VII. CONCLUSIONS

These studies were conducted for McGhan Medical Corporation by

to determine the potential of Leaf Valve and Overlay Assembly to compromise the immune system. In female B6C3F1 mice implanted with Leaf Valve and Overlay Assembly Test Article for 28 days, no biologically significant effects were observed on standard toxicological parameters, including spleen weights, thymus weights, thymus histopathology and leukocyte number. The statistical increase in the percentage of eosinophils observed only in the low dose animals appears to be the result of a low percentage of eosinophils in the sham control group and not related to an effect of the Test Article.

In general, the Leaf Valve and Overlay Assembly did not affect immune parameters when evaluated with an extensive panel of immune function assays. While an increase in the spleen antibody-forming cell response (specific activity only) and a decrease in natural killer cell activity was observed in animals of the middle dose group, neither the low nor the high dose groups of animals differed significantly from the sham control animals. Furthermore, B cells, T cells, T cells subsets and the mixed leukocyte response (MLR) were not affected at any dose level of Test Article exposure.

The results from this comprehensive immunotoxicological evaluation demonstrate that, under the experimental conditions used, exposure to Leaf Valve and Overlay Assembly does not adversely affect the immune system.

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