ATTACHMENT F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 10 2002

The Honorable Bob Graham
United States Senator
2252 Killearn Center Boulevard, Suite 300
Tallahassee, Florida 32309-3573

Dear Senator Graham:

Thank you for the letter of February 7, 2002, on behalf of your constituent, Mr. Michael J. Pappas, Ph.D., of South Orange, New Jersey, regarding compassionate use for the Beuchel-Pappas Total Ankle Implant.

Generally, the Food and Drug Administration (FDA or the Agency) is prohibited from releasing information about any product before the Agency that is not releasable under the Freedom of Information Act. This prohibition does not apply in the case of a request from a Chairman of a House or Senate Committee which has jurisdiction over FDA matters, or where a product sponsor has authorized in writing the release of the information. In this instance, however, certain information about the trial is releasable because this clinical trial is the subject of a regulatory action initiated by the Agency.

Compassionate use is a provision in the Investigational Device Exemption Policy, which allows persons access to investigational devices without being part of a clinical study. Compassionate use requests are reviewed on a case-by-case basis. Each compassionate use request is evaluated by weighing the anticipated benefits of the investigational device against the potential risks to the subjects, taking into account each patient's medical condition, so that it can be determined if the investigational device is the only available satisfactory alternative to meet the patient's needs. This assessment is performed using the medical information on the specific patient as presented from the referring physician as well as the data presented to FDA by the study sponsor in their study progress reports.

On May 26, 1999, the subject trial was approved for a certain number of patients. At this time, the study is currently closed to enrollment because the sponsor has enrolled all of the subjects necessary for their trial. On August 27, 2001, the sponsor requested "continued access" to the investigational devices while a marketing application was being prepared. This request was denied on September 27, 2001, due to inspection findings identified during FDA's inspection of Endotec's facility during the period of August 20 through September 10, 2001, and inspections conducted at the clinical site of Mark H. Feldman, DPM, on August 20 through September 24, 2001. A summary of the major findings can be found in the enclosed FDA letter dated February 14, 2002, which notifies Endotec, Inc., that the Application

Integrity Policy has been applied to them. Accordingly, FDA was unable to grant "continued access" because the data upon which this decision would be based was determined to be unreliable. More specifically, FDA was unable to determine from Endotec's data whether the device is likely to be effective with no significant safety concerns.

Patients may wish to seek the following options for the treatment of severely arthritic ankles: ankle fusion; a legally marketed, constrained, ankle replacement device (e.g., DePuy Agility Ankle); and other investigational ankle replacement devices. Although we cannot disclose information regarding investigational devices, there is one investigational device that has been publicly acknowledged in the medical literature, the Scandinavian Total Ankle Replacement (S.T.A.R.)[1,2,3].

There may be other experimental therapies for your constituent's condition that are being evaluated. Clinical trials being sponsored by the National Institutes of Health or other Federal agencies can be found by accessing the website: *http://clinical trials.gov.*

Thank you again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

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[1] American Academy of Orthopaedic Surgeons 2001 Annual Meeting; State-of-the-Art in Total Ankle Arthroplasty: "Scandinavian Total Ankle Rationale & Design," M.J. Coughlin.

[2] Mayo Clinic Jacksonville News, "Daytona Beach woman has six artificial joints including new ankle implants," Erik Kaldor, January 24, 2001.

[3] University of Pennsylvania Orthopaedic Journal, "Evolution of Total Ankle Arthroplasty," S. Sodha, S.Y. Wei, E.Okereke, Vol 13, Spring 2000, pgs. 18-21.