March 28, 1983

Dr. Leroy B. Randall
Chief, Patent Branch
Office of the General Counsel
Department of Health and Human Services
National Institutes of Health
Westwood Building, Rooom 5A03
Bethesda, MD 20205

Dear Dr. Randall:

Please consider this letter responsive to the solicitation for public comments as published in the Federal Register, Volume 48, No. 24, Friday, February 4, 1983, on whether the government should approve a seven year extension of an exclusive license issued to Bristol-Myers Company to make, use and sell cisplatin compounds as anticancer agents.

The three specific questions proposed by the Department will be specifically treated below.

1. Would the public best be served by extending the existing exclusive license to Bristol-Myers to further develop the product?

   It is the collective conclusion of the universities which are members of (COGR or NACUBO) that extension of the license would best serve the public. The reasons for this conclusion are the following:

   a. The performance of Bristol-Myers under the exclusive license appears to have been exemplary. That Company spent substantial sums, approximately $46 million, in developing the compound for use in the treatment of certain types of cancers and timely made the invention available to the public for its use and benefit.

   b. It is our understanding that Bristol-Myers under an extension of the exclusive license is willing to commit at least $28 million for needed research and development to explore and expand the application of cisplatin to the treatment of other types of cancers and that this effort could increase the use of the compound approximately nine-fold. Importantly, the increased usage is directly equated with the number of patients which could benefit from such treatment and who could be given some hope for the future.

   c. The public has been fully served by the activities of Bristol-Myers under the present agreement and all indications are that it

will continue to be fully served by the intended commitment in further research and develoment efforts if the exclusive license is extended.

d. There is no evidence that under the exclusive licensing arrangement any person was denied access to cisplatin, because of cost or any other reason, for treatment of a cancerous condition responding to the applications approved by the Food and Drug Administration.

2. Would it be in the best interest of the public to permit marketing of cisplatin on a nonexclusive basis and invite as many pharmaceutical companies to apply as possible?

It is the considered opinion of (COGR or NACUBO) that such action could well be adverse to the best interest of the public for the following reasons:

a. The economic motivation which is required for the commitment to substantial research and development expenses, and which can be readily supplied by utilizing the patent incentive, would be lost since the opportunity to recoup those expenses from the sale of the product under an exclusive licensing arrangement would have been negated.

b. At best one could anticipate a fragmented approach to further research and development to expand the application of cisplatin to the treatment of other than the presently indicated cancerous conditions if only nonexclusive licenses were available. Experience indicates that, in general, nonexclusive licensees are reluctant to spend significant amounts of money to develop a market for a product to which their competitors have ready access.

c. Here, issuing nonexclusive licenses without limitation would merely dilute the share of the current market available to any one company and would thereby reduce the potential and actual revenue flowing from the sale of the product by such company and would strongly mitigate any commitment to expending monies for additional research and development.

d. Bristol-Myers because of its past commitment and experience in the field can bring the benefits of additional research and development on expanded uses of cisplatin to the public in the shortest possible time whereas that anticipation can not be attributed to a nonexclusive licensee who may be merely beginning the effort to obtain regulatory clearance for present cisplatin indications and with little or no background experience or

facilties now committed to such effort.

3. How should the government exercise its rights with respect to this invention in a manner that would best promote the public health?

Without reservation (COGR or NACUBO) believes that public health would best be promoted by extending the exclusive license which Bristol-Myers now enjoys for the following reasons:

a. Bristol-Myers is willing to make a current substantial commitment to the additional research and development necessary to expand the uses of cisplatin against other forms of cancer.

b. Bristol-Myers is in the position to expeditiously carry forward such research and development because of its past experience. Therefore, the public would have the benefit of access to the results of such research and development in the shortest possible time.

c. The past record of Bristol-Myers under the exclusive licensing arrangement speaks loudly as to its capabilities, intentions and willingness to commit to a rather extensive research and development effort - an effort which is wholly in the public interest.

d. The requested extension of time for the exclusive license is not for the remaining period of patent life and the further efforts by Bristol-Myers to expand the applications of cisplatin will permit the later entry of other companies into a broadened market.

In summary, and although there is a possibility that the extension of the exclusive license might delay reductions in the cost of therapy utilizing cisplatin for the present patient population, the extension of the exclusivity would appear to be the only way to insure a timely commitment to the further research and development necessary to benefit many more patients. In balance, the latter consideration far outweighs the former and will permit the kind of continuing cooperative arrangement which will lead to full utilization of the potential of the technology which has been licensed to Bristol-Myers.

Very truly yours,