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Senator Edward Kennedy
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Senator Judd Gregg
Russell Senate Office Building
Room 393
Washington, DC 20510

Dear Senators Kennedy and Gregg:

I write to express my support of the Greater Access to Affordable Pharmaceuticals Act of 2001 ("GAAP"), which amends the Hatch-Waxman Act of 1984 (the "HWA"). I attach a Policy Statement which details the arguments made in this letter.

In the past several years, State Attorneys General have filed five antitrust suits to remedy the harm caused by brand-name and generic manufacturers' manipulation of loopholes in the Hatch-Waxman Act ("HWA"), thereby delaying generic entry. These are:

? *State of Ohio, et al. v. Bristol-Myers Squibb, Co.*, concerning the anti-cancer drug Taxol® (the "Taxol litigation");

? *State of Alabama, et al. v. Bristol-Myers Squibb Co., et al.*, concerning the anti-anxiety drug Buspar® (the "Buspar litigation");

? *State of New York, et al. v. Aventis, S.A., et al.*, concerning the anti-hypertension drug Cardizem CD® (the "Cardizem litigation");

? *State of Florida, et al. v. Abbott Laboratories, Inc.*, concerning the anti-hypertension drug Hytrin® (the "Hytrin litigation"); and

? *Commonwealth of Pennsylvania v. Schering-Plough Corp. et al*, concerning the potassium supplement K-Dur 20 ("the K-Dur 20 litigation").

Through these cases, and other multi-state investigations, this Office has gained substantial experience with the shortcomings of the HWA. GAAP will be an important step in correcting these problems, and in ensuring consumers access to affordable medication.

GAAP specifically alleviates two critical problems caused by the HWA, which the cases brought by the Attorneys General illustrate:

? The Thirty Month Stay - Under the HWA, brand-name manufacturers list unexpired patents with the FDA in a compendium known as the "Orange Book." The FDA does not evaluate the merits of the listing, and relies on the manufacturer's representations as to the listing's validity. An Orange Book listing carries a rich reward – an automatic 30-month stay against certain potential generic entrants whom the manufacturer has sued for patent infringement, *despite the absence of any court finding that the infringement claim has any validity whatsoever*.

Problems caused by this provision are illustrated by the facts of the *Buspar* litigation. In that case, Bristol-Myers Squibb ("BMS") sought to extend its patent monopoly for its profitable buspirone anti-anxiety medication. As BMS's buspirone patent was about to expire, BMS received a patent for a metabolite that the body naturally produces – which BMS claimed was the result of introducing buspirone into the body. BMS then had the FDA list the patent in the Orange Book eleven hours before the first generic alternative to buspirone was to obtain FDA approval. Although BMS explicitly stated to the United States Patent Office that its new patent did *not* cover buspirone, its Orange Book entry made precisely the opposite claim. As a result, generic makers of buspirone were barred from the market, and consumers paid millions more than they would have paid, had a generic alternative been available.

GAAP helps alleviate this problem in two essential ways. *First*, a brand-name manufacturer will no longer be able to obtain the 30-month stay for follow-on patents. Had GAAP been in place, BMS's scheme would not have been possible. *Second*, in certain instances, GAAP allows generic manufacturers to challenge fraudulent Orange Book listings in court.

? The 180-day exclusivity period - HWA gives certain generic entrants who are the first to seek FDA approval for their drugs a 180-day exclusivity period during which no other generic alternative to the same brand-name drug may come to market. While this provision was intended to provide an incentive for generic entry, in several instances, brand-name manufacturers have paid their generic counterparts to stay off the market, without the generic forfeiting its right to exclusivity. This creates a perpetual bar to entry by other generics. Thus, in both the *Hytrin* and *Cardizem* cases, no generic version of the brand-name drug could be sold until litigation and investigations by the Federal Trade Commission led the parties to cancel their agreements.

GAAP would render impossible such permanent barriers to generic entry. Under the pending bill, if generic entry does not take place within sixty days of the generic drug's approval, the next generic manufacturer in line may enter the market. Conduct now being challenged in costly and time-consuming litigation would simply not have taken place had GAAP been in effect.

Case-by-case and after-the-fact investigations and litigation are no substitute for fixing the problems inherent in the HWA. For that reason, I applaud the efforts of Senators Schumer and McCain, and those of other GAAP sponsors, and urge the speedy passage of this important and beneficial bill.

Sincerely,

Eliot Spitzer

cc: Senator Charles Schumer
Senator John McCain