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March 12, 1993

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Honorable John W. Clark
Acting Assistant Attorney General
Antitrust Division
U.S. Department of Justice
Washington, DC 20530

Dear Mr. Clark:

**Re: Pharmaceutical Manufacturers Association,
Request for Business Review Letter**

This is a request for a Business Review Letter made on behalf of the Pharmaceutical Manufacturers Association pursuant to the provisions of 28 C.F.R. § 50.6.

1. IDENTITY OF THE REQUESTING PARTY

The Pharmaceutical Manufacturers Association is an incorporated association that represents more than 100 research-based pharmaceutical companies that discover, develop and produce most of the prescription drugs used in the United States. The hallmark of PMA members is their commitment to discovery research on new biological and pharmaceutical products, and the development of new therapies, preventatives and systems of therapy. A copy of the Association's by-laws and a list of its present membership are appended as Exhibits A and B, respectively.

The Association estimates that, taken together, the dollar sales of its member companies account for more than 90% of the total annual U.S. sales of prescription drugs.

2. BACKGROUND OF THE REQUEST

The rising cost of healthcare in the United States, including the cost of prescription drugs, has been the subject of national debate in recent months. The Pharmaceutical Manufacturers Association and its member companies have been and

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are desirous of cooperating and participating in the effort to contain such costs. To that end, the Association's Board of Directors adopted a resolution on December 10, 1992, that provided as follows:

BE IT RESOLVED:

Mr. Mossinghoff [the Association's President] is directed as soon as possible to discuss with President-Elect Clinton, his transition staff, members of his Administration and Members of Congress whether these Government officials would have an interest in exploring whether individual pharmaceutical manufacturers should undertake voluntarily and independently to hold for a reasonable period of time -- given stable market conditions and Government policies that are supportive of innovation -- the increase in the weighted average of changes in the net prices of that company's prescription drug products to an approximate level not greater than one or more externally controlled economic indices such as the Consumer Price Index, and whether such actions should be confirmed to the Government by a series of reports to document actual results of these undertakings.

The full text of the action taken on December 10th is appended as Exhibit C.

Prior to the adoption of that resolution, several member companies, acting individually and unilaterally, already had announced and implemented programs committing them to limit price increases in much the same manner as that contemplated in the resolution. Since the resolution's adoption, other companies, again acting individually and unilaterally, also have taken similar actions. To date, the Association believes that 10 companies representing over 40% of the dollar sales of prescription drugs in the United States have made public commitments to limit future price increases.

Since the adoption of the resolution, Mr. Mossinghoff, the Association's President, has met with representatives of the Administration and Members of Congress to discuss healthcare issues in general and the resolution in particular. In those meetings, some senior Government officials have expressed their belief that means must be found to contain healthcare costs during the transition from the present system to a Managed Competition system in which competition among providers of healthcare will, in and of

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itself, restrain healthcare costs. Nonetheless, to date, the Government has neither embraced nor rejected the program contemplated in the resolution.

3. THE ACTION CONTEMPLATED

Subject to the Division's response to this request for a Business Review Letter, the Association proposes an undertaking in the form set out below. The Association's management 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.

The undertaking contemplated is intended as an interim measure only. By its own terms it will expire with the enactment and implementation of the Government's national program for healthcare. It has four basic elements. First, it sets out a pricing policy by which member companies, acting individually and unilaterally, would agree to be bound. Essentially, each member company signing the undertaking would commit to limit its price increase, if any, on the entire line of its prescription drug products in any calendar year to an amount not to exceed the increase in the CPI. New prescription drug products are to be covered by the pricing policy, but only after they have been introduced into the market. Assuming favorable business review and the adoption and implementation of the undertaking by the Association and its member companies, the effect would be to limit aggregate price increases for prescription drugs to amounts not exceeding increases in the CPI, pending Government action on healthcare cost containment.

The second element in the proposed undertaking involves reporting performance by individual companies and the Association's membership as a whole on price increases for the preceding calendar year. All reports would be prepared on a common basis to be established by the Association's certified public accountant. With a single exception, the reporting method contemplated is typical of that followed by trade associations generally where proprietary information is involved. The exception is that the Association would report the results of Association-wide and individual company performance to the Secretary of Health and Human Services who would then be free to make such use of the information as she saw fit. Moreover, the certifications and supporting data would be open to review by the GAO.

The third element of the proposed undertaking attempts to put in place a mechanism for insuring that consumers receive the benefits of the price-increase limiting policy that the company adopted on signing the undertaking. The mechanism is straightforward: Any company whose price increase on the entire line of its prescription drug products in any year exceeds the CPI increase would agree to reduce any price

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increase in the subsequent year so as to achieve a rolling average price increase not to exceed the CPI increase.

The fourth, and final, element of the undertaking is a "sun-set" provision. The undertaking is premised on two assumptions: first, that overall healthcare reform will be enacted within a reasonable period of time; and second, that the reform will take the form of Managed Competition. Should either or both of these assumptions fail to materialize, any member may declare its undertaking terminated.

The proposed undertaking reads:

1. That, given stable market conditions and Government policies that are supportive of innovation, each member of the Association agrees, and affirms by signature to a copy of this undertaking, to hold the annual increase, if any, in the weighted average of changes in the net prices (*i.e.*, actual transaction prices net of all discounts, rebates and other similar adjustments) of its prescription drug products, including new products following their introduction into the market, to a level not greater than the increase in the Consumer Price Index;
2. That each member signatory to this undertaking shall certify, through its regularly engaged independent certified public accountant, to the Association's regularly engaged certified accountant that its price increase, if any, for prescription drugs during the preceding calendar year conformed to the provisions of paragraph 1 of this undertaking; that the Association's accountant shall, in turn, certify to the Secretary of Health and Human Services that, on the basis of individual certifications received by it, the price increases, if any, charged by the Association's members in the aggregate for the preceding calendar year conformed to paragraph 1 of this undertaking and shall append to such certification to the Secretary a copy of the certification received from each member company;

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3. That, any member company signatory to this undertaking whose price increase in any calendar year was in excess of that provided for in paragraph 1 of this undertaking agrees that, in the calendar year next following, it shall reduce its aggregate price for prescription drugs to a level necessary to account fully for the amount of such excess in the preceding calendar year; and,
4. That, continued adherence to this undertaking assumes enactment of overall healthcare reform establishing a Managed Competition system within a reasonable period.

4. **THE EFFECTS OF THE UNDERTAKING**

Assuming a favorable Business Review Letter from the Division on this request, and the adoption of this undertaking by the Association and its implementation by members, acting individually, the benefits to all consumers could be substantial. Illustratively, although prescription drugs account for less than 8% of the annual cost of healthcare in the United States, their cost may not be covered by insurance available to cover other aspects of healthcare. Thus, one benefit of this proposal would be to limit price increases on a portion of healthcare costs paid directly by consumers.

Another important benefit would be to contain price increases on a relatively small, but nonetheless important component of healthcare costs during the period of Government study, proposal, enactment and implementation of a comprehensive national healthcare program, using Managed Competition to restrain healthcare costs. The undertaking proposed would be simple, direct and easily implemented without the bureaucratic costs and inefficiencies inherent in any system of direct Government price controls on thousands of individual pharmaceutical products now on the market.

In the Association's view, these and other important consumer benefits flow from implementing the proposal without injury to competition or violation of the antitrust laws. In fact, the proposal preserves the dynamics of competition subject only to the self imposed limitation adopted by member companies that, acting unilaterally, determine to limit their upward pricing freedom on the market-basket of prescription drugs they sell to annual increases in the CPI. Thus,

- The undertaking does not contemplate the exchange of prices or price related information between or among competitors, nor does it facilitate the exchange of such information.

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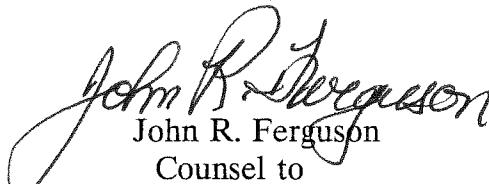
- Since, with one or two exceptions arising in the case of the newest and smallest members of the Association, every member sells multiple prescription drugs serving more than one therapeutic end use, member companies will remain free to set their own prices on individual drugs; it is only to the entire line of that company's prescription drugs that the undertaking has application.
- Taken as a whole, the prescription drug industry is not highly concentrated. Thus, no member company holds more than a 7.6% share of market. And, more than 20 companies' dollar sales must be included to reach a 75% share of the market.
- The undertaking leaves to each individual member company all decisions on research and development, activities that have made the U.S. prescription drug industry the World's leader.
- Considered as a whole, the benefits to consumers and competition outweigh any possible detriment. See Broadcast Music v. Columbia Broadcasting System, Inc., 441 U.S. 1, 8-9, 99 S.Ct. 155, 60 L.Ed.2d 1 (1979); Chicago Board of Trade v. United States, 246 U.S. 231, 38 S.Ct. 242, 62 L.Ed. 683 (1918).

Should the Division desire, the Association is prepared to provide further economic support demonstrating the consumer benefits and absence of anticompetitive effects of the proposed undertaking.

COMPLETENESS OF THIS REQUEST

This request for a Business Review Letter contains all of the relevant data and copies of operative documents and references any and all understandings, oral or written. The Association respectfully asks that this request receive expedited consideration. We will be happy to provide any other information or documents requested by the Division.

Sincerely yours,


John R. Ferguson
Counsel to
Pharmaceutical Manufacturers Association