ENDOTEC

ATTACHMENT A

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The Honorable Mark Foley
Member, U.S. House of Representatives
County Annex Building
250 North West Country Club Drive
Port St. Lucie, Florida 34986

Dear Congressman Foley:

It has come to my attention that a patient in your constituency has written to you about a case where the FDA has refused to allow the use of the B-P Ankle device to treat her. Also, I understand that after your enquiries to the FDA you were informed that the FDA were refusing approval of Compassionate Use on the grounds that the data gathered from the FDA inspections was determined to be unreliable and that there are other treatments which are more safe and effective.

Although, I do not agree with the FDA's position, it is understandable based on a superficial, bureaucratic evaluation. It is true that the data we presented does not meet the FDA's ever changing criteria and thus is not acceptable to the FDA as clinical trial data. Thus, if that is the only information available and it is not acceptable, then the FDA's position that the trial data was not sufficient for them to make a determination of whether the device is likely to be effective with no significant safety concerns is not unreasonable.

The problem is that in the case of the B-P ankle the FDA ignores the published results of over twenty years of clinical experience with the B-P and similar devices. The results of this clinical experience demonstrate, that the data is at least as reliable as the data used by the FDA to support their contention that other devices are more suitable for this patient and that the B-P ankle is at least as safe as these supposed alternates (see Buechel et al "Eighteen-Year Evaluation of Cementless Meniscal Bearing Total Ankle Replacements" enclosed). It should be noted that the published data supporting the B-P ankle, which Endotec has provided to the FDA, is at least as reliable as the references cited in their letter to you (see the summary of our reclassification petition, which is enclosed).

If these judgments on safety and efficacy were referred to knowledgeable ankle specialists they would conclude that it is at least as safe, if not safer, than legally marked devices. This is in fact what has occurred since several such specialists have requested the Compassionate Use of the B-P ankle. The position of the FDA, therefore, in effect states that they know better than these specialists what is good for their patients. The FDA is in effect practicing medicine an activity it is not qualified to do and an activity that congress attempted to prevent in their legislation giving the FDA jurisdiction over medical devices.

There is a major problem in the FDA that needs your help to resolve. We have asked several other members of congress for this help. About twenty years ago the FDA approved classification criteria for ankles based on device constraint characteristics. The criteria were that semi-constrained devices are class II and thus are eligible for relatively easy 510(k) approval and general sale but that if they are unconstrained they are class III and thus must undergo extremely costly PMA approval. Even if the original determination on which criteria are based is reasonable, which I do not believe it is, the experience of the past twenty years with the devices on which the determination was based has shown that these criteria are dangerously flawed. All of the devices on which these criteria are based have failed and been abandoned. None are available today. It is now well known that in most instances constraint is undesirable. It tends to introduce unnecessary forces, which tend to increase wear and loosening. Further constraint characteristics, by themselves, are not sufficient to identify a safe device. There is more to proper device design than constraint and thus the whole classification concept is flawed.

The current classification system used by the FDA is a major danger to patients with degenerative ankle joints. It allows, and thus promotes, the use of ankle types that are well known to be unsafe thus increasing the likelihood of additional damage to patients receiving such joints. Further, these criteria prevent the use of the mobile bearing device types that are the type most widely used in the rest of the world and have quite good long-term clinical results. Thus the current criterion should be revised to reflect the knowledge of today rather than that of twenty years ago (see the summary of our reclassification petition which is enclosed).

The FDA has told us that they will not consider revising the existing criteria but will only consider a possible additional category covering new devices. Unfortunately our petition makes it clear that the current criterion needs to be scrapped. The FDA seems hostile to this petition. The petition has been waiting review for more than a year. They refused to acknowledge receipt of the petition even after several requests. They failed even to assign a number to the petition. We feel that the application of the Application Integrity Policy (AIP) is primarily an effort to squash this petition. Others feel the same. (See independent publications by "The Gray Sheet" and the "FDA Review" enclosed).

The application of the AIP seems clearly inappropriate in this instance. This policy is intended to apply to cases where there have been dishonest acts. No such acts have been alleged in the FDA audit (9.10.01) or letter (2.14.02) and no such acts have taken place. No subversion of the FDA review processes has occurred or is charged in the aforementioned letter. Since there has been no dishonest or subversive acts, or allegations of such acts the application of the AIP in this case is clearly not justified.

The AIP was applied to Endotec under the "wrongful act" section that may expand its use by stating that such an act can include 'a pattern of errors whether caused by incompetence, negligence, or a practice, such as inadequate standard operating procedures or a system-wide failure to ensure the integrity of data submissions'. Endotec admits that initially the clinical trial was not properly monitored. Yet,

procedures have been implemented for over 6 months to correct the needed items mentioned and the effect of these actions is largely documented. Endotec feels that these actions, along with the other information provided in both our responses (2/22/02 and 3/06/02), should have been considered in FDA's deliberations concerning the application of the AIP to Endotec.

Further the AIP states that 'Under this policy, conducting a validity assessment ordinarily will require further information from the applicant.' We never had the opportunity to provide this information and were not afforded the opportunity to address these problems or to defend our actions with regards to it.

If Endotec had been given the opportunity to defend our case then perhaps this extreme action could have been avoided. Six months have passed since the audit and our response to the FDA Form 483. During this period corrective actions were taken to improve our clinical trial procedures and their implementation. The FDA should have included these facts in their deliberations of whether to apply the AIP. It did not do so. Endotec was denied the opportunity of providing it by not being notified in accordance with the FDA's own stated policy of a pending AIP review.

We suspect that sudden, unexpected, use of the AIP and the failure of the FDA to follow its expressed policy to notify us that it was considering the use of the AIP against us was the result of the need for the FDA to quickly produce a means for explaining their refusals of Compassionate Use. Actually such use was terminated well prior to the application of the AIP to us contrary to the impression given in their letter to you. This termination produced a flood of letters from patients and congressional members asking the FDA to explain their actions. The AIP was applied to us very shortly after a presentation on TV channel 10 in Ohio on the plight of a woman that was denied Compassionate use of our ankle. The presentation was quite critical of the FDA and produced congressional inquiry into the case.

The problem faced by the FDA at that time was that their confidentiality policy prevented their release of information on the clinical trials. Thus their ability to explain their actions was limited. Since the AIP is public information the use of the AIP allowed them to now release this information helping them in their predicament. They probably felt the need to act quickly so as to minimize the damage resulting from their action and thus they skipped an essential step in their application of the AIP thus preventing a hearing of our case. This theory is supported by comparing the letter to you with the one to Ms. Claudianna Wilson enclosed.

Even if the use of the AIP is justified the policy states that only those applications that are affected by the unreliable data are to be suspended. Yet the FDA suspended all applications before the Orthopaedics division including those, which are clearly not affected. Thus although the FDA has come down hard on us for not following proper clinical trial monitoring procedures they have failed to follow their own written procedures in their treatment of us.

I am a resident in your constituency; Endotec Inc. is a Florida manufacturer. There is a dire need for congressional intervention to remove the reclassification petition from the AIP list and into the hands of an independent orthopedic panel. The FDA is, at

present, encouraging the use of ineffective devices while at the same time prohibiting the sale of safer devices that have been proven to be superior after over 20 years of clinical experience.

The present classification system has not produced any safe devices and as a consequence there is an urgent need for viable ankle prostheses to serve the best interests of the public. By assisting us in our quest for fairness regarding an impartial review of the reclassification petition, you will not only be helping Ms Claudianna Wilson, but thousands of people throughout the state and the country.

I would be most appreciative if you could make arrangements for me to meet with you or your staff to discuss this matter.

Yours sincerely

Michael J. Pappas Ph.D. P.E.

Michael J. Pappas Ph.D., P.E.
President

Encl.

C.c. C. Wilson, M. Feldman