STATEMENT OF THE COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS

FDA Public Meeting on PDUFA Reauthorization – Feb. 16, 2007

I. INTRODUCTION

My name is Alan Kirschenbaum. I am a principal in the law firm of Hyman, Phelps & McNamara in Washington, D.C. I am appearing today on behalf of the Council on Radionuclides and Radiopharmaceuticals, or CORAR. CORAR is an association of companies that manufacture and market radiopharmaceuticals used in diagnostic procedures and also for therapeutic purposes.

I would like to focus on a user fee issue that is quite narrow, but critical to a very important type of diagnostic imaging drug: positron emission tomography drugs, or PET drugs. PET drugs raise unique issues under PDUFA. In order to explain why, allow me to provide some background on PET drugs.

II. BACKGROUND ON PET DRUG DISTRIBUTION

PET drugs are produced by tagging (or "labeling") a substrate compound with a positron emitting isotope, which is produced in cyclotrons. These are devices that accelerate protons or deuterons to the high energies needed for a nuclear reaction to occur and for nuclear particles to be released. Once injected, the isotope travels through a patient's bloodstream and is distributed in certain tissues. Using a PET camera that detects the nuclear particles emitted, nuclear physicians produce computerized images of biochemical processes and tissue structures within the body. Physicians use these images to diagnose, stage, and monitor diseases like certain cardiac diseases, epilepsy, dementias, and cancer.

Because the radioactive half-lives of PET drugs extend only up to a few hours, they must be used soon after they are prepared. Therefore, PET drugs are prepared by PET drug facilities (traditionally nuclear pharmacies) only as needed and in close proximity to the medical facilities where they are used. This distinguishes PET drugs from other diagnostic and therapeutic drugs, which typically have long shelf-lives and, therefore, can be manufactured at centralized facilities and distributed over long distances for commercial use.

PET drugs have an unusual regulatory history, which I do not have time to explain in detail here. Suffice it to say that, pursuant to a provision of the FDA Modernization Act of 1997 ("FDAMA"), there is currently a moratorium on FDA's regulation of PET products as "new drugs." Therefore, NDAs are not yet required in order to market these drugs, but they will be required once the moratorium has ended in two to three years.

III. THE ESTABLISHMENT FEE PROBLEM

PET drugs raise user fee problems that are unique among pharmaceuticals and that obviously were not contemplated by Congress when it enacted PDUFA. Due to the short half-lives of PET drugs, a commercial manufacturer that supplies PET drugs nationally, or even regionally, requires multiple, small cyclotron facilities located throughout the U.S. or the region. If such a manufacturer were to submit an NDA, each of these facilities would have to be identified in the NDA as a manufacturing establishment, and the company could be subject to enormous establishment fees annually. For example, one PET drug manufacturer operates 44 cyclotron facilities nationwide. If these were used to manufacturer and supply a particular PET drug under an NDA, this company would have to pay over $13 million annually in establishment fees (based on FY 2007 user fee rates).

This is an obvious and serious problem. Annual company revenues for some PET drugs would not even pay for the $13 million in annual establishment fees in the above example, much less recover the costs of development, production, marketing and provide a profit. The market for PET drugs is miniscule compared to the market for many therapeutic drugs, yet, absent relief, some PET drugs will be burdened with much higher fees than multi-billion dollar drugs like Lipitor. When the moratorium ends, no commercial PET manufacturer will be able to stay in business under these circumstances, and patient access to these innovative, life-saving diagnostics will be severely diminished.

IV. SOLUTION

How can this problem be resolved? CORAR proposed an administrative solution in a Citizen Petition submitted to the FDA on August 31, 2005, to which we are awaiting a response from the Agency. However, we believe that a legislative solution is the surest way to resolve the issue for all PET producers. We are proposing an amendment that would limit establishment fees to one per NDA for commercial PET manufacturers. In addition, many PET drugs are produced by not-for-profit academic medical centers with one cyclotron for use within the same institution. Our proposal is to exempt these facilities from all establishment fees where the PET center is operated by or affiliated with a medical center, has only one cyclotron, and the PET drugs produced are for use within the medical center.

Nine years ago in FDAMA, Congress mandated a special regulatory framework to accommodate the unique characteristics and distribution of PET drugs. Since PET drug NDAs were not required then, the issue of user fees did not need to be addressed in PDUFA III. However, with the end of the moratorium approaching, now is the time to resolve this problem.

On behalf of CORAR, I would like to thank the Agency for the opportunity to bring this issue to your attention and provide input into the reauthorization process. We will be submitting written comments as well.