DEPARTMENT OF JUSTICE
Antitrust Division

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March 20, 1998

David William Livingston, Esquire
Vice President, Corporate Secretary & Counsel
American Heart Association
National Center
7320 Greenville Avenue
Dallas, Texas 75231-4596

Dear Mr. Livingston:

This letter responds to your September 24, 1997, request for a statement from the Department of Justice of its current enforcement intentions regarding proposed changes to the American Heart Association Pharmaceutical Roundtable ("PRT"). The PRT was previously reviewed at the time of its formation, and a business review letter was issued by the Department of Justice on April 28, 1989, indicating the Department had no current intention to challenge the formation of the PRT or its activities. Based on the information you have supplied to us, we have no current intention to challenge the proposed changes to the PRT.

You represent that the PRT was formed, and continues to be used, primarily for the purpose of sponsoring and funding basic biomedical research by independent researchers. The research will continue to relate broadly to the causes, prevention, and treatment of cardiovascular diseases, including stroke, and will continue to be of a basic, as opposed to an applied, nature. In addition, the PRT will also begin funding "targeted research", a more specific type of basic research. In this context, targeted research refers to the area of outcomes and health services research when the American Heart Association ("AHA") targets a specific area of interest in the cardiovascular field.

Future research will not be oriented in any way toward the improvement or development of commercial products. Furthermore, the knowledge obtained from the research funded by the PRT will be published and otherwise made public, rather than used privately by the AHA and/or any member company of the PRT.

Membership in the PRT will continue to be open to all pharmaceutical manufacturers, foreign and domestic, that agree to the obligations and contributions required of all industry members of the PRT. There are currently no plans to limit the number of industry participants or to close membership in the PRT. The AHA also will continue to be a member of the PRT, and will be represented in the PRT by individuals who are members of the AHA.

In addition to the AHA, the original founding members of the PRT were Ciba-Geigy, Bristol-Myers, Sandoz, Squibb, Winthrop Pharmaceuticals, Wyeth-Ayerst Laboratories, and Genentech, Inc. Boehringer-Ingelheim has also been a regular member since the PRT was formed. The pharmaceutical manufacturers who are members of the existing PRT are Astra Merck, Inc., Bristol-Myers Squibb, Genentech, Inc., Parke-Davis, Pfizer, Inc., Sanofi Pharmaceuticals, Inc., and Wyeth-Ayerst Laboratories. Astra Merck, Inc., Bristol-Myers Squibb, Novartis Pharmaceutical Corp., Rhone-Poulenc Rorer, Inc., Parke-Davis, Pfizer, Inc., and Wyeth-Ayerst Laboratories have all expressed their desire to become members of the new, modified PRT.

Each industry participant of the PRT will sign a separate agreement with AHA that will be binding only between the AHA and that individual industry member. The agreements will commit each industry member to contribute $1,000,000 per year for three years.[1] The three-year term of each member agreement begins January 1, 1998, and ends December 31, 2000. The combined annual contributions will be used to fund specific basic biomedical research projects selected by vote of the PRT members from a list of projects that have been previously reviewed and approved by AHA's standing volunteer peer review committees and the AHA Board of Directors. Each PRT industry member, individually or together with other industry members, may also select and fund additional particular peer-reviewed and AHA-approved basic biomedical research projects through the PRT, in addition to those selected and funded by the PRT membership as a whole.

The industry members of the PRT will continue to have no role in initiating or designating research projects to be reviewed by the established AHA peer review committee procedures. The industry members will not monitor, supervise, or in any way direct or control any research projects funded by them collectively or individually through the PRT. Nor will

[1]Thus, annual contributions will be increased from the current level of $200,000 per annum ($300,000, if the industry member was a Founding Member) to $1,000,000 per annum, and the term of the agreements will be decreased from the current level of five years to three years.

they be entitled, either collectively or individually, to any rights to patents or patentable interests resulting from research funded by them through the PRT. The AHA fully expects, and will encourage, wide dissemination of the results of any research funded by the PRT through annual progress reports, articles published in scientific journals, and presentations at scientific meetings.

The research projects funded by or through the PRT will continue to be performed by academic researchers at independent nonprofit institutions; that is, the projects will be performed neither by employees of industry members nor at facilities of industry members. There will not be any contractual relationship between the PRT and the funded researchers or their sponsoring institutions. Researchers working at private, for-profit companies will not be eligible for funding through the PRT.

The AHA will remain the sole administrator of the PRT's programs. Both the required annual contributions and any additional funds individual members may contribute through the PRT to particular AHA-approved projects will be administered by the AHA and distributed, according to its established procedures, to the academic or other nonprofit institutions where the funded researchers work or perform their research. These independent institutions will remain responsible for supervising the research.

Membership in the PRT will continue not in any way to limit the ability of the industry members to conduct or fund any research independently of the PRT, including research similar or related to research being funded by or through the PRT. It will be the PRT's general policy, however, to make no funding awards to projects already receiving funding from another source, or that duplicate other projects. The emphasis will remain on the discovery of new knowledge in the cardiovascular field. No restrictions will be imposed on members of the PRT concerning their independent conduct or funding of research outside the PRT's channels.

The industry members of the PRT will receive recognition for their participation in the PRT. Their firms' names may be associated with the particular research projects that they fund and mentioned in research papers published in scientific journals, in AHA's own journals and newsletters, and at scientific gatherings and conventions. Industry members may use a logo or symbol specially designed for the PRT in their own product and institutional advertising to publicize their financial support for, and close association with, AHA-sponsored basic biomedical research.

The Department of Justice will not challenge a true joint research and development venture on antitrust grounds, unless the Department determines that the venture will have anticompetitive effects in a properly defined relevant market that outweigh the venture's

procompetitive benefits. See National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4302 (Supp. 1997) (stating legal standard used to judge conduct under federal antitrust laws for research and production joint ventures is the rule of reason). Legitimate research joint ventures are not usually on balance anticompetitive, particularly in the case of joint ventures to perform basic, non-appropriable research.

In the case of the PRT, even though its membership will remain open to all pharmaceutical manufacturers, it is unlikely to harm competition in any relevant market, particularly in the market for biomedical research. The PRT has been, and will remain, essentially a funding device. Although the Department's current enforcement intention would not necessarily be different in the absence of such limitations, the PRT's proposal greatly limits its industry members' contacts with, and control over, the AHA projects they fund. Moreover, the proposal does not appear to contain anything that will have significant anticompetitive spill-over effects in any market, including the market for biomedical research.

For the foregoing reasons, the Department has no current intention to challenge the proposed future activities of the PRT. In accordance with out normal practice, however, the Department of Justice reserves the right to bring an enforcement action in the future, if the actual operation of the PRT proves anticompetitive in purpose or effect.

This statement is made in accordance with the Department's Business Review Procedure, 28 C.F.R. § 50.6. Pursuant to its terms, your business review request and this letter will be made publicly available immediately. In addition, any supporting data that you do not timely identify to be confidential business information under paragraph 10(c) of the Business Review Procedure will also be made publicly available.

Sincerely,

/s/

Joel I. Klein