

Testimony of

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before the

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Chairman Stupak, Ranking Member Shimkus, and Members of the

Subcommittee, good morning. I am Kim Taylor, the President of Ortho Biotech, and I am pleased to be here today to speak with you about direct-to-consumer advertising, and in particular, the broadcast television advertisements of Ortho Biotech's medicine Procrit,^{*} which the company stopped airing three years ago.

Ortho Biotech, a member of the Johnson & Johnson family of companies, is a leading biopharmaceutical company that provides innovative products and services designed to help enhance the lives of individuals with serious chronic illnesses. Ortho Biotech is a leader in the research and treatment of anemia, which is a blood condition identified by a deficiency of hemoglobin sufficient to cause symptoms. Hemoglobin is a component of red blood cells, and its purpose is to transport oxygen from the lungs to all tissues of the body. Symptoms of anemia include weakness and fatigue because the tissues of the body are not getting enough oxygen to function properly.

A class of medicines known as erythropoiesis-stimulating agents (ESAs) can treat anemia because they are biologically similar to the naturally occurring protein erythropoietin,

^{*} Procrit (epoetin alfa) is a registered trademark of Ortho Biotech Products, L.P.

which stimulates red blood cell production. The first ESA approved in the United States was epoetin alfa, the medicine that is marketed by Ortho Biotech under the brand name Procrit.

Ortho Biotech distributes Procrit under an agreement with Amgen, the initial developer of epoetin alfa. Under that agreement, Ortho Biotech distributes the medicine for patients not on dialysis. The FDA granted the first approved indication for the medicine, the treatment of chronic renal failure, in 1989. Since then, the FDA has approved three additional indications: In 1991, it was approved for the treatment of anemia in zidovudine (AZT) therapy in HIV-infected patients. In 1993, the medicine was approved for the treatment of anemia associated with cancer chemotherapy. And in 1996, the FDA approved the medicine for administration before surgery as a means to reduce transfusions.

Because the Subcommittee expressed interest in our history of Procrit television advertisements, which focused on the treatment of anemia associated with cancer chemotherapy, I will focus my testimony on this indication.

When the FDA approved Procrit for the treatment of chemotherapy-induced anemia, it premised the approval on the ability of ESAs to treat anemia by increasing a patient's hemoglobin, reducing the likelihood that a chemotherapy patient would require a transfusion of red blood cells, and reducing the amount of blood that would be needed in the case of transfusion. ESAs are very effective at reducing a chemotherapy patient's need for transfusions. As the FDA stated in its March 2008 briefing for the Oncologic Drugs Advisory Committee review of ESAs, "[a]cross several studies, approximately 50% of anemic patients receiving chemotherapy required transfusions as compared to approximately 20-25% of patients who received ESAs concurrently with chemotherapy."

The development of a product that could reduce chemotherapy-related transfusions was important to patients. Before Procrit and other ESAs became available, anemic chemotherapy patients faced the choice of living with anemia, which could require interrupting chemotherapy treatment, or accepting the discomfort and medical risks associated with transfusions, including HIV, Hepatitis B and C, bacterial infection, and transfusion-related acute lung injury, each of which can be fatal. Avoidable transfusions also burden the blood supply. Because the only source of blood is the voluntary donation by individuals, the blood supply is under constant pressure.

I would like to describe for the Subcommittee my understanding of the process by which Ortho Biotech undertook direct-to-consumer advertisements for Procrit. I should note, at the outset, that I was not employed with Ortho Biotech at the time, so I have no first hand knowledge of these events. I have, however, endeavored over the past several weeks to gather and become familiar with the history of Ortho Biotech's Procrit advertisements.

During the middle 1990s, cancer doctors began to have a greater awareness of a practice that is generally called "supportive care." Supportive care is treatment given to prevent, control, or relieve complications and side effects of an illness or its treatment. Management of chronic cancer pain is perhaps the most well known supportive care measure, and the treatment of chemotherapy-induced anemia is another example. Consistent with an increased focus on supportive care, researchers investigated the use of Procrit to address chemotherapy patients' anemia and decrease the need for transfusions. Studies validated the use of Procrit in this way.

At the same time, many patients with chemotherapy-induced anemia were underdiagnosed for the condition. Some patients were even unaware that anemia could cause fatigue and tiredness. Others were not candid about their fatigue for fear that their doctor could

possibly interrupt their lifesaving chemotherapy treatment. Indeed, cancer patients described fatigue as having a significant impact on their daily lives, yet there was low awareness that chemotherapy related fatigue may be caused by anemia and that there were treatments for chemotherapy-induced anemia. In this environment, Ortho Biotech undertook a comprehensive educational campaign that included programs of outreach to doctors, patient educational campaigns, and direct-to-consumer advertising. Ortho Biotech believed that direct-to-consumer advertising, as one part of a broader comprehensive educational effort, was an effective way to raise awareness about chemotherapy-induced anemia.

I should pause here to note that our parent company, Johnson & Johnson, was a key player in the development of industry guidelines for direct-to-consumer advertising. In addition to adhering to the industry-wide guidelines, Johnson & Johnson adopted its own internal guiding principles that are even more rigorous than the industry guidelines. Although the development of the Procrit advertisements preceded these guidelines, the creative development process for the Procrit advertisements was carefully reviewed by Ortho Biotech's Promotional Review Committee. This group is composed of individuals from the legal, regulatory, medical, clinical, and health care compliance departments of the company. Through consultation and review of the activities of the Procrit marketing group, the Promotional Review Committee ensured that the advertisements complied with FDA regulations and were consistent with the approved indications.

Our development of the Procrit ads began with an assessment of the patient audience that would be viewing the ads, including extensive individual interviews with chemotherapy patients. Our goal was to understand the patients, their needs, and the most effective way to reach those who may be suffering from chemotherapy-induced anemia.

The Procrit broadcast advertisements ran from 1998 until 2005. All of the ads communicated the same general theme: chemotherapy-induced anemia can cause fatigue and weakness, and Procrit may alleviate those symptoms by addressing the chemotherapy-induced anemia. A central message of each and every advertisement was to encourage the patient to talk with his or her doctor about the symptoms of anemia. Only through discussing these symptoms with a doctor could the doctor then make the medical determination of whether that patient would benefit from Procrit.

As the Committee reviews Ortho Biotech's direct to consumer broadcast advertisements for Procrit, I would like to stress four fundamental points. *First*, the statements in the advertisements regarding the benefits of Procrit were true, responsible, and substantiated by scientific studies showing that administration of Procrit led to significant improvements in the symptoms of anemia in chemotherapy patients. *Second*, the advertisements were consistent with the FDA-approved indication for Procrit – in this case, the treatment of chemotherapy-induced anemia. The advertisements, therefore, discussed the symptoms of chemotherapy-induced anemia – such as fatigue and weakness – and very carefully made clear that Procrit treats chemotherapy-induced anemia or increases red blood cells. *Third*, the advertisements began five years after Procrit was approved for treatment of chemotherapy-induced anemia, well beyond the pharmaceutical industry's and Johnson & Johnson's own internal guidelines on direct-to-consumer advertising. *Fourth*, the advertisements were submitted to the FDA as required by regulations, and Ortho Biotech had extensive and ongoing discussions with appropriate FDA officials about the content of the advertisements. As the state of the medical knowledge evolved over time, Ortho Biotech has worked collaboratively with the FDA to ensure that new and relevant information was included in the label and raised as appropriate in the advertisements.

In mid-2005, Ortho Biotech ended its Procrit direct-to-consumer broadcast advertising. Ortho Biotech's decision to conclude the Procrit broadcast advertisements was related in part to the reason that we began the ads in 1998 – the awareness in the doctor and patient community about the symptoms and treatment of chemotherapy-induced anemia. By the early 2000s, Ortho Biotech believed that patients suffering from chemotherapy-induced anemia were aware of Procrit as a treatment option to discuss with their physicians, and that ESAs were established as within the standard of care for chemotherapy-induced anemia. Given this heightened awareness and other business considerations, Ortho Biotech concluded that further investment in Procrit direct-to-consumer advertising was no longer warranted. We have no current plans to resume Procrit direct-to-consumer television advertisements.

Procrit remains an important medicine for its approved indications. Procrit and other ESAs continue to provide significant benefits to patients with chemotherapy-induced anemia, particularly when an ESA is the only available means to reduce the need for blood transfusions. Procrit is safe and effective for the treatment of chemotherapy-induced anemia when it is used in accordance with its FDA-approved prescribing information.

I would be happy to answer any questions that you might have.