REQUEST FOR EXTENSION OF BRISTOL'S EXCLUSIVE LICENSE FOR CISPLATIN

SUMMARY

- Bristol currently has an exclusive license for the development and marketing of cisplatin.
- Bristol has received FDA approval for use of cisplatin in the treatment of cancers that kill 23,000 Americans annually, and has invested over $46 million in developing these uses.
- But cisplatin has a far greater potential: half of the individuals in this country who would otherwise die of cancer could benefit from cisplatin treatment if the many promising new uses for the drug are developed. If Bristol is able to continue developing cisplatin, it could be used to treat a much larger number of patients -- conservatively estimated at approximately 216,000 -- or a ninefold increase over present use.
- Although Bristol has already embarked on the necessary research and development program, and plans to commit at least $28.0 million for needed research and development alone, Bristol will not be able to continue this effort due to the unintended consequences of this country's drug regulatory system if its exclusive license is allowed to expire. A basic lesson of pharmaceutical economics is that once a product loses its patent protection and goes generic, the original manufacturer's investment in that product declines.
- Because of the regulatory system's strong disincentive in this instance to investment in further research, it is also unrealistic to expect that any other pharmaceutical manufacturer would or could replace Bristol's pioneering work in developing cisplatin and obtaining FDA approval for additional indications if the drug goes generic.
- Even if NCI attempted to fill the clinical void, it would have to reorient its limited resources away from its traditional concentration on basic research; this might delay or limit the achievement of the full potential of cisplatin. Further, if NCI had to assume responsibility for filing NDA's, this would represent a radical departure from traditional drug marketing practices in this country.
- Bristol can work within the stringent requirements of the regulatory system to maximize the beneficial use of cisplatin; however, Bristol needs an extension of its exclusive license to enable the company to accomplish this task.
- The disincentive arising from the regulatory system can be readily solved by extending Bristol's exclusive license rights. HHS, after consultation with NCI, has statutory and regulatory authority to approve an extension of Bristol's license.

RECOMMENDATION

Bristol's exclusive license for cisplatin should be extended for seven years beyond the exclusivity expiration date of December 26, 1983.