

GAO

Testimony

Before the Sub. on Fisheries and Wildlife Conservation and the Environment, Com. on Merchant Marine and Fisheries; the Sub. on National Parks and Public Lands, Com. on Interior and Insular Affairs; and the Sub. on Forests, Family Farms and Energy, Com. on Agriculture, House of Representatives

For Release on Delivery
Expected at
10:00 a.m., EST
Wednesday
March 4, 1992

CANCER TREATMENT

Efforts to More Fully Utilize
the Pacific Yew's Bark

Statement of James Duffus III, Director,
Natural Resources Management Issues,
Resources, Community, and Economic
Development Division



Messrs. Chairmen and Members of the Subcommittees:

I am pleased to provide our views on H.R. 3836, the Pacific Yew Act of 1991. Our views are based on limited work to date for the Chairman of the Subcommittee on Regulation, Business Opportunities, and Energy, House Committee on Small Business, who has agreed to having us share with you today our observations on the issue of whether the Pacific yew's bark is being fully utilized. I must stress that our observations are limited to the issue of full utilization and are based on ongoing work. As such, they are tentative and subject to change.

In summary, the limited supply of Pacific yew bark coupled with existing and potential demand necessitate that the bark be utilized to the extent practicable. However, for a variety of reasons, not all of the bark which could have been collected on federal lands in 1991 was collected. Both the responsible federal land-managing agencies and private industry are taking or planning actions to more fully utilize the bark, and increased utilization should occur in 1992. These actions appear consistent with the provisions of H.R. 3836 that are intended to achieve full utilization of the Pacific yew's bark.

BACKGROUND

The bark of the Pacific yew is the only approved source of taxol, an anticancer drug discovered through research supported by the National Cancer Institute. Initial clinical trials of taxol show progress in treating some women with ovarian cancer, and the drug is also being tested in the treatment of other types of cancer. Estimates of the number of cancer patients who could potentially benefit from the drug approach 60,000 a year.

Although inventories of the Pacific yew have not been completed, it is generally recognized that future demand will outstrip the amount of taxol that can be produced from the bark. About 60 pounds¹ of bark are needed to produce enough taxol to treat one cancer patient for 1 year. This is about the equivalent of the bark from three average Pacific yew trees. The greatest concentration of existing Pacific yew trees in the United States is found on federal lands in the Pacific Northwest that are managed by the Department of Agriculture's Forest Service and the Department of the Interior's Bureau of Land Management (BLM).

In January 1991, the National Cancer Institute and Bristol-Myers Squibb, Co. (Bristol-Myers), a major pharmaceutical company, entered into a cooperative agreement to collaborate in research on and the development of taxol as an antitumor agent. Prior to entering into the cooperative agreement, Bristol-Myers had entered

¹All amounts shown are in dry weight.

into a contract with Hauser Chemical Research, Inc. (Hauser) in 1990 to collect the Pacific yew's bark, process it, extract the taxol, and supply the taxol to Bristol-Myers. Hauser then formed a subsidiary, Hauser Northwest, Inc., to collect and initially process the bark. Hauser Northwest, in turn, contracted with other companies and individuals to collect the bark.

In June 1991, the Secretaries of Agriculture, the Interior, and Health and Human Services entered into a Memorandum of Understanding to give their best efforts, consistent with applicable laws and policies, to help obtain the Pacific yew bark needed to produce taxol. Pursuant to this Memorandum of Understanding, the Forest Service and BLM individually entered into cooperative agreements with Bristol-Myers to provide Pacific yew bark to the company. The Forest Service and Bristol-Myers then agreed to a Pacific yew program plan for the remainder of fiscal year 1991 which defined in more detail the parties' obligations under the cooperative agreement. Both the Forest Service and BLM are in the process of developing similar program plans with Bristol-Myers for fiscal year 1992.

During 1991, almost 900,000 pounds of Pacific yew bark was collected from Forest Service and BLM lands, primarily in Oregon. This will be enough bark to provide sufficient taxol to treat about 15,000 cancer patients for 1 year. The bark is primarily collected from dead trees left from harvests of trees to be sent to sawmills, and from living trees that are harvested and stripped. The bark is peeled either mechanically or by hand in the field or mechanically at Hauser Northwest's plant.

SOME USABLE PACIFIC YEW BARK
WAS NOT COLLECTED IN 1991

Our work to date has shown that neither the cooperative agreements between Bristol-Myers and the Forest Service and BLM nor the 1991 program plan between the Forest Service and Bristol-Myers established full utilization as a goal or requirement. Moreover, it is generally agreed that not all of the usable bark which could have been collected on federal lands in 1991 was collected.

Usable Pacific yew bark was not collected primarily for four reasons. First, not all yew bark was collected before sawmill timber harvesting began. To avoid damage to the bark, it should be collected before the timber that is destined for the sawmills is harvested. Otherwise, Forest Service and BLM officials agree that a significant percentage of the yew bark may be lost in some instances when the trees are dragged to centralized collection points (slippage in yarding) or crushed by other, larger trees that are cut down during falling operations. Both the Forest Service and BLM instructed their field personnel to have the yew bark collected before sawmill timber was harvested whenever practicable, and a number of existing Forest Service sales contracts were

modified to exclude the yew tree. However, the yew bark was not always collected before the sawmill timber was harvested.

Second, usable bark was not always collected from branches and stems of smaller diameter. In 1991, the Forest Service and BLM allowed bark collectors to decide whether all feasibly collectable bark had been collected. This, coupled with the inability of Hauser Northwest's earlier mechanical equipment to debark yew logs smaller than about 4 inches in diameter, resulted in collectable yew bark being left on branches and stems of smaller diameter.

Third, usable bark was not always collected from trees which were scattered throughout wide geographical areas. Both the Forest Service and BLM generally allowed bark collectors to decide on whether there were sufficient numbers of yew trees in an area to warrant collection. As a result, some collection decisions were driven by cost-effectiveness rather than by a goal of full utilization.

Finally, some yew bark was not collected before the taxol content had deteriorated or the bark was burned. The taxol content of dead tree bark diminishes over time, and if the bark is not collected within a certain period of time (usually within 18 months after a tree has died) the trees are either abandoned or burned. During 1991, the decision to collect was left, to a large extent, to Hauser Northwest's judgment.

A FULL-UTILIZATION MANAGEMENT STRATEGY HAS BEGUN TO EMERGE

On the basis of our work to date, it appears that all parties to the cooperative agreements have taken actions to more fully utilize the bark of the yew tree in fiscal year 1992. For example, both the Forest Service and BLM have established policies to monitor salvage operations to ensure that usable bark buried by logging debris is not overlooked and burned along with other debris. The Forest Service has also instructed its field personnel to ensure that bark from smaller yew branches and stems be utilized.

For its part, Hauser Northwest's current harvest guidelines for its collectors instruct them to collect bark from all limbs 1 inch in diameter and larger. A Hauser Northwest official informed us that a new portable mechanical debarker has been developed that can peel the bark from stems and limbs as small as 1 inch in diameter. Also, collectors have been instructed to return to prior sites to salvage collectable yew bark left on branches and stems of smaller diameter, according to the official. In addition, Forest Service, BLM, and Hauser Northwest officials report that purchasers of sawmill timber are being very cooperative in allowing the bark of the Pacific yew to be collected before other, larger trees are harvested, whenever practical.

But in a January 1992 memorandum to its field personnel, the Forest Service stated that the agency needs to assume more administrative responsibility for the acceptability of Pacific yew bark utilization. Toward this end, both Forest Service and BLM officials have informed us that they are working with Bristol-Myers to include provisions in their Pacific yew program plans for fiscal year 1992 to more fully utilize the tree's bark. This will require, among other things, that the two agencies (1) assign responsibilities for ensuring increased utilization among the respective parties to the cooperative agreements, (2) establish utilization standards to determine whether all feasibly collectable bark has been collected, and (3) monitor compliance with the utilization provisions of the program plans.

FULL UTILIZATION WOULD BE A REQUIREMENT
UNDER H.R. 3836

Ongoing and planned actions by the Forest Service and BLM appear consistent with the full-utilization provisions of H.R. 3836. However, there is neither a legislative mandate nor an administrative requirement to fully utilize the bark of the Pacific yew. Because existing and future demand clearly exceed the current supply of taxol, we believe that the full-utilization provisions of H.R. 3836 should be enacted to provide both a clear legislative requirement to more fully utilize the tree's bark as well as a statutory basis for promulgating implementing regulations.

- - - - -

Messrs. Chairmen, this concludes my prepared statement. I will be happy to respond to any questions you or other members of the Subcommittees may have.