the primary justifications that brands have offered for their conduct.

V. REBUTTAL OF JUSTIFICATIONS

Brand firms have vigorously contested antitrust liability for REMS-related behavior. This Part rebuts the four justifications on which the brands have most frequently relied. The first two, based on the case law, contend that there is no duty to deal and that, in any event, there is no prior course of dealing between the parties. The other two center on business arguments based on concerns about safety and product liability.

A. Duty to Deal

The brands' first justification, the most expansive one under the case law, is that they have no duty to deal with generics. Actelion contended that it "is under no duty to deal with or assist its would-be generic competitors," as the "well-settled rule of law is subject to narrow and rare exceptions, none of which

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[321] *See, e.g.*, Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962) ("[P]laintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each."); LePage's Inc. v. 3M, 324 F.3d 141, 162 (3d Cir. 2003) ("[C]ourts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."); *In re* Gabapentin Patent Litig., 649 F. Supp. 2d 340, 359 (D.N.J. 2009) ("If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability."); *In re* Neurontin Antitrust Litig., 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009) ("If an antitrust plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions may trigger antitrust liability as an overall scheme."); Abbott Labs. v. Teva Pharms., 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claim[] that those acts as a group have an anticompetitive effect even if the acts taken separately do not."); *see generally In re* Suboxone Antitrust Litig., 2017 WL 36371, at *9 (E.D. Pa. Jan. 4, 2017) (citing cases and finding that conduct during SSRS process "may be considered as one aspect of the overarching scheme claim").

[322] *See* HOVENKAMP, JANIS, LEMLEY, LESLIE, & CARRIER, IP AND ANTITRUST, *supra* note 209, ch. 15 (providing details on causes of action).

applies" to the denial of samples.[323] Speaking even more broadly, it asserted that "[t]his right to choose with whom to do business—and to choose not to do business with a rival—is a cornerstone of America's free enterprise system, and is consistent with basic free market principles."[324] Continuing the theme of hyperbole, Celgene asserted that even if its "insistence on appropriate procedures and guarantees were not motivated by the safety of fetuses and the survival of its business, antitrust law still would not require it to deal with its potential rivals."[325]

To be sure, the *Trinko* Court was skeptical of refusal-to-deal cases, stating that "as a general matter, the Sherman Act 'does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal.'"[326] On the other hand, the "high value" that the Court has "placed on the right to refuse to deal with other firms does not mean that the right is unqualified."[327] "Under certain circumstances," the Court continued, "a refusal to cooperate with rivals can constitute anticompetitive conduct and violate [Section] 2."[328] While there might not be a general duty in many contexts, the unique pharmaceutical regulatory setting, when combined with conduct that fails the no-economic-sense test, suggests an exception for REMS behavior.

The facts of REMS denials resemble those of cases in which the Supreme Court has found liability. For starters, drug samples are readily available. The Court in *Trinko* found that the defendants in the *Aspen Skiing* and *Otter Tail* cases offered ski lift tickets and power transmission, respectively, which were already available to the public.[329] By contrast, Verizon was required to share unbundled network elements, a "brand new" service "exist[ing] only deep within [Verizon's] bowels" that it "offered not to consumers but to rivals, and at considerable expense and effort.[330] For REMS programs that the FDA requires after the drug is already on the market, by definition the product is available. And even when a sample is requested before approval, the brand is in the business of

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[323] Memorandum of Law In Support of Plaintiffs' Motion for Judgment on the Pleadings and to Dismiss Counterclaims, Actelion Pharm. Ltd. v. Apotex, Inc., at 2, 2013 U.S. Dist. Ct. Briefs LEXIS 27858.

[324] *Id.* at 12.

[325] Brief in Support of Defendant Celgene Corporation's Motion to Dismiss, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 4 (May 25, 2014); *see also* Koren Wong-Ervin, *Does Aspen Skiing Apply to Intellectual Property Rights?*, ABA SECTION OF ANTITRUST LAW IP COMMITTEE NEWSLETTER, at 7 (Summer 2013) ("Forcing a patent holder to sell generic companies samples of its patented drug would be unprecedented.").

[326] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) (*citing* United States v. Colgate & Co., 250 U.S. 300, 307 (1919)).

[327] *Id.* (*citing* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 601 (1985)).

[328] *Id.*

[329] *Id.* at 410.

[330] *Id.*

producing drugs, and the provision of a sample after the drug is manufactured does not require additional effort.[331]

A second element is conduct that makes no economic sense absent the impairment of generic competition. The Court in *Aspen Skiing* found exclusionary conduct where a defendant was "willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival."[332] In contrast, the *Trinko* Court denied liability where Verizon could obtain only a "cost-based rate of compensation."[333] Brands refusing to sell samples lose the opportunity to obtain at least a market (and sometimes significantly higher) price for samples.[334]

Third is the ineffectiveness of the regulatory regime. The *Trinko* Court underscored the importance of regulation in the setting of the Telecommunications Act, which was effectively enforced through financial penalties, daily or weekly reporting requirements, and the suspension or revocation of long-distance approval.[335] Carving out a role for antitrust, the REMS regime is not working as intended, with an ineffective FDA unable to fix the problem and eager to punt competition issues to the FTC.[336]

Finally, compelled dealing raises three concerns that the *Trinko* Court lamented but that are not present here. First, the Court worried that sharing "may lessen the incentive for the monopolist, the rival, or both to invest in [their] economically beneficial facilities."[337] But there are not material effects on incentives that need to be accounted for since a central provision of the Hatch Waxman Act involved generics experimenting on drugs before the end of the patent term and piggybacking on brand studies.[338] The legislative history makes clear that "experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent" and that "prevention of such activity would extend the patent owner's commercial exclusivity beyond

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[331] *See supra* note 284 and accompanying text.

[332] Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 610–11 (1985).

[333] 540 U.S. at 409.

[334] *See supra* notes 266-274 and accompanying text. *See generally* HOVENKAMP, JANIS, LEMLEY, LESLIE, & CARRIER, IP AND ANTITRUST, *supra* note 209, ch. 15.03(B) ("While monopolists have no general duty to help their competitors, they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition.").

[335] *See* Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 412–14 (2014).

[336] *See supra* notes 255-263 and accompanying text. For a discussion of Congress's attempts to avoid the blocking of generic competition and Senators' frustration with how REMS programs have been misused, see *supra* notes 56-62 and accompanying text.

[337] *Trinko*, 540 U.S. at 408.

[338] *See* Carrier, *supra* note 148, at 43–45 (discussing enhanced innovation incentives through patent term extensions, nonpatent market exclusivity, and an automatic 30-month stay of FDA approval).

the patent expiration date."[339] In addition, Congress anticipated that "the benefits to the government and the general citizenry [would] be substantial" from the experimental-use provision and that, as a result, "generic drugs [would] be able to be placed on the market between 18 months and 2 years earlier than without this provision," which would "assist in the reduction of health care costs," which was of particular "importan[ce] to the poor, the under-insured, and the elderly."[340]

The second concern, that sharing "requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill suited,"[341] also does not apply. A one-time sale of a sample does not implicate such planning, and even a shared REMS program will not require judicial coordination, at worst devolving into separate REMS controlled by the brand and generic. Third, the concern that "compelling negotiation between competitors may facilitate the supreme evil of antitrust: collusion"[342] is absent. Again, a one-time sale does not threaten such collusion. And the brands' and generics' different incentives—with brands seeking to delay generic entry and generics seeking expedited entry—significantly reduce the possibility of collusion.[343]

B. Prior Dealing

Defendants have offered a second, narrower, argument against compelling dealing with generics: that a refusal-to-deal claim requires a prior course of dealing between the parties. Celgene, for example, has contended that there is an "affirmative duty to deal with competitors" only when two requirements are satisfied, including "a prior course of dealing between the parties."[344] And Actelion's counsel asserted that "it's fairly well established that . . . prior profitable course of dealing is th[e] dividing line . . . on a refusal to deal case between a legitimate refusal to deal . . . and the kind of fairly egregious conduct

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[339] H.R. REP. NO. 98-857, pt. 1, at 46 (1984); *see also id.* ("Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time" and such a time "should be a definite time," followed by "immediate competition").

[340] H.R. REP. NO. 98-857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2714 (noting that "the nature of the interference with patent rights . . . is necessitated by the very nature of the industry" and that Congress "has merely done what [it] has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest").

[341] *Trinko*, 540 U.S. at 408.

[342] *Id.*

[343] *See supra* note 148 and accompanying text.

[344] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 10 (Dec. 22, 2014). Showing the broad acceptance of the no-economic-sense test, the other was that "the alleged monopolist irrationally forsook short-term profits for long-term anticompetitive gain—in other words, its actions made 'no economic sense.'" *Id.*

at the outer bounds of Section 2 liability."[345]

A careful reading of the case law, however, reveals that a prior course of dealing is not a prerequisite for a refusal-to-deal claim. The classic case of *Otter Tail*[346] imposed a duty to deal where there was not a prior course of dealing,[347] with *Trinko*'s citation of the case affirming its continued validity.[348] And the course of dealing in *Trinko* involved (1) a voluntary relationship that was (2) "*presumably profitable*." [349] Of course, prior dealing could show the abandonment of a profitable revenue stream in a voluntary relationship, offering evidence of a lack of economic sense. But such a set of facts is not needed for this conclusion. In other words, a previous, ongoing relationship is *sufficient*, but not *necessary*, to show conduct that lacks economic sense.

Several courts that have examined the issue in the context of REMS denials have understood prior dealing as one (but not the only) setting in which exclusionary conduct could be demonstrated. In its hearing on a motion to dismiss, the court in *Apotex v. Actelion* found that the classic *Aspen Skiing* case presented facts other than a prior course of dealing (including a "refusal to sell at retail") that could provide evidence of anticompetitive conduct.[350] Similarly, the court in *Mylan v. Celgene* stated that Third Circuit cases found that prior dealing is "relevant but not dispositive" and that even though "Mylan essentially admits that it has not pled a prior course of dealing between the parties," it alleged a "plausible Section 2 claim"[351] because it "pled other facts to demonstrate that the defendant's actions were motivated only by long-term anticompetitive gain."[352]

The setting of denied samples shows how a prior-dealing requirement is not appropriate. The reason is that there typically will not be such a relationship between the parties. REMS programs involve new drugs that have not previously been on the market, precluding a preexisting relationship between the brand and generic. The generic, by definition, is seeking a sample of the drug to *enter the*

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[345] *Actelion v. Apotex* transcript, *supra* note 52, at 27.

[346] Otter Tail Power Co. v. U.S., 410 U.S. 366 (1973).

[347] *See* Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50, 53 (Fall 2012).

[348] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 10, 17 (Dec. 22, 2014).

[349] *Trinko*, 540 U.S. at 409 (emphasis in original).

[350] *Actelion v. Apotex* transcript, *supra* note 52, at 13–14.

[351] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 13, 17 (Dec. 22, 2014).

[352] *Id.* at 17. To the contrary, the court in *Suboxone* neglected *Otter Tail* and restrictively interpreted *Aspen Skiing*, finding it to be "the only Supreme Court case recognizing a failure to deal as anticompetitive" and contending that it did not apply because of the absence of a "long-standing, preexisting course of dealing." *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 687 (E.D. Pa. 2014).

market. Because the sale of samples is likely to be a one-time event, if the generic had previously engaged with the brand, it would not need a sample. Nor is the conclusion different for shared REMS systems. A generic seeking to use a single shared REMS also is seeking to enter the market for the first time, which precludes a prior relationship with the brand.

Generics' need for samples to engage in bioequivalence testing is at the core of the Hatch-Waxman Act, the FDAAA, and 50 state substitution laws. Requiring a prior course of dealing in a setting in which a generic is seeking samples so it can reach the market for the first time makes no sense.

In fact, a prior-dealing hurdle would privilege a particular set of facts. As Judge Posner has explained, it would be "perverse" to make the "encouraging gestures" of a prior course of dealing "the fulcrum of an antitrust violation."[353] To the contrary, the "essential feature" of a refusal-to-deal case is "a monopoly supplier's discriminati[on] against a customer because the customer has decided to compete with it."[354] A prior course of dealing reveals that sales are possible—in fact that they occurred. But a request by a generic to buy a sample at the market rate removes the facts from a hypothetical setting and places them in the real-world context in which the brand has a clear opportunity for profit. A brand's refusal should not be immunized because of the absence of a particular set of facts in a setting in which those facts, by definition, are not likely to be present.

In addition to arguments based on the case law, defendants have offered business arguments based on concerns about generic safety and increased exposure to product liability claims.

C. Safety

Brands have stated that their denials are justified because of safety concerns. Celgene, for example, contended that the sale of samples imposed safety concerns as the "ingestion of . . . two teratogenic drugs [which produce birth defects] by unknown, healthy subjects entails risk of fetal exposure, which is why Mylan discusses its safety measures at length" and "need not accept others' conclusions that the these measures are adequate."[355] In a different case, Celgene "question[ed] the efficacy" of the generic's "study protocol's safety."[356] And Actelion explained that it "has an obvious and legitimate commercial interest to make sure that its liability, reputational issues, and concerns are taken into

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[353] Olympia Equip. Leasing Co. v. W. Union Tel. Co., 797 F.2d 370, 376 (7th Cir. 1986); *see generally* Federal Trade Commission's Brief as *Amicus Curiae*, Mylan Pharms., Inc. v. Celgene Corp., Case No. 2:14-CV-2094-ES-MAH, at 13 (D.N.J. June 17, 2014) (describing concerns with requirement based on prior course of dealing).

[354] *Olympia Leasing*, 797 F.2d at 377.

[355] Brief in Support of Defendant Celgene Corporation's Motion to Dismiss, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 17 (May 25, 2014).

[356] Lannett Co. v. Celgene Corp., 2011 WL 1193912, at *2 (E.D. Pa. Mar. 29, 2011).

account and are dealt with."[357]

In fact, brands' concerns that a generic's use of samples *automatically* poses a heightened risk for which they would be responsible are misplaced. Use does not occur in a vacuum. The FDA ensures the safety of not only brand drugs but also generics. The agency tightly regulates the use of samples, including through clinical trials.[358] As a generic official has explained, "merely having a sample doesn't mean a company has unfettered discretion to use it improperly, to have poor clinical trials, [or] to expose their employees to risk" since the FDA "continues to monitor what happens to that sample."[359] In addition, safety concerns are significantly reduced as many of the samples are used for lab testing rather than on humans.[360] Roxane's attorney explained that generics "have been buying samples and using them for years and years and years, of both REMS-covered and non-REMS-covered drugs, and there has never been some parade of horribles in terms of a brand being forced to come in and monitor what we're doing."[361] Finally, safety concerns are weakened when brands provide samples to noncompeting research organizations.[362]

In *Mylan v. Celgene*, to offer one example, the FDA approved the safety protocols that generic firm Mylan putd in place for Revlimid and Thalomid.[363] Mylan submitted its Thalomid protocols to the FDA, which approved them and gave additional recommendations the generic needed to follow in its studies.[364] After the FDA approved Mylan's Revlimid protocols, the agency informed Celgene that it was assured of Mylan's planned testing.[365] The FDA then disclosed its approval of the generic's safety protocols to the brand.[366]

The FDA instituted such a notification process after generics had expressed

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[357] *Actelion v. Apotex* transcript, *supra* note 52, at 100.

[358] *CREATES Act Hearing*, *supra* note 32 (statement of Beth Zelnick Kaufman at 1:49); *see also Actelion v. Apotex* transcript, *supra* note 52, at 66 (generics must "submit adverse events reports to FDA").

[359] *Id.* at 1:49.

[360] *Actelion v. Apotex* transcript, *supra* note 52, at 58 ("The first round and the vast majority of the actual product that you would use as samples are for lab testing . . . in test tubes and dissolution studies" that do not "involve . . . patients," with only a "very small minority" used in the "in vivo study . . . give[n] to patients").

[361] *Id.* at 65.

[362] *Id.* at 110; *In re* Thalomid and Revlimid Antitrust Litig., 2015 WL 9589217, at *15 (D.N.J. Oct. 29, 2015).

[363] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 5–6, 8–9 (D.N.J. Dec. 22, 2014).

[364] *Id.* at 5–6.

[365] *Id*. at 5, 8. Celgene refused to provide samples after the FDA's approval even though it had previously required that Mylan obtain that approval.

[366] *Id*. at 8.

concern that REMS programs were preventing competition.[367] In particular, the agency was "aware of instances" in which a brand "refused to sell drug[s]" to generics "seeking to conduct the testing needed to obtain approval," with the brand "cit[ing] the REMS ETASU as justification."[368] For that reason, generics can request that the FDA send a statement that makes clear that (1) "[t]he Agency has determined that the protocols, informed consent documents, and informational materials contain safety precautions comparable to those in the applicable REMS ETASU"[369] and that (2) it "will not consider it a violation of REMS for the RLD sponsor to provide the designated potential ANDA applicant (or its agent) [with] a sufficient quantity of drug product to allow it to perform the testing necessary to support its ANDA and otherwise meet the requirements for ANDA approval."[370]

If brands are not satisfied with the FDA's oversight of drug samples, they are not without options. For starters, a brand's development of its own REMS program allows it to exercise control over the generic REMS program. The FDA has made clear that if it "approv[es] a generic drug and there is a REMS in place for the innovator drug, the requirements are the same for the ANDA product."[371] Because brands thus have control over generic REMS through their own

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[367] Ed Silverman, *FDA Tries to End Dispute Between Brand-Name and Generic Drug Makers*, WALL ST. J., Dec 4, 2014, http://blogs.wsj.com/pharmalot/2014/12/04/fda-tries-to-end-dispute-between-brand-name-and-generic-drug-makers/ [https://perma.cc/8F69-FV8M]; *see also* Complaint for Declaratory Judgment, Actelion Pharm. Ltd. v. Apotex, Inc., 1:12-cv-05743, ¶ 33 (D.N.J. Oct. 17, 2013) (Actelion contends that REMS program prevented sale because "[u]nder the FDA-mandated REMS program," it "may not distribute Tracleer to Apotex, Roxane, or . . . any other entity that does not specifically qualify under Tracleer's REMS").

[368] FDA, *How to Obtain a Letter*, *supra* note 31, at 2.

[369] *Id.* at 4. For challenges in obtaining an FDA letter, see *Actelion v. Apotex* transcript, *supra* note 52, at 57, 67 (FDA sometimes "sat on . . . [letter] requests for years and never responded to them" and other times would not "review . . . protocol[s]" because they "already issued a guidance, and when there's a guidance already out there, [they] are not going to review individual one-off requests"); *id.* at 57 (same); *id.* at 75 ("The FDA does not have a formal process for approving generic companies' protocols. . . . The [agency] does not collect any fees. There are not any dedicated personnel. There are no timelines. There is no set process. Instead, there is a single staffer . . . [who is] very frustrated").

[370] FDA, *How to Obtain a Letter*, *supra* note 31, at 4. *Compare Actelion v. Apotex* transcript, *supra* note 52, at 20–21 (Actelion "would sell" sample upon receiving FDA letter) with *id.* at 45 (generic contends that after receipt of FDA letter, Actelion responded that "'[t]his changes nothing'" and "'you don't get [the sample]'"). *See also In re* Thalomid and Revlimid Antitrust Litig., 2015 WL 9589217, at *15 (D.N.J. Oct. 29, 2015) ("plausible inference" that defendant's reliance on distribution programs "pretextual" since it "continued to refuse to deal" even after generics provided FDA letters indicating that agency would not take action if Celgene provided samples).

[371] Terry Toigo, FDA, *A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS)* (42:00), https://collaboration.fda.gov/p97727926/?launcher=false&fcsContent=true&pbMode=normal [https://perma.cc/7PVG-EJ4P] (last visited Jan. 14, 2017).

programs, they can implement the steps they believe are necessary to ensure that a drug's benefits outweigh its risks, with their requirements carrying over to generics.[372]

Brands also have control in the shared REMS setting. In fact, the lack of good-faith negotiation in this context, with the FDA unsuccessful in mediating an SSRS in all 13 cases in which it attempted to negotiate resolution, provides an indication that brands' safety-related concerns[373] might not be wholly authentic. The agency has explained that it "approve[s] drugs with REMS if they are particularly risky" and that "[w]hen they go generic, the generics also need to have this risk system around them."[374] And the FDA has made clear that if generics and brands cannot successfully negotiate shared REMS, the programs will be "equal."[375]

Safety issues are even less relevant for brands' creation of their own restricted-distribution protocols not required by the FDA. In these cases, even if the FDA does not believe that the plan is necessary since the drug's benefits outweigh its risks, brands still can use the systems to prevent generics from obtaining the drug.[376] The agency has not been successful in addressing this problem. It has "done everything [it] can," including writing letters making clear that "REMS does not require" restricted programs and "refer[ring] the [programs] to [the Federal Trade Commission]."[377] Despite this, the agency "still continue[s] to get complaints from generic companies that they cannot get a hold of the drug to make the comparison they need to do."[378]

In short, (1) the requirement that generic REMS satisfy the same requirements as brand REMS, (2) the FDA's active role in monitoring generics and providing notifications to brands of safety protocols, and (3) brands' frequent lack of good-faith negotiations concerning shared REMS show that brands cannot offer safety as a legitimate justification for refusing to provide samples or

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[372] *See Brief Overview*, *supra* note 18, at 4.

[373] *See supra* notes 355-357 and accompanying text.

[374] *Sudden Price Spikes*, *supra* note 61, at 115 (quoting Dr. Woodcock).

[375] *Id*. at 116. *See also* Lippmann, *supra* note 320, at 16 ("FDA may waive the requirement for a SSS and permit the ANDA to use a "different, *comparable* aspect of the ETASU") (emphasis in original; quoting Section 505-1(i)), *id.* at 17 (REMS for ANDA(s) have "[s]ame goals" and "[s]ame ETASU," which "[c]ontain[s] the same elements" and "[m]ust achieve [the] same level of safety"); FDA letter to William Franzblau, Docket No. FDA-2013-P-0572, at 6, Oct. 7, 2013 (stating that brand and generic firms in SSRS "have been subject to the same ETASU, implementation system, and assessments").

[376] *See Sudden Price Spikes*, *supra* note 61, at 115; FDA Center for Drug Evaluation and Research, *Risk Evaluation and Mitigation Strategy (REMS) Public Meeting* transcript, July 28, 2010 at 268 (asserting that generics cannot determine if restricted distribution system is required by FDA).

[377] *Id.*

[378] *Id.*

cooperate in shared REMS programs.[379]

D. Product Liability

Brand firms also have defended their refusal to provide samples to generics on the grounds of product liability.[380] Celgene, for example, contended that its sale of samples imposed heightened risks, stating that it "would face increased exposure to products liability suits for sales to generic ANDA filers," as "[s]ome courts have accepted the notion that a branded drug manufacturer may be liable for injuries caused by the generic drug it did not sell."[381] It also worried that "Mylan makes lengthy allegations regarding its willingness to indemnify Celgene" while noting that "Celgene is not required to accept these risks even with indemnification."[382] In a separate case, Celgene complained that a proposed generic insurance policy "has inadequate limits of liability and does not cover human clinical trials."[383] Relatedly, in the SSRS context, brand firm Reckitt "reportedly turned down numerous invitations to participate in meetings with the Generics . . . until the Generics agreed to a number of conditions . . . including 'an upfront agreement that all manufacturers would share the costs of product liability for future potential lawsuits.'"[384]

Most fundamentally, such claims are not consistent with the Hatch-Waxman Act, which antitrust must be "attuned to" and take "careful account" of.[385] As discussed above,[386] generic access to samples during the patent term was an essential aspect of the regime, allowing generics to avoid replicating clinical studies. Allowing brands to deny samples based on product-liability (or safety) justifications would undermine the carefully balanced tradeoff between competition and innovation at the heart of the Hatch-Waxman Act. In particular, it would give brands protection beyond the powerful incentives they received such as patent term extensions, nonpatent market exclusivity for new chemical entities and new clinical investigations, and an automatic 30-month stay for brands that sued generics that had challenged the patent's invalidity or claimed

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[379] Safety-based defenses also are not supported by case law that rejects the undermining of the competition regime. *See infra* notes 392–398 and accompanying text.

[380] A related argument is that brands would suffer reputation harms from generic conduct. *See, e.g.*, Anna Fabish, *Why REMS Abuse Doesn't Belong in Antitrust Litigation*, LAW360, Apr. 23, 2015.

[381] Brief in Support of Defendant Celgene Corporation's Motion to Dismiss, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 17 (May 25, 2014).

[382] *Id*.

[383] Lannett Co. v. Celgene Corp., 2011 WL 1193912, at *2 (E.D. Pa. Mar. 29, 2011).

[384] *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 675 (E.D. Pa. 2014).

[385] Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004).

[386] *See supra* notes 225–236 and accompanying text.

noninfringement.[387]

Nor is the centrality of samples to the Hatch Waxman Act diminished in any way by the FDAAA, as this legislation never anticipated a separate testing regime for drugs subject to REMS.[388] Excuses based on product liability or safety could, in contravention of the statute, lead to the "block[ing] or delay[ing]" of generic competition.[389] The FDAAA also did not envision a redefinition of responsibilities by which brands could shield themselves from product-liability or safety claims. In fact, the legislative history reveals a concern that REMS programs could be used to preempt state product-liability lawsuits.[390] The drafters explained that "[t]he additional regulation of pharmaceutical products proposed in this legislation is an effort to provide consumers with increased protection, not an effort to provide pharmaceutical manufacturers with immunity from liability when their products harm consumers."[391]

If a refusal to provide samples could be justified on product-liability or safety grounds, a central pillar of the Hatch Waxman Act would be undermined. For a brand firm could *always* offer such excuses, preventing access to the samples on which the Act was based. Such arguments also are undercut by Supreme Court decisions rejecting attempts to undermine the competition regime. In *National Society of Professional Engineers v. United States*,[392] the Court considered an ethics code that prohibited competitive bidding to "minimiz[e] the risk that competition would produce inferior engineering work endangering the public safety."[393] The Court made clear that such a ban "imposes the [association's] views of the costs and benefits of competition on the entire marketplace" and that any attempt to justify such a ban "on the basis of the potential threat that competition poses to the public safety and the ethics of its profession is nothing less than a frontal assault on the basic policy of the Sherman Act."[394] The Court concluded that recognition of an exception for projects affecting safety "would be tantamount to a repeal of the statute" and that courts "cannot indirectly protect the public against this harm by conferring monopoly

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[387] Carrier, *Unsettling Settlements*, *supra* note 148, at 43–45, 62.

[388] Tucker et al., *supra* note 221, at 77. Relatedly, ETASU measures were designed to "minimize the burden on the health care delivery system" and "not be unduly burdensome on patient access to the drug." 21 U.S.C. § 355-1(f)(2)(C, D).

[389] *See supra* notes 250–253 and accompanying text.

[390] H.R. REP. 110-225, at 197 (2007).

[391] *Id. See also* CONG. REC. S11831-32 (daily ed. Sept. 20, 2007) (statement of Sen. Kennedy) ("By enacting this legislation, we do not intend to alter existing state law duties imposed on a drug manufacturer to obtain and disclose information regarding drug safety hazards either before or after a drug receives FDA approval and labeling" since "[w]e do not believe that the regulatory scheme embodied in this act is comprehensive enough to preempt the field or every aspect of state law.").

[392] 435 U.S. 679 (1978).

[393] *Id.* at 681.

[394] *Id.* at 695.

privileges on the manufacturers."[395]

Similarly, the Court in *Federal Trade Commission v. Indiana Federation of Dentists*[396] rejected an attempt by dentists to refuse to submit x-rays to insurers for use in benefit determinations.[397] The Court held that such a refusal, which would "lead to the reduction of costs through the selection of inadequate treatment," is not appropriate because "the argument is, in essence, that an unrestrained market in which consumers are given access to the information they believe to be relevant to their choices will lead them to make unwise and even dangerous choices."[398] Explaining the broad applicability of the *Engineers* decision, the Court found "no particular reason to believe that the provision of information will be more harmful to consumers in the market for dental services than in other markets."[399]

In addition to attempting to circumvent the Hatch-Waxman Act, brands' concerns about product liability overstate plaintiffs' success in holding them accountable for harms caused by generics. In this setting, claims typically take the form of a failure to warn consumers about drug risks.[400] But as the American Law Reports ("ALR") explains, "[u]nder traditional liability theories, a manufacturer of a product is not liable for injuries to a user of another manufacturer's product."[401] For that reason, "most courts hold that a manufacturer has no duty to warn consumers about the risks of using another manufacturer's product, and therefore have rejected actions seeking to hold a name brand manufacturer of a prescription drug liable for injuries sustained by a consumer of a generic version of the drug on theories of products liability."[402] The ALR collects cases in which consumers injured by consuming a generic

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[395] *Id.* at 695–96.

[396] 476 U.S. 447 (1986).

[397] *Id.* at 448.

[398] *Id.* at 463.

[399] *Id.*

[400] *In re* Thalomid and Revlimid Antitrust Litig., 2015 WL 9589217, at *16 (D.N.J. Oct. 29, 2015). The bioequivalence testing itself typically does not expose brands to product liability claims because it "generally [does] not require[] . . . clinical (human) data." U.S. Food & Drug Administration, *Abbreviated New Drug Application (ANDA): Generics* (last updated Feb. 27, 2017), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/.

[401] *Liability of Name Brand Drug Manufacturer for Injury or Death Resulting from Use of Prescription Drug's Generic Equivalent*, 56 A.L.R.6TH 161, https://advance.lexis.com/api/permalink/4be255e7-0355-4edf-b732-0e79c5bfc37a/?context=1000516. [https://perma.cc/AVN7-NJVJ].

[402] *Id.* at 2.

were not able to hold the brand manufacturer liable in Alabama,[403] Arkansas,[404] California,[405] Colorado,[406] Florida,[407] Georgia,[408] Kentucky,[409] Louisiana,[410] Massachusetts,[411] Minnesota,[412] Nevada,[413] New York,[414] North Carolina,[415] Oklahoma,[416] Pennsylvania,[417] Texas,[418] Utah,[419] and West Virginia.[420] To similar effect, the Sixth Circuit, "[a]fter conducting a state-by-state . . . analysis [under *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)] . . . conclude[d] that the highest courts in each of the 22 implicated states would not recognize Plaintiffs' misrepresentation claims under their respective state laws."[421]d

As an example, the court in *Cousins v. Wyeth Pharmaceutical*[422] rejected a product-liability claim against a brand manufacturer for injuries from consuming a generic version, holding that there was no duty because (1) the brand firm "did not design, manufacture, or sell the [generic] product" to the consumer and thus "owed no legal duty" and (2) in the absence of such a duty there could be no

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[403] Barnhill v. Teva Pharms., 2007 WL 5787186 (S.D. Ala. 2007).

[404] Bell v. Pfizer, Inc., 716 F.3d 1087 (8th Cir. 2013); Fullington v. Pfizer, Inc., 720 F.3d 739 (8th Cir. 2013); Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056 (W.D. Ark. 2009).

[405] LeBeau v. Roxane Labs, 2003 WL 21054640 (Cal. App. 4th Dist. 2003).

[406] Sheeks v. American Home Prods., 2004 WL 4056060 (Colo. Dist. Ct. 2004).

[407] Howe v. Wyeth, Inc., 2010 WL 1708857 (M.D. Fla. 2010).

[408] Swicegood v. Pliva, Inc., 543 F. Supp. 2d 1351 (N.D. Ga. 2008).

[409] Smith v. Wyeth, 657 F.3d 420, 423–24 (6th Cir 2011) ("The plaintiffs' argument—that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs—has been rejected by all but one of the courts that have considered it."); Franzman v. Wyeth, Inc., 451 S.W.3d 676 (Mo. Ct. App. E.D. 2014).

[410] Morris v. Wyeth, Inc., 2009 WL 4064103 (W.D. La. 2009).

[411] Kelly v. Wyeth, 2005 WL 4056740 (Mass. Super. Ct. 2005).

[412] Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009).

[413] Moretti v. Wyeth, Inc., 2009 WL 749532 (D. Nev. 2009).

[414] Goldych v. Eli Lilly, 66 Fed. R. Serv. 3d 799 (N.D.N.Y. 2006).

[415] Stoddard v. Wyeth, Inc., 630 F. Supp. 2d 631 (E.D.N.C. 2009).

[416] Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262 (W.D. Okla. 2009).

[417] Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006).

[418] Cousins v. Wyeth Pharm., Inc., 2009 WL 648703 (N.D. Tex. 2009).

[419] Beutella v. A.H. Robins Co., 2001 WL 35669202 (Utah Dist. Ct. 2001).

[420] Meade v. Parsley, 2009 WL 3806716 (S.D. W. Va. 2009).

[421] *In re* Darvocet, Darvon, and Propoxyphene Prods. Liability Litig., 756 F.3d 917, 939 (6th Cir. 2014); *see also id.* ("Every circuit court of appeals that has addressed the issue is in accord" that generic consumers could not sue brand manufacturers for injuries caused by generic drugs).

[422] 2009 WL 648703 (N.D. Tex. 2009).

liability in tort to the consumer.[423] Similarly, in *Fields v. Wyeth*,[424] the court rejected the argument that the brand should be held liable on the grounds that "it was foreseeable" that doctors prescribing the generic "would rely on information" provided by brands, as the court found that such an argument "attempts to create a duty" on the brand "irrespective of the company that produced" the drug.[425] And the court in *Foster v. American Home Products* explained that "[t]here is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control."[426] Finally, rejecting the product-liability argument in the REMS setting, the court in *In re Thalomid and Revlimid Antitrust Litigation* made clear that "[t]he possibility that [a brand] could be liable for a generic drug's harm is . . . not a legitimate justification that would support its refusal to supply generic manufacturers with samples."[427]

Brand liability under a failure-to-warn theory implicates labeling, but brands and generics "have different federal drug labeling duties."[428] As the Supreme Court made clear in *Wyeth v. Levine*, "through many amendments to [pharmaceutical] regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times" and that "[i]t is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market."[429] In contrast, a generic is "responsible for ensuring that its warning label is the same as" that of the brand.[430] Because, by law, a generic's labeling must be identical to that of the brand drug,[431] a brand controls its own liability.[432]

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[423] *Id.* at *2.

[424] 613 F. Supp. 2d 1056 (W.D. Ark. 2009).

[425] *Id.* at 1060.

[426] 29 F.3d 165, 170 (4th Cir. 1994); *see id.* ("The premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer's drug has been consumed.").

[427] 2015 WL 9589217, at *16.

[428] PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 (2011).

[429] 555 U.S. 555, 570-71 (2009). *See, e.g.*, 21 C.F.R. § 201.80(e) (requiring brand to revise label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); 21 C.F.R. § 314.80(b) (imposing responsibility for post-marketing surveillance on brand); 73 Fed. Reg. 49605 (noting that brands "continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information").

[430] *Mensing*, 564 U.S. at 613; *see* 21 U.S.C. § 355(j)(2)(A)(v).

[431] 21 U.S.C. § 355(j)(2)(A)(v).

[432] The brand also would not be responsible under theories based on the manufacturing of a generic drug. *E.g.*, *In re* Thalomid and Revlimid Antitrust Litig., 2015 WL 9589217, at *16 (D.N.J. Oct. 29, 2015); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 317 n.16 (2008).

If there were any question as to brands' concerns with product liability, they would be dispelled by their *refusal to accept generics' proposals to indemnify* them for product liability claims.[433] Similar to insurance and self-insurance, generic indemnification can serve a vital role in managing brand risk. But the cases reveal brands' lack of interest in such risk management.

In *Mylan v. Celgene*, for example, Mylan agreed, over the course of a 5-year negotiation for the sale of Thalomid, to indemnify Celgene for liability resulting from Mylan's studies.[434] Even at the time of this Article, nearly eight years after the parties signed an indemnification agreement in April 2009, the sale had not occurred.[435] And for the sale of Revlimid, Mylan offered Celgene an executed indemnification agreement though Mylan alleged that it "requested the purchase of limited Revlimid samples for bioequivalence testing, offering to pay market value," to which Celgene responded with a "voluminous information request" and rejection of "Mylan's offer to enter into an indemnification agreement, which included nearly every concession to terms Celgene requested" during earlier negotiations on Thalomid.[436]

In short, brands have used concerns related to refusals to deal, a prior course of dealing, safety, and products liability as justifications for their refusals to sell samples to generics and participate in shared REMS. These excuses are not supported. If brands' justifications do not apply, there is no reason for them to deny samples that it makes economic sense to provide or participate in shared REMS programs that would make sense and address purported business concerns. In other words, there is no economic reason for this conduct in a setting in which generic competition is a foundation of the regulatory regime. This is a hallmark of a monopolization violation.

CONCLUSION

An oft-discussed topic today is high drug prices resulting from the absence of generic competition. A linchpin to reduced prices is generics' ability to access a sample to demonstrate the equivalence needed to enter the market. Through a regulatory regime intended for a different purpose, brands are denying necessary samples and not negotiating in good faith in shared REMS programs. Just as concerning, they are justifying this behavior with rationales at odds with the

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[433] This refusal also casts doubt on safety-related concerns. *See* Kellie Lerner, *REMS and Antitrust: Latest Litigation Lessons*, ROBINSKAPLAN, June 3, 2015, http://www.robinskaplan.com/resources/articles/rems-and-antitrust [https://perma.cc/FZ97-ALM5] ("[A] brand company's refusal to agree to an indemnification would appear to mitigate any argument that its refusal to deal stems from safety concerns.").

[434] Transcript of Oral Opinion, Mylan Pharms. Inc. v. Celgene Corp., No. 2:14-cv-02094-ES-MAH, at 6 (D.N.J. Dec. 22, 2014).

[435] *Id.*

[436] Plaintiff Mylan Pharmaceuticals' Brief in Opposition to Celgene's Motion to Dismiss, Civ. Action No. 2:14-cv-02094-ES-MAH, 2014 U.S. Dist. Ct. Briefs LEXIS 1435 (D.N.J. June 16, 2014).

caselaw, regulations, and economic realities of the industry.

While other pharmaceutical conduct has received more attention, it is time to focus the spotlight on sharing. For antitrust law is well-equipped—in fact is critical given Congress's inaction and the FDA's ineffectiveness—to remedy anticompetitive behavior. In the process, it promises to reduce drug prices and restore the intended balance of innovation and competition in the pharmaceutical industry.