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John R. Ferguson, Esquire
Swidler & Berlin
3000 R Street, N.W.
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Washington, D. C. 20007-3851

Dear Mr. Ferguson:

This letter responds to your request on behalf of the Pharmaceutical Manufacturers Association ("PMA") for a statement pursuant to the Department of Justice Business Review Procedure, 28 C.F.R. § 50.6, of the Department's present enforcement intentions regarding PMA's proposal to implement a program whereby its member companies would commit to limit their price increases on their entire line of prescription drug products in any calendar year to an amount not to exceed the increase in the Consumer Price Index ("CPI"). For reasons explained below, the Department currently intends to bring suit to challenge the program if PMA and its members go forward with this proposal.

We understand that PMA is a trade association that represents more than 100 research-based pharmaceutical companies that develop, produce, and market most of the prescription drugs used in the United States. We further understand that PMA members account for over 90% of the dollar sales of prescription drugs in the United States and that these sales were estimated to have been slightly over $50 billion in 1992. According to your submissions, PMA has developed the proposed program in response to concerns about controlling health care costs, including the cost of prescription drugs, pending adoption, and implementation of comprehensive health care reform.

Under PMA's program, each participating member company would sign a commitment to limit the annualincrease in the "weighted average of changes in the net prices" of its

prescription drug products to a level not greater than the increase in the CPI. New drug products would not initially be included in the commitment, but would be covered in the next calendar year following their introduction into the market. Each participating company would certify to PMA, through the company's independent accounting firm, that its increase for the previous year conformed to the agreement. PMA, in turn, would certify, through its accountant, to the Secretary of Health and Human Services that the price increases of the companies in the aggregate conformed to the limit. The General accounting Office would have the right to audit the underlying records that each company would maintain to demonstrate its compliance. In addition, each participating company whose price increase in any calendar year exceeded the limit would reduce its aggregate increase in the following year to a level necessary to account fully for the excess in the preceding year.

PMA has stated that this program is intended as an "interim" measure to contain prices. The arrangement is to end with the adoption and implementation of overall health care reform, which PMA envisions will establish a managed competition system, including the addition of prescription drug products to the standard benefit package, assuming this reform occurs within a reasonable period. According to your submissions, PMA also states that if the proposed health care reform "is not one to which the pharmaceutical industry can give its support," then PMA may abandon this program.

We understand that each PMA member company will decide unilaterally whether to participate in the program and is free to withdraw at any time. Your letter requesting a business review notes, however, that PMA "anticipates that each of its member companies will subscribe to this undertaking, thereby committing itself to the pricing policies and program stated in the proposed undertaking."

According to your submissions, it is contemplated that, if PMA implements this program, PMA, apparently through an independent accounting firm, will establish the mechanism for calculating the "weighted average of changes in the net prices" of covered drugs. Participating members will agree to this definition and will also agree to a common definition of new drugs.

After careful consideration of the information you have provided, as supplemented by our own independent inquiries, the Department believes that the proposed program would violate the antitrust laws. An agreement among independent competitors that interferes with free and open price competition by restraining individual pricing decisions is a per se violation of the Sherman Act. The per se rule has been applied to agreements

among competitors that fix or set the prices at which goods or services are sold as well as agreements that set price-related terms but not the specific price at which transactions occur. Thus, the Supreme Court has held an agreement to eliminate free credit granted by wholesalers to retailers to be per se illegal even though there was no agreement with respect to invoice prices. Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643 (1980).

The Supreme Court has also made clear that agreements that set maximum prices are as equally illegal as agreements that set minimum prices. Arizona v. Marcopa County Medical Society, 457 U.S. 332 (1982). Such maximum price-fixing agreements create the risk that the maximum prices will become minimum or uniform prices.

The PMA proposal is an arrangement among competitors that limits individual pricing decisions on its face. The participants agree to the maximum overall price changes that they will adopt in the future. This agreement, like all agreements that tamper with the price structure, "cripple[s] the freedom of traders and restrain[s] their ability to sell in accordance with their own judgment." Kiefer-Stewart Co. v. Seagram & Sons, 340 U.S. 211, 213 (1951). The participants in PMA's program also will agree on the products to be included (the definition of "new drugs") and the methodology to be used in calculating the average weighted price increases each year. In view of its structure and nature, the PMA program falls within the types of agreements that the Supreme Court has held to be per se illegal. */

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*/ This letter evaluates the PMA proposal as a whole. However, if PMA were to adopt only the part of its proposal providing for agreement upon terms and methodology for calculating its members' price increases and on reporting and auditing procedures, we still would have competitive concerns, since in this context such agreements would likely facilitate an agreement on price levels, as originally proposed.

While PMA suggests that this program is less intrusive and would be preferable to mandatory price controls, collective private action with respect to prices is not an acceptable alternative under the antitrust laws to governmental policies regulating economic activity. Moreover, there is no certainty that, in the absence of PMA's program, mandatory price controls would be adopted.

As your own submissions and other information indicate, price competition in the pharmaceutical industry has been increasing rapidly in recent years and is expected to increase further as managed care assumes a larger role in providing health care. In that regard, we wish to emphasize that the antitrust laws do not prohibit individual firms from adopting and announcing pricing policies that are intended to contain or limit increases in the prices of their products. We are aware that a number of drug companies have adopted unilateral policies designed to respond to concerns about escalating health care costs. Nothing in this letter should be construed as a statement of the Department's position with respect to unilateral action by individual members of PMA or others to control price increases in the future.

This statement is made in accordance with the Department's Business Review Procedure, 28 C.F.R. § 50.6, a copy of which is enclosed. Pursuant to its terms, your business review request and this letter will be made publicly available immediately. Your supporting documents will be publicly available within 30 days of the date of this letter unless you request that any part of the material be withheld in accordance with Paragraph 10(c) of the Business Review Procedure.

Sincerely yours,

/s/

Anne K. Bingaman
Assistant Attorney General