**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Division of Medical Imaging and Radiopharmaceutical Drug Products (DMIRDP)**

**Public Meeting**
**"Radioactive Drugs for Certain Research Uses"**

**November 16, 2004**

**Advisors and Consultants Conference Room 1066**
**5630 Fishers Lane**
**Rockville, MD 20857**

**The transcript of this public meeting (posted 11/26/04) has been amended to include the following corrections:**

**Page 70 (3rd paragraph):**

The major step came in 1977. The ICRP adopted a new concept called effective dose equivalent. They decided that, hey, let's pick out six sensitive organs. The gonads carry the hereditary defects; they were the most sensitive at that time. The least sensitive in that list of six was 0.03 and in between were breast, thyroid, red marrow and lungs. Then the way of computing a single number--and this has been mentioned--was to take the dose to each organ, the six weighted, multiply by its sensitivity weighting factor, add that together and this would come up with a single number that reflected risk to an occupationally exposed patient at this time.

**Page 72 (last paragraph):**

The ICRP then publishes tables of effective dose of new radiopharmaceuticals and the Society of Nuclear Medicine put its MIRD technique into software. I think largely the work of Michael Stabin, and that was available to anyone. It was called MIRDOSE. That was recently replaced by

OLINDA, which was FDA approved this year. And, put in the hands of the investigators a tool to calculate effective dose for just about anything. There is a database of 850 radionuclides and you can imagine any one of those can be labeled to any pharmaceutical so it really leaves little left to do.