

Orthognathic Surgery
TMJ Surgery
Dental Implants
Oral Surgery
Pre Prosthetic Surgery
Facial Trauma
Facial Cosmetic Surgery



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Michael J. Ryan
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rock Hill, Maryland 28050

Dear Mr. Ryan:

It is my understanding that the FDA Advisory Panel for rhBMP-2/HCS for oral and maxillofacial surgery applications is meeting on Thursday, November 9, 2006. As a nationally recognized oral and maxillofacial surgeon with a specialty practice heavily involved in dental implantology in Charlotte, NC, I would like to offer my opinion on the use of rhBMP for maxillofacial applications. In my practice I perform many dental implant reconstructions in both the maxilla and mandible and the demand for implant dentistry has grown dramatically over the last 5-10 years. These patients are compromised by the lack of bone support where it is needed to restore the loss of teeth. I am frequently challenged by difficult maxillary and mandibular reconstruction problems secondary to local bone atrophy following dental extractions, periodontal disease, trauma and congenital deformities.

I have become knowledgeable of bone morphogenic protein from my association with clinical investigations with rhBMP-2, professional presentations, knowledge of the scientific literature, and national and specialty meetings. I also have direct experience with the impressive clinical results in my own patients utilizing this protein.

Presently oral and maxillofacial surgeons have a number of bone graft alternatives. The gold standard is the patient's own bone, an autograft. It is osteogenic, it contains viable bone cells at the time of transplantation, it is osteoinductive, it actively promotes or enhances bone formation, and is osteoconductive, acting as a structural framework or scaffold for new bone formation. Unfortunately, an autograft is in limited supply because we are limited by the patient's own anatomy of their iliac crest, anteriorly or posteriorly, or the tibia. In many cases we have very little or no autograft at all. Additionally, the bone graft harvest surgery contributes significantly to postoperative pain that can be permanent and can lead to other complications.

When an autograft is not available or is inadequate, we may resort to the use of an allograft, banked bone or cadaver bone. Allografts are mainly osteoconductive and have no osteogenic properties. Allograft bone formation rates are lower than autografts and take much longer to heal. Additionally, allografts have the risk of disease transmission. Modern bone processing is affective in eradication of bacteria and viruses, however, prions are very difficult to detect and there is no processing method that has been validated for their removal.

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October 31, 2006

Beyond autografts and allografts, surgeons can use bone graft extenders, xenografts and/or alloplasts. These products are mainly osteoconductive, are poorly osteoinductive if at all, and not osteogenic. They are the last line of bone graft materials and informed maxillofacial surgeons have little confidence in their efficacy in obtaining new bone formation for dental implant applications. Initial success and long-term maintenance of dental implants are dependent upon osseointegration, or adaptation of viable bone to mechanically stabilize titanium dental implant fixtures.

Recombinant human bone morphogenic protein is an ideal substitute for autografted bone for many reasons. The new bone formation in animals model and in human trials is the same or better than the gold standard autograft. With the production facility there is an unlimited supply of rhBMP. Recombinant BMP will eliminate the need for bone graft harvesting which will eliminate the associated pain, potential complications and costs.

The major downside of dental implant surgery is when the dental implant fails. This can occur secondary to a major complication such as an infection but in the compromised patient a major reason for failed surgery is the failure of grafted bone to form new bone to provide dental implant integration. This is a problem that is common to all dental implant surgeons.

A product that markedly enhances our ability to grow bone with few documented side affects is an extremely valuable adjunct in the treatment of the edentulous jaws. Recombinant BMP is a breakthrough product that represents the best of medical research and advanced technology. It has been thoroughly tested in animal models and human trials. It is consistently proven better and safer than our present alternatives. It has also proven itself clinically in the orthopedic application of spinal fusion. It is time to get rhBMP into the maxillofacial region where it is desperately needed for the optimum care of our patients.

I have no vested interest in the rhBMP product clinically nor do I have financial interest in the company that is sponsoring the marketing of rhBMP nor its research. My only interest is the successful dental rehabilitation of my compromised patients. Anything that I can do to insure the safety and efficacy of my surgery will be of benefit to them and to the specialty of oral and maxillofacial surgery as a whole. I hope that you will see fit to approve the use of rhBMP in the maxillofacial region and further, see fit to include other maxillofacial applications for this breakthrough technology.

Sincerely,



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