Concurring Statement of Commissioner Jon Leibowitz Federal Trade Commission v. Watson Pharmaceuticals et. al.

The Commission and the California Attorney General have brought a critically important antitrust case. This is yet another example of pharmaceutical companies turning competition on its head -- in this instance involving AndroGel, a steroid marketed in part to older men. Here, instead of trying to bring a low-cost competitive drug to market, the generic companies (Watson, Par, and Paddock) are now selling the monopoly product, AndroGel, which is manufactured by Solvay. Denied the possibility of the dramatic savings brought by generic competition -- which can drive prices down to as little as ten percent of the brand price -- American consumers, especially the elderly and the uninsured, are the victims here. So is the federal government, which pays nearly one-third of the nation's prescription drug costs overall and will have to pay dramatically higher prices for AndroGel.

Eliminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today. The reason why is simple: illegally delaying generic entry on even a single drug can cost consumers billions of dollars. And our annual reports on patent settlements suggest a very worrisome trend: nearly half of all brand-generic patent settlements -- 28 out of 61 in fiscal years 2006-2007-- include some type of payment to the generic and the generic's agreement to stay out of the market. Generic entry prior to patent expiration, which had been a common occurrence until the past few years, is at risk of becoming the rare exception. Congress enacted the landmark 1984 Hatch-Waxman Act to encourage early generic entry and save consumers money, but these anticompetitive deals threaten to destroy that benefit and make crucial portions of the Hatch-Waxman Act extinct in all but name.

What will happen if this disturbing trend continues? Prescription drug costs will increase; consumers, employers, and the federal government will pay the higher brand prices because it is more profitable for the generic to take a payment not to compete than to enter the market.

So I strongly support our two-pronged approach to eliminating these unconscionable deals. First, we will continue to challenge patent settlements that are anticompetitive and force consumers to pay more for much needed drugs. Second, we will advocate for legislation along the lines of the bipartisan measure (introduced last Congress by Senators Kohl, Obama, Grassley, Durbin, and Schumer as well as Representatives Waxman, Dingell, and Rush), which would offer a simple, effective and straightforward solution to the problem by banning payments from the brand to the generic while permitting legitimate settlements.

Either way, eliminating the pay-for-delay problem will help ensure that the nation can afford health care reform and that our nation's citizens can afford prescription drugs. Failure to do so will make reforming health care and expanding health care coverage that much more difficult.

¹ As then candidate Obama explained to the American Antitrust Institute during the campaign, "[a]n Obama administration will ensure that the law effectively prevents anticompetitive agreements that artificially retard the entry of generic pharmaceuticals onto the market, while reserving the incentives to innovate that drive firms to invent lifesaving medications." Statement of Senator Barack Obama for the American Antitrust Institute, available at http://www.antitrustinstitute.org/archives/files/aai-%20Presidential%20campaign%20-%20Obama%209-07_092720071759.pdf