



Antitrust Modernization Commission
Attn: Public Comments
1120 G Street, N.W., Suite 810,
Washington, D.C. 20005

Dear Members of the Antitrust Modernization Committee:

These comments are submitted pursuant to the request for public comments published in the Federal Register on May 19, 2005.

Introduction

Community Catalyst is a national nonprofit organization that builds consumer and community participation in the shaping of our health system to ensure quality affordable health care for all. Founded in 1997, Community Catalyst has worked with low income communities, consumer organizations, and policymakers in over 30 states to create consumer advocacy capacity and improvements in health care and other human services. The Ford, W. K. Kellogg, Public Welfare, Nathan P. Cummings, John D. and Catherine T. MacArthur, Surdna and Annie B. Casey foundations are among national foundations supporting aspects of the organization's work. Prior to 1997, Community Catalyst was the Massachusetts office of Families USA Foundation.

A key initiative of Community Catalyst is the **Prescription Access Litigation (PAL) Project**. PAL was created in 2001 to make prescription drugs more affordable. It uses class action litigation and public education to bring an end to illegal pharmaceutical price inflation. PAL is a diverse coalition of over 100 organizations, including state-based groups representing 35 states and the District of Columbia as well as several national organizations. PAL's cases challenge a variety of illegal practices that are regularly committed by pharmaceutical industry players. To date, PAL members have filed 23 sets of class action lawsuits on behalf of "indirect purchasers" including individual consumers, consumer organizations, and third-party payors. These cases challenge a variety of illegal practices:

- Antitrust violations by drug companies seeking to keep cheaper generics off the market;
- Illegal and deceptive marketing of drugs, both to consumers and to physicians;
- Illegal practices by Pharmacy Benefit Managers (PBMs), including failing to pass on rebates to their client health plans and manipulation of health plan formularies for their own financial gain; and
- "Gaming" the drug reimbursement system, such as through inflation of the Average Wholesale Price benchmark.

Thus far, four PAL cases have been settled. These four cases concerned the prescription drugs Augmentin, BuSpar, Lupron and Relafen. The indirect purchaser settlement funds in these cases have totaled \$344 million.

As noted above, one major category of PAL cases challenges various anticompetitive practices within the pharmaceutical industry, including:

- Brand name drug manufacturers filing multiple patents in order to delay the entry to the market of a cheaper generic version of a drug;
- Brand name drug manufacturers paying a generic manufacturer to refrain from producing a generic equivalent of a brand name drug;
- Brand name manufacturers filing frivolous patent infringement lawsuits against generic manufacturers in order to extend their monopoly over a drug and prevent a generic version from coming to market;
- Generic drug manufacturers signing an agreement to split up the market for a drug, thereby maintaining a higher-than-normal price for the drug; and
- Brand name drug manufacturers signing an exclusive agreement with a generic company to manufacture a generic version of a brand-name drug, but agree to maintain a higher-than-normal price for the drug.

It is our view that one of the reasons that US prescription drug prices are higher than anywhere else in the world is that pharmaceutical companies have regularly violated laws meant to protect consumers. Thus, for the PAL coalition, litigation on behalf of indirect purchasers is an essential tool to compensate those individuals and entities that have been overcharged as a result of the violations. It also serves as an opportunity to change the way the drug industry does business and to deter other companies from engaging in future illegal behavior. **We feel strongly that the standing of indirect purchasers to pursue antitrust claims under state law should be preserved.**

Responses to Certain Questions Posed by the AMC

G. Indirect Purchaser Litigation

1. What are the costs and benefits of antitrust actions by indirect purchasers, including their role and significance in the U.S. antitrust enforcement system? Please be as specific as possible.

As the AMC is well aware, antitrust law “rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of resources, the lowest prices, the highest quality and the greatest material progress”. *Northern Pacific Railway Co. v. United States*, 356 U.S. 1, 4 (1958). Antitrust is meant to protect “competition, not competitors”. *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962). Thus, it is well-recognized that when trade is restrained in an anticompetitive fashion, it is not only competitors that are harmed, it is also those who have not derived the benefit of competition.

The primary goals of the seminal antitrust laws, the Sherman and Clayton Acts, were to curb abusive and monopolistic conduct, to promote free and open trade and to protect both consumers and businesses. As antitrust law has evolved, it has been widely recognized as a means of protecting consumers and for recovering damages that individual consumers could not pursue on their own.

Private actions on behalf of indirect purchasers serve as a complement to state and federal actions by, respectively, state Attorneys General, the U.S. Department of Justice (DOJ), and the Federal Trade Commission (FTC). Unfortunately, the state Attorneys General, the DOJ, and the FTC have limited resources and benefit from the resources brought to bear by the private bar.

There have, in fact, been instances in which the private bar on behalf of indirect purchasers have worked hand-in-hand with the state Attorneys General to bring about a positive result. In one such case, *In re Buspirone Antitrust Litigation, MDL-1413* (S.D.N.Y.), in which PAL members were lead plaintiffs, private attorneys helped to create a \$42 million consumer settlement fund that was administered by the Attorneys General involved in the case. It was also this sort of synergy among the private bar, Attorneys General and the FTC that led to the imposition of unprecedented injunctive relief against the defendant drug company.

In other instances, the private bar has led the way, bringing cases that the Attorneys General or the FTC have not had the resources or interest in pursuing. For instance, in *In re Relafen Antitrust Litigation, 01-12239WGY* (D.Ma) a case in which PAL member groups served as lead plaintiffs, the indirect purchaser class filed a case whereas neither the Attorneys General nor the FTC was involved. It was only after the case was settled (for \$75 million) that Attorneys General from certain states intervened on behalf of their citizens. Similarly, in *In re Warfarin Sodium Antitrust Litigation*, private parties and their counsel achieved a groundbreaking settlement worth \$44.5 million, with no involvement of state Attorneys General.

As mentioned in the introduction above, private actions on behalf of indirect purchaser classes have resulted in direct benefit to consumers and third-party payors. The following cases in which PAL members served as plaintiffs have been settled:

Augmentin	\$29 million
Buspar	\$90 million
Lupron	\$150 million
Relafen	\$75 million
TOTAL END-PAYOR SETTLEMENT FUNDS	\$344 million

In addition, a number of other indirect purchaser class actions on drug price issues in which PAL was not involved have settled:

Cardizem	\$80 million
Hytrin	\$30.7 million
Lorazepam and Clorazepate	\$135 million
Paxil	\$65 million
Remeron	\$33 million
Taxol	\$55 million
Warfarin Sodium (Coumadin)	\$44.5 million
TOTAL END-PAYOR SETTLEMENT FUNDS	\$443 million

The above demonstrates that, just in the past five years, antitrust actions against drug manufacturers by state Attorneys General and private plaintiffs have resulted in settlements of more than three-quarters of a billion dollars. This represents a single industry, for a single set of antitrust practices. Numerous other cases are underway, some of which will no doubt produce similar results.

These settlements have brought real money to real consumers and third-party payors who have been overcharged as a result of the illegal and anticompetitive actions alleged in these cases. Critics have often accused consumer class actions of not providing real and meaningful relief to consumer class members (such as so-called “coupon settlements”). While there are exceptions, these critiques are largely inaccurate. This is particularly true in the drug pricing antitrust cases. Each of the settlements listed above provided significant monetary compensation to both consumer and third party payor classmembers. In addition, several of these settlements also included *cy pres* distributions to charitable organizations providing benefits or services to classmembers who did not make claims. Yet, at the same time, the amounts of these settlements were reasonable given the strength of the claims and were not unduly burdensome to the defendants. In each of them, the settlement represented a proportion of the plaintiffs’ claimed damages, which reflects the fact that these represented compromises between the parties.

These settlements also had an appropriate deterrent effect. Without these indirect purchaser actions, companies would have a real disincentive to comply with the law, knowing that they will either not be caught or that the consequences of their actions will be minimal. None of the settlements were so large as to threaten defendants with bankruptcy or to constitute over-deterrence. In fact, the size of the settlements and the deterrent value could have been increased within reasonable limits if the approximately twenty states that have not legislatively repealed - *Illinois Brick* had done so.

Indirect purchaser standing is particularly important in the arena of drug patents and generic drug entry. First and foremost, prescription drugs are not like other consumer products – they are critical and often life-saving medical treatments. The health, well-being and even survival of consumers should not be held hostage to the sacrificed to the greed of drug companies that would violate antitrust laws.

Second, the patent system represents a major exception to the antitrust regime. Nothing is more contrary to the purposes of antitrust than monopolies. Yet to reward and promote innovation, patent holders are given a monopoly over their invention for twenty years. In the prescription drug arena, the expiration of a patent opens the door to generic competition. A patent-protected monopoly is of enormous value to a drug company. The expiration of a patent on a single drug can reduce profits by billions of dollars a year. The temptation to engage in illegal behavior to extend a patent monopoly has proved irresistible to numerous pharmaceutical companies.

Given that the patent system is the only blanket exception to the prohibition against monopolies, extraordinary care must be taken to ensure that that exception is not exploited to the detriment of consumers and competition generally. To paraphrase Thomas Jefferson, eternal vigilance is the price of the promotion of innovation through patents. No reasonable enforcement mechanism which assists in this vital project of protecting the antitrust regime should be foreclosed. Indirect purchaser standing is one such mechanism, and a particularly important one for individual consumers who have been wronged by antitrust practices.

2. What burdens, if any, are imposed on courts and litigants by the difficulty of consolidating state court antitrust actions brought on behalf of indirect purchasers with actions brought on behalf of direct purchasers, and how have courts and litigants responded to them? What impact, if any, will the Class Action Fairness Act of 2005 have in this regard?

In the world of drug pricing litigation, the consolidation of state antitrust actions brought on behalf of indirect purchasers with those brought on behalf of direct purchasers has not proven burdensome. In general, the Multidistrict Litigation (MDL) process has simplified the cases, with both courts and litigants developing the necessary expertise and structures to handle these complex matters.

The plaintiffs' antitrust class action bar has developed elaborate methods of coping with the complexities of these class action cases so that all interests are well-represented. First, in drug pricing actions coordinated by the Judicial Panel on Multidistrict Litigation, the direct purchaser action is completely separate from the indirect purchaser action. The practice in these cases is to have no overlap between counsel for direct and indirect purchasers. The two cases proceed separately but concurrently. While the factual and legal record supporting a settlement or judgement in either case overlaps significantly (and often completely), settlement negotiations proceed independently for the two actions. Defendants, who are large, sophisticated commercial entities, are able to negotiate at arm's length and avoid any duplicative recoveries.

Second, within the indirect purchaser class, a leadership structure is typically established early on in the case. Lead counsel, who comprise an Executive Committee, are chosen and approved by the court. When an initial settlement is reached with defendants, separate counsel from among the plaintiffs' counsel are designated by the lead counsel to represent the two subclasses of the indirect purchaser class: (1) consumers and (2) third-party payors (TPPs). This "consumer representative" and "TPP representative" negotiate an allocation of the damages among the two subclasses. These structural protections, which were affirmed this year by the Third Circuit Court of Appeals in *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516, (3d Cir., 2004) ensure that each subclass is adequately and vigorously represented. PAL has worked hard to

ensure that the counsel chosen to represent the consumer and third-party payor subclasses in drug pricing cases are not only experienced in these cases, but also have the background and credentials to truly represent the interests they are designated to serve.

The following PAL antitrust cases have been or are being consolidated by the Judicial Panel on Multidistrict Litigation and have (or have had) parallel direct purchaser actions: Buspar, Augmentin, Relafen.

In answer to the AMC's question regarding the impact of the Class Action Fairness Act (CAFA), our experience thus far indicates that CAFA should not have a significant impact on the type of drug pricing cases in which PAL members are involved. Most antitrust cases on drug pricing are nationwide class action lawsuits that are already filed in federal court. Further, we feel that the process of coordination by the Judicial Panel on Multidistrict Litigation, coupled with the thorough review of global settlements provided by the receiving District Court under F.R.C.P. 23, largely vitiates the danger of multiplicity of suits, inconsistent adjudications and duplicative recovery. To the extent that the provisions of the Class Action Fairness Act address those concerns, it provides an additional – if largely unnecessary – layer of protection.

3. Does Illinois Brick's refusal to provide indirect purchasers with a right of recovery under federal antitrust law serve or disserve federal antitrust policies, such as promoting optimal enforcement, providing redress to victims of antitrust violations, preventing multiple awards against a defendant, and avoiding undue complexity in damage calculations?

It is our view that in order to fulfill the deterrence and compensatory goals of antitrust law, indirect purchaser actions are absolutely essential. As noted above, private actions are working well as a complement to state and federal enforcement actions. As evidence that they are working well, we have observed a marked decrease in the number of antitrust violations being alleged in the drug pricing arena in the past several years. We believe this to be the product of the actions brought by PAL members, Attorneys General and other private parties. Had indirect purchaser standing not been available, we believe it likely that antitrust violations in drug pricing would not have lessened. Similarly, a prospective removal of indirect purchaser standing would most likely be followed by an increase in antitrust activity by pharmaceutical companies.

Thus we believe it essential for the continued availability of state indirect purchaser remedies

4. What actions, if any, should Congress take to address the inconsistencies between state and federal rules on antitrust actions by indirect purchasers? For example, should Congress establish Illinois Brick as the uniform national rule by preempting Illinois Brick repealer statutes, or should it overrule Illinois Brick? If Congress were to overrule Illinois Brick, should it also overrule Hanover Shoe, so that recoveries by direct purchasers can be reduced to reflect recoveries by indirect purchasers (or vice versa)? Assuming both direct and indirect purchaser suits continue to exist, what procedural mechanisms should Congress and the courts adopt to facilitate consolidation of antitrust actions by indirect and direct purchasers?

We believe that at this stage, the mechanisms in place to address indirect purchaser standing are more than sufficient. Concerns about the possibility of duplicative recoveries against defendants and overlapping cases are addressed both in the various state indirect purchaser statutes as well

as through the multidistrict litigation process. **It is our view that Congress need not take any further action at this point.**

Conclusion

In sum, based on our experience with antitrust class action lawsuits in the drug pricing arena, we believe that indirect purchaser class action litigation is essential to fulfilling the goals of antitrust law, that is, to deter companies from restraining competition and to compensate the victims (individual consumers and third-party payors) who have overpaid as a result of the illegal conduct.

We encourage the members of the Commission to visit both the Community Catalyst (www.communitycatalyst.org) and PAL (www.prescriptionaccess.org) websites to learn more about our drug pricing litigation.

We are happy to answer any questions the Commission may have about our work or the viewpoints expressed in these comments.

Sincerely,

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