PAL Prescription Access Litigation
A Community Catalyst Initiative

June 5, 2006

Federal Trade Commission/Office of the Secretary
Room H-135 (Annex J)
600 Pennsylvania Avenue, N.W.
Washington D.C. 20580

Re: FTC Project No. P062105: Authorized Generic Drug Study

To Whom It May Concern:

The Prescription Access Litigation Project and the undersigned organizations submit the following comments on the Federal Trade Commission's Proposed Collection of Information referenced above.

The Prescription Access Litigation Project ("PAL"), an initiative of Community Catalyst, is a coalition of 120 consumer, healthcare, labor, senior, legal services, and women's health organizations in 35 states and the District of Columbia that work on issues related to the cost of prescription drugs. PAL works to make prescription drugs more affordable for consumers through public education and class action litigation that challenges illegal tactics by the pharmaceutical industry. Many of the 26 sets of class action lawsuits our members have filed to date challenge antitrust violations by drug companies seeking to keep cheaper generics off the market**.**

Community Catalyst, Inc., a national nonprofit organization, is a recognized leader in health care advocacy and consumer education that builds consumer and community participation in the shaping of the U.S. health system to ensure quality, affordable health care for all.

The Prescription Drug Market and the Importance of Generics

The cost of prescription drugs in the United States is becoming increasingly onerous, particularly for consumers who depend on these treatments for chronic and life-threatening medical conditions. It is not uncommon that uninsured and underinsured consumers are forced to choose between having enough to eat and purchasing their medications. Beyond market forces, there is virtually nothing to prevent drug companies from charging exorbitant prices for a particular drug. For example, in 2003, the manufacturer of the AIDS drug Norvir, Abbott Laboratories, raised the price of the drug from $54 a month to $265 a month.[1] There have been recent instances of

[1] "A Cancer Drug's Big Price Rise Disturbs Doctors and Patients," Alex Berenson, The New York Times, March 12, 2006.

pharmaceutical manufacturers drastically increasing prices of life-saving cancer treatments for which there appears to be no apparent justification other than their ability to do so.[2]

The cost of drugs for consumers, insurers and government programs is highest when a drug is under patent protection and faces no competition from generic versions. Generics, which offer the same benefits of brand drugs at much lower cost, are essential players in the prescription drug market, saving consumers and third party payers more than $10 billion each year.[3] In 2004, the average price of a generic prescription drug was $28.71, compared to $95.54 for a brand-name.[4] According to a recent study, as the patents of several blockbuster brand drugs expire over the next five years, Medicare Part D and its beneficiaries could save more than $23 billion by switching to generics in just a few therapeutic classes.[5] A single health plan, Blue Cross Blue Shield of Michigan, reported saving close to $30 million in one year through a statewide "pharmacy competition" which was successful in convincing upwards of 100,000 consumers to switch to generics.[6]

Generics are not only less expensive than brand-name drugs, but the rate of inflation of the price of generics is much lower than that of brand-name drugs. Two recent AARP studies of several hundred commonly prescribed medications showed that in 2004, the price of generics rose by only 0.5%, while that of brand-name drugs rose by 7.1%, more than 14 times faster.[7]

Generics and Competition

Once a drug's patent expires, the price of the first generic to enter the market is typically 20-30% less than the price of the previously patent-protected brand name drug. Following the six-month period of exclusivity enjoyed by the first generic approved, the price often falls to 40% (or lower) of the original price of the brand name drug.[8] The more generic versions are on the market, the lower the average price. The average cost of a drug with one to five generic manufacturers is $23.40, but this cost drops to $19.90 when there are 16 to 20 manufacturers in the market.[9] Thus, generics are a vital tool to promote competition in the prescription drug market and to lower the price of drugs for consumers and other payors.

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[2] Id.

[3] "Generic Drugs and the Bottom Line: A Special Report Provided by Blue Cross Blue Shield of Michigan," http://www.theunadvertisedbrand.com/pdfs/genericdrugs_specialreport.pdf (accessed May 2, 2006).

[4] Generic Pharmaceutical Association, Statistics, http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/Statistics.htm. (Accessed May 1, 2006)

[5] "PCMA: Seniors, Medicare Program could Save at Least $23 Billion through 2010 with New Generic Drugs," Pharmaceutical Care Management Association, April 18, 2006, available at http://www.pcmanet.org/newsroom/2006/Pr_4_06/pr_04_18.htm.

[6] "Generic Drugs and the Bottom Line: A Special Report Provided by Blue Cross Blue Shield of Michigan," http://www.theunadvertisedbrand.com/pdfs/genericdrugs_specialreport.pdf (accessed May 2, 2006).

[7] "Brand-Name Drug Prices Keep Going Up," assets.aarp.org/www.aarp.org_/articles/legislative/watchdog_april_04-web.pdf

[8] "United States: The Pros and Cons of Generic Drugs," Francesca Holzheimer, Global Insight, accessed May 10, 2006, *at* http://www.globalinsight.com/Perspective/PerspectiveDetail2832.htm.

[9] Generic Pharmaceutical Association, Frequently Asked Questions, *at* http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/FAQs/faqs.htm (Accessed May 1, 2006).

Brand-Name Drug Company Tactics to Deny Consumers Access to Generics

Brand-name drug manufacturers are well aware of the impact generic competition has on their profits, and in several cases they have manipulated the patent system to limit or delay the entry of generics into the market. These anti-competitive tactics include filing multiple or fraudulent patents, prosecuting frivolous patent infringement cases against generic companies, filing sham citizen petitions, changing products close to patent expiration to extend patent life, and paying off would-be generic competitors not to bring their generic versions to market or challenge patents. These tactics have had the effect of limiting patient access to less expensive alternatives and have contributed significantly to the skyrocketing U.S. prescription drug bill. There have been several recent consumer antitrust lawsuits against brand-name drug companies that alleged this type of conduct. The following are only a few examples:

- **Augmentin:** A consumer and third-party payor class action lawsuit against GlaxoSmithKline alleged that it committed fraud upon the U.S. Patent Office to extend the patents for the antibiotic Augmentin, thereby preventing generic versions of the drug from entering the market. In October 2004, the case was settled for $29 million.

- **Relafen:** A consumer and third-party payor class action lawsuit against GlaxoSmithKline claimed that it continued to list an unenforceable patent for the drug Relafen and then brought a series of frivolous patent infringement lawsuits against generic drug companies to delay generic competition. In May 2004, the case was settled for $75 million.

- **Buspar:** This consumer, third-party payor and state Attorney General class action lawsuit alleged that Bristol Meyers Squibb stalled the entry of generics to the market by illegally filing a new patent on the anti-anxiety drug Buspar on the eve of the date the current patent was due to expire. In November 2003, the case was settled for over $100 million.

Other lawsuits against brand drug companies alleging antitrust violations that are now pending include *In re Oxycontin Antitrust Litigation*, MDL 1603 (claiming Purdue Pharma used fraudulent patents and sham lawsuits to keep a generic off the market) and *In re Neurontin Antitrust Litigation*, MDL 1479 (claiming Pfizer and Warner Lambert used illegitimate secondary patents and baseless lawsuits to keep generics off the market).

Authorized Generics: The Next Wave of Anti-Competitive Practices

The Hatch Waxman Act was amended by the Medicare Modernization Act in 2003 to close some of the loopholes exploited by brand-name firms (e.g. limiting brand-name drug manufacturers to one 30-month patent extension). In the wake of these changes, the use of authorized generics as a tactic to undermine generic competition increased. Authorized generics gave brand-name manufacturers a tool to protect themselves against the substantial loss of profits that comes with the entry of a real generic version of the drug. Hatch Waxman's provision of 180 days of exclusivity to the first successful filer of an Abbreviated New Drug Application (ANDA) creates an incentive for a generic manufacturer to incur the significant risks and expenses involved in

filing such an application, trying to create a non-infringing version of the drug, and facing the almost-inevitable patent infringement lawsuit from the brand-name manufacturer. By introducing a "pseudo-generic" competitor during this vital 180 day period, authorized generics weaken and undermine the incentive for generic manufacturers to take those risks. Undermining the incentive created by Congress in the Hatch Waxman Act harms consumers by creating the risk that generic companies will not file ANDAs, or will file them later, delaying the availability of lower-cost generics to consumers.

An authorized generic may appear to be pro-competitive. However, the benefits to consumers and the market are illusory and extremely short-term.[10] The price of an authorized generic is often only slightly lower than the brand-name drug (e.g. often no more than 5%). This demonstrates that the intent is not to foster true competition but merely to sabotage the ability of the ANDA filer to take advantage of the 180-day exclusivity period provided for by Hatch Waxman. Many firms that "produce" authorized generics are simply store fronts lending their name to branded manufacturer, further underscoring that this is purely a deceptive practice. Moreover, the fact that most authorized generics disappear from the market after the 180 days shows that they are neither intended to promote competition nor in fact do so.

The 180-day exclusivity period is key to ensuring the introduction of generics. Like the patent protection that creates the innovation incentive for a brand-name manufacturer, the exclusivity period creates the incentive for a generic company to take on the risk involved in challenging an allegedly invalid or non-infringed brand-name drug's patent. Congress has crafted a delicate balancing of private incentives and public interests in both the patent system and the Hatch Waxman Act. Upsetting that balance not only thwarts the intent of Congress in enacting and amending Hatch Waxman, but harms the public by undermining the incentive designed to bring cheaper drugs to market faster. Not surprisingly, generic drug companies have vigorously challenged the FDA's decision to allow authorized generics.[11]

Another concern is that authorized generics provide brand drug companies with the power to coerce generic drug companies to enter into settlement agreements to keep generics off the market. The FTC recently issued a report documenting a disturbing rise in the number of settlement agreements in which brand-name provided compensation to generic manufacturers in exchange for agreeing to restrictions on their ability to market generic versions of branded drugs.[12] The most recent example of such an agreement where the FTC has taken action involves Warner Chilcott Corporation and Barr Pharmaceuticals.[13] The complaint alleges that Warner Chilcott paid Barr $20 million to delay market entry of the generic version of the drug Ovcon for

[10] "We'll Sell Generics Too," David A. Balto, Legal Times, March 20, 2006, Volume XXIX, NO. 12.
[11] "Battle Over Authorized Generics Grows Increasingly Heated." Martin Sipkoff, Drug Topics Supplements, April 1, 2005.
[12] "Summary of Agreements Filed in FY 2005, A Report by the Bureau of Competition" www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf
[13] U.S. District Court for the District of Columbia, Civil Action No. 1:05-CV-2179-CKK (D.C.D.C.), filed November 7, 2005.

five years.[14] Such agreements are blatantly contrary to the intent of Hatch-Waxman, clearly anticompetitive, and very harmful to consumers and other purchasers of prescription drugs.

The threat of an authorized generic can increase the pressure on an ANDA filer to agree to a delay in the entry of its generic to settle a patent infringement suit – by reducing the value of the exclusivity period, an authorized generic can reduce the incentive of a generic challenger to vigorously defend against a patent suit. Thus, authorized generics contribute to the delay in generic entry that is produced by such settlements.

The FDA has stated its opinion that it lacks the authority to prohibit authorized generic marketing during the 180 day period of exclusivity, explicitly denying calls for such a prohibition from Mylan Pharmaceuticals and other generic manufacturers.[15] However, at least one federal judge has questioned the logic of this interpretation. In August of 2004, U.S. District Judge Irene Keeley referred to the marketing of authorized generics as leaving a "gaping black hole" in laws intended to protect market competition.[16] Regardless of whether or not the FDA is correct in its interpretation of *its* statutory mandate, the FTC has separate and independent authority to regulate and prohibit anticompetitive conduct, of which authorized generics is clearly an example.

Recommendations on Authorized Generics

We believe that authorized generics are anti-competitive, undermine the Hatch-Waxman Act, and harm all purchasers of prescription drugs (consumers, health insurers, employers and government health programs). We therefore make the following general recommendations:

- **Prohibit the Marketing of Authorized Generics during the 180-day Exclusive Marketing Period**
  Once a drug patent expires or is found invalid, every incentive provided to generic drug companies under the Hatch-Waxman Act should be preserved to encourage competition within this market. We encourage the FTC to adopt an interpretation of the Hatch-Waxman Act and relevant antitrust statutes that would prohibit the marketing of authorized generics during the 180-day exclusive marketing period allowed to the first manufacturer for which an ANDA is approved.

- **Prohibit and Prosecute Anticompetitive Agreements Between Brand Companies and Traditional Generic Companies**
  Agreements between generic manufacturers and brand drug companies that delay or restrict generic entry (such as "reverse payments") interfere with competition and harm consumers.

[14] April 2006, *available at* http://www.ftc.gov/bc/0604rxupdate.pdf
[15] See Mylan Pharmaceuticals, Inc. "Citizen Petition Docket No. 2004P-0075," dated February 17, 2004, and "Comment of Apotex Corp. in Support of Citizen Petition Docket No. 2004P-0075/CP1" March 24, 2004, *available at* http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf.
[16] "Battle Over Authorized Generics Grows Increasingly Heated." Martin Sipkoff, Drug Topics Supplements, April 1, 2005.

We encourage the FTC to continue to aggressively challenge such agreements as antitrust violations.

Recommendations on the Study to be Conducted

We commend the FTC for its decision to conduct this study. This information will be particularly useful as a tool for Congress to make an informed decision on whether further legislation needs to be adopted surrounding the marketing of authorized generics. We also hope that this study will lead to greater monitoring and enforcement by the FTC of the full spectrum of anticompetitive tactics and agreements used to delay generic market entry.

We have some recommendations regarding the study design:

- **Broaden the Scope of the Study to Study the Long Term Effects of Authorized Generics:** As proposed, the study of internal drug company documents will provide a primarily quantitative perspective on the market effects of authorized generics. This focus, however, will not provide the basis for an examination of the long-term effects of authorized generics on the prescription drug market. It is in the longer term that the true impacts of authorized generics become most apparent. Much of the information concerning these longer-term effects is qualitative and narrative in nature, rather than quantitative. We are concerned that an emphasis purely on quantitative data might lead the study to wrongly conclude that authorized generics are not a significant problem. We specifically recommend that the FTC incorporate into the study design qualitative and narrative testimony from experts and generic drug manufacturers on the long-term effects.

- **Broaden the study to focus on other anticompetitive practices affecting the availability of generics**, such as so-called "reverse payments." As described above, the use of "authorized generics" is just one arrow in the anticompetitive quiver of brand-name pharmaceutical companies. Often, these tactics are used in concert – such as combining the "sticks" of patent infringement suits and authorized generics with the "carrot" of a reverse payment settlement. The long-term impact of authorized generics cannot be evaluated in isolation from these other tactics. Thus, we recommend that the FTC broaden the study to include the range of other tactics used to suppress or delay generics and improperly extend the patent life of branded pharmaceuticals.

- **Hold hearings to examine the long-term impact of those practices**. The data and documents provided to the FTC as part of this study will provide invaluable information on authorized generics. However, the FTC would benefit greatly from in-person testimony from a variety of experts on this topic, including brand-name and generic manufacturers, consumer advocates, economists, insurers, state regulators and others. A hearing affords the opportunity for clarifications, questions-and-answers, and dialogue among stakeholders that is not possible in a study relying purely on document production. We encourage the Commission to hold one or more public hearings on these issues, and to publicize them widely to both the industry and the public.

Conclusion

The brand-name prescription drug industry is among the most profitable in the United States, and the cost of prescription drugs is continually rising. Brand-name drug company tactics that stifle competition in the name of profits harm consumers, employers, insurers and government health programs. In passing the Hatch-Waxman Act, Congress expressed its view that generic competition from is essential to ensuring the affordability of prescription drugs. Congress also acknowledged the need not only to create an incentive for the first would-be generic entrant, but to protect that incentive. This was reinforced by the recent amendments to Hatch-Waxman.

We fully support the FTC's efforts to determine the extent that authorized generics affect the cost and thus the availability of generics over time. We hope that the FTC will take our recommendation to expand the scope and type of data collected in the study. We further hope that the study will lead the FTC to take aggressive action to prohibit the marketing of authorized generics. Finally, we hope that increased enforcement and oversight on authorized generics will be part of a broader and robust effort to curtail and prohibit a range of anticompetitive tactics used to delay or prevent generic entry.

We appreciate the opportunity to submit these comments.

Sincerely,

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Also on behalf of:

Action Alliance of Senior Citizens of Greater Philadelphia
Philadelphia, PA

American Federation of State, County and Municipal Employees (AFSCME)
Washington, DC

The Annie Appleseed Project
Delray Beach, FL

Florida CHAIN (Community Health Action Information Network)
Plantation, FL

Gray Panthers California
Sacramento, CA

The Greenlining Institute
Berkeley, CA

Health Care for All
Boston, MA

National Women's Health Network
Washington, DC

Patients Not Patents
Washington, DC

United Senior Action of Indiana
Indianapolis, IN

Wisconsin Citizen Action
Madison, WI