Statement of Commissioner Jon Leibowitz

Concurring in Part and Dissenting in Part in the Matter of Cephalon, Inc.

Matter Number 061-0182

I join in the Commission's decision to bring an action against Cephalon for these anticompetitive deals and commend staff for their excellent work. I also entirely agree that monopolization is an appropriate theory of liability – after all, Cephalon engaged in a practice of paying off its potential competitors to maintain its monopoly profits. Sadly, pay-for-delay settlements, if not stopped, will continue to grow exponentially – costing consumers and the federal government (which pays more than 30 percent of prescription drug costs) literally billions of dollars in excess charges. In this instance, they will cost patients taking Provigil – a crucial drug for those who suffer from narcolepsy and for members of the armed services in Iraq – more than a billion dollars through years of delayed competition.

Nevertheless, I dissent in part. I also would have named as a defendant any generic company that took these pay-offs and now refuses to relinquish their 180-day exclusivity, thus blocking generic entry into the Provigil market that otherwise could occur in 2008. In the context of this case, I would not sue any company that, to its credit, offered to relinquish – because eliminating that exclusivity would open the door to imminent generic entry for Provigil.

Currently, Barr, Ranbaxy, Teva, and Mylan share the 180-day exclusivity for modafinil (the active ingredient in Provigil). Under the Hatch-Waxman Act, the FDA cannot approve any other generic Provigil product until 180 days after one of those first-filers has marketed its product. Because the settlements prevent entry by any of these

firms until April 2012, no other generic – even if its product does not infringe or Cephalon's patent is invalid – can enter the market until six months later. So Cephalon – without ever having to test its patent – is guaranteed protection from competition until 2012. Here, the 180-day exclusivity, *which Congress created to reward generics for entering early*, does precisely the opposite: it extends the brand's monopoly, forcing consumers to pay excessive prices for Provigil throughout the span of these illegal deals.

If all four companies were to forego their exclusivity, there is every reason to believe that others would enter this nearly $800 million market – and quickly. Apotex and Caraco have already received tentative approval from the Food and Drug Administration, and Cephalon has not sued either one. At this point, only the 180-day exclusivity prevents these companies from receiving final FDA approval and going to market. Ironically, if either Apotex or Caraco were to enter, the four settling generics could also immediately enter the market with their own competing products under the very terms of their patent settlements with Cephalon. Ultimately, there could be as many as six or seven competitors in the market. Prices would likely fall by as much as 80 or 90 percent, an enormous benefit that consumers and the federal government could see as early as this year.

And what would relinquishment cost the settling generics?

Apparently, not very much.

Under the current settlements, the four generics will each have to wait more than four years to enter the market. When they do, competition from multiple competitors will limit profits. They will also likely be competing in a much smaller market in 2012 because Cephalon intends to switch patients to a new, similar product, Nuvigil, which

already has FDA approval and will not be susceptible to generic competition for at least several additional years.

So why would a generic company refuse to relinquish its exclusivity when that exclusivity arguably has little value to the generic but creates near iron-clad protection for Cephalon's Provigil monopoly? Why would companies that have made the hallmark of their business delivering low-cost drugs actually prevent that result from happening here?

The answer is as troubling as the settlements themselves. Here, the non-relinquishing generics appear to be sending a clear signal to PhRMA Companies: you can do business with us in the future; we will protect your monopolies.

Although I am confident the Commission will win this case against Cephalon, it will likely take years, as most antitrust cases do. In the meantime, Congress should pass the bipartisan legislation – now moving through both Houses – that would ban these pay-for-delay deals completely (while still allowing legitimate settlements). Moreover, as it is drafting much-needed legislation to create a pathway for generic biologics, Congress should try to ensure that it does not create a loophole that lets pharmaceutical companies conspire to exploit consumers through yet a new avenue of pay-for-delay deals. Finally, in exercising its general oversight responsibility over the pharmaceutical industry, Congress should consider asking these generics whether they are willing to waive this right (shared exclusivity) that arguably has very little financial value to them when the benefits of waivers to American consumers seem so substantial – and, if not, why not.

Relinquishment, of course, should not be an amnesty program for generics in every pay-for-delay case. Here, however, relinquishment means that hundreds of

thousands of people would likely pay significantly less now for much-needed medication rather than having to wait until 2012. To my mind, these extraordinary circumstances justify not naming any generic company that would be willing to relinquish its exclusivity.