

1 (Recess.)

2 DR. RAMSEY: We're going to go ahead and begin  
3 with our afternoon presentation. So if everyone would  
4 please come in and take a seat, we're turning the podium  
5 over now to Dr. Udo, who will tell us about nitrogen-13  
6 clinical pharmacology, pharmacology, and toxicology.

7 Thank you, Dr. Udo.

8 DR. UDO: Thank you. Good afternoon, ladies  
9 and gentlemen. I am David Udo, a reviewer with the Office  
10 of Clinical Pharmacology and Biopharmaceutics of CDER.

11 The information I'm going to present today is  
12 from reviews of literature articles on pharmacology,  
13 toxicology, and clinical pharmacology of N-13 ammonia. The  
14 pharmacology/toxicology review was done by my colleague,  
15 Dr. Adebayo Lanionu. The clinical pharmacology review was  
16 done by me.

17 These reviews were focused on the use of N-13  
18 ammonia for measurement of myocardial blood flow by the PET  
19 technique in patients with known or suspected coronary  
20 artery disease.

21 In this presentation, we will cover the  
22 following aspects of N-13 ammonia: The concept of blood  
23 flow measurement, pharmacokinetics, and metabolism. An  
24 attempt will be made to relate pharmacokinetics or  
25 metabolism to safety. And then in the end a summary will

1 be provided.

2           Following intravenous administration of N-13  
3 ammonia, the blood takes it to the coronary vasculature.  
4 And for our purpose, I'm going to say that we're going to  
5 find in the myocardium N-13 ammonia in the blood flowing in  
6 the coronary capillaries from where it entered the  
7 extravascular compartment of the myocardium and, finally,  
8 into the intracellular compartment where, in a reaction  
9 mediated by glutamine synthetases, it is transformed into  
10 glutamine and trapped therein. That is, inside the cell.

11           And so we can see that we have three distinct  
12 compartments in the myocardium where you can find N-13  
13 ammonia for kinetic purposes. This can be presented  
14 schematically, as shown. K1 and K2 are intercompartmental  
15 real constants for the blood in the capillary and the  
16 extravascular space of the myocardium. K3 represents the  
17 rate of metabolic conversion of N-13 ammonia to N-13  
18 glutamine.

19           Our focus is K1. K1 is a composite rate  
20 constant which represents blood flow and the single pass  
21 extraction of ammonia from the capillary into the  
22 extravascular space. Since the extraction is very close to  
23 1, then K1, which is a product of E and F, already defined,  
24 approximates F, and therefore provides an estimate of  
25 measurement of blood flow.

1                   Now how do we obtain the value of K? K is  
2                   obtained by solving the three-compartmental equation which  
3                   described the time course of N-13 ammonia in the myocardial  
4                   tissue. And we have said K1 is the blood flow. So, by  
5                   obtaining data and putting in the appropriate  
6                   concentrations, K1 can be determined which approximates  
7                   blood flow.

8                   Now, let us examine the pharmacokinetics  
9                   aspects of N-13 ammonia. In the literature, articles  
10                  revealed that doses that were administered were mostly in  
11                  the range of 10 to 20 millicuries. This was associated  
12                  with a mass dose of 0.05 to 0.1 micromole of N-13 ammonia,  
13                  which translates to 0.80 to 1.60 micrograms.

14                  The physical half-life of N-13 ammonia is  
15                  approximately ten minutes. It's half-life in the blood, as  
16                  determined by accurately taken blood samples, is  
17                  approximately three minutes. It's half-life for myocardium  
18                  and the brain, as determined from imaging data, are no more  
19                  than two minutes and three seconds, respectively.

20                  Now how is N-13 ammonia handled in the body so  
21                  as to show it its way out? That brings us to the subject  
22                  of metabolism. N-13 ammonia is metabolized to N-13 urea,  
23                  which is its major metabolite. Other metabolites of this  
24                  imaging agent include neutral amino acids, and traces of  
25                  acidic amino acids, mainly glutamate and aspartate.

1                   Now, could anything that relates to  
2 pharmacokinetics effect the safety of this imaging agent?  
3 And so we get back into examining what really is the amount  
4 of ammonia that is already in the body produced by various  
5 metabolic processes. The normal range of ammonia in humans  
6 is 12 to 55 micrograms per deciliter, which translates to  
7 720 to 3300 micrograms in a 70 kilogram man. And so, if  
8 you throw in this 0.80 to 1.60 into that amount, it appears  
9 to me that it is like throwing a teaspoon full of salt into  
10 an ocean; it will not change the salinity. So I think that  
11 this amount would not cause any significant increase in the  
12 amount of ammonia in the body and, subsequently, would not  
13 effect a net drug imbalance of the body.

14                   In reference to metabolism and safety, we find  
15 that urea is readily eliminated in urine. And the small  
16 amount that is generated from the small dose of N-13  
17 ammonia then would not be a real problem, in my opinion.  
18 Amino acids are normal components of body tissues. So  
19 based on this, it is reasonable to expect that the  
20 metabolic products of N-13 ammonia would not significantly  
21 affect the safety of this imaging agent.

22                   And so the next thing I had to look at was  
23 radiation absorbed doses to various organs of the body. I  
24 had to go to the information that is published by the ICRP  
25 and then generate a dosimetry table in the units we usually

1 use in regulatory arena; that is, rem per millicurie. And  
2 so this would do is that the clinician can use the  
3 dosimetry table as a calibration curve to determine the  
4 radioactivity dose that would cause acceptable radiation  
5 exposure in different tissues. This is only a small part  
6 of the table. The whole table is in the review that has  
7 been put in the files of the FDA.

8 And to summarize, we can say that due to the  
9 high extraction of ammonia from coronary capillaries into  
10 the myocardial extravascular space, the value of K1  
11 obtained via the three-compartmental equation that  
12 describes this time course in the myocardium can yield a  
13 reasonable estimate of myocardial blood flow. As we see,  
14 ammonia is effectively eliminated from the body.

15 I've already talked about the dosimetry thing,  
16 that it would be a calibration curve which allows the  
17 physician to determine a dose that is appropriate for a  
18 given population. And finally, we can say that the  
19 pharmacology, toxicology, and pharmacokinetics of N-13  
20 ammonia do support its use for myocardial indications.  
21 Thank you.

22 DR. RAMSEY: Thank you very much.

23 I think we will hold questions until after the  
24 second presentation, and the second presentation is  
25 entitled "Safety and Effectiveness in Oncology," by Dr.

1 Florence Houn.

2 DR. HOUN: Good afternoon again. I'm going to  
3 be talking about N-13 ammonia in use of PET for myocardial  
4 perfusion. My teammates include Sonia Castillo, who helped  
5 with the review. She's a Ph.D. from the University of  
6 Washington in Seattle, and a postdoctorate from the Harvard  
7 School of Public Health, and she's been with the FDA for  
8 three and a half years. Also, Ms. Kaye Cho was the project  
9 manager. David Hussong was our microbiologist. Ravi  
10 Kasliwal was the chemist. Dr. Lanionu was the pharm/tox  
11 reviewer. Dr. Udo did the biopharm.

12 My preliminary conclusions are a finding of  
13 effectiveness to assess myocardial perfusion in the  
14 evaluation of coronary artery disease in patients with  
15 known or suspected coronary artery disease through stress  
16 and rest testing. In the literature, single doses of up to  
17 25 millicuries were studied, usually administered as two IV  
18 doses, during rest and then at stress, up to 20 millicuries  
19 each.

20 I'm going to kind of run through these slides  
21 because I've talked about them before in terms of the  
22 general structure of the talk. You've heard about our  
23 guidances and how we've been using them. I'm going to  
24 discuss the intended use of N-13 ammonia, the external  
25 standards of truth for the studies, our search methodology,

1 selection criteria, review of findings, and conclusions.

2 I'm not going to talk very much on this.

3 Again, the guidance for clinical effectiveness was  
4 discussed, when studies in the literature could be used to  
5 support indications.

6 The draft medical imaging guidance also  
7 provided some structure for me in terms of looking at what  
8 should be included in studies in terms of adequate and  
9 well-controlled design.

10 In terms of its intended use, a cursory review  
11 of the N-13 ammonia literature found a couple of different  
12 uses for this drug, including identification of malignancy,  
13 perfusion of various organs, and the assessment of  
14 myocardial perfusion. The bulk of the literature focused  
15 on myocardial perfusion, and that's what I focused on in  
16 terms of trying to find effectiveness.

17 The advantages for this agent in terms of  
18 evaluating myocardial perfusion include that it's minimally  
19 invasive, there are kinetic models available to allow for  
20 quantification, there is the ability to correct for photon  
21 attenuation because of body habitus. Also, it provides a  
22 functional or physiologic claim in terms of looking at  
23 perfusion, and ammonia tissue concentration almost linearly  
24 relates to the flow over zero to 300 CC's per minute per  
25 100 grams of tissue. It's highly extractable, as Dr. Udo

1 was talking about, from the circulation into myocardial  
2 cells, where it's rapidly metabolized.

3 In terms of an external standard of truth for  
4 myocardial perfusion, many studies were done comparing to  
5 coronary angiography. Angiography is typically viewed as a  
6 gold standard for anatomy, for coronary artery disease, and  
7 at times for blood flow. We know it's good in terms of  
8 identifying anatomy. It presents two-dimensional  
9 information, but there are problems with coronary  
10 angiography in that the endpoint in terms of percent  
11 stenosis on an angiogram doesn't take into account many  
12 factors, such as the geometric complexity of the actual  
13 atherosclerotic vessel.

14 There are variations in terms of the extent of  
15 the length of the stenoses, diffuse disease. There's  
16 collateralization, viscosity. Angles of various takeoffs  
17 of vessels affect flow rate, hypertension with or without  
18 hypertrophy, and even heart rate.

19 So in trying to address what can be used as a  
20 standard to look at myocardial perfusion, one solution that  
21 authors had looked at was the use of quantitative  
22 angiography through validated software programs to try to  
23 eliminate observer bias and allow calculation of coronary  
24 perfusion as a function of flow. In some of the papers I'm  
25 going to talk about, the use of stenosis flow reserve is



1 presented, and that's defined as the flow at maximum  
2 vasodilation versus at rest.

3 The search criteria you've heard earlier: the  
4 same time period, from 1990 to 1998; online databases that  
5 were in English and that dealt with human clinical trials  
6 information. We got a lot of assistance from ICP in  
7 finding articles as well. In all, 76 articles were  
8 generated from the above search criteria.

9 In terms of selection criteria, we looked at  
10 N-13 ammonia PET studies that compared to an appropriate  
11 clinical standard of truth. Some of this would be in terms  
12 of anatomy relating it to angiography. In terms of a  
13 functional standard for microperfusion, we looked at  
14 various other comparators, such as wall motion through echo  
15 or through ventriculography, exercise testing. A variety  
16 of other standards were used in terms of trying to assess  
17 microperfusion.

18 We also looked at articles that had a relevant  
19 clinical study question and were not experimental in  
20 design. A well-described clinical population was included,  
21 and there were some types of procedures to reduce bias,  
22 such as masking, randomization. In all, the selection  
23 criteria generated 14 articles. Two of them I'm going to  
24 discuss at greater length. These were the larger studies.  
25 One is a feasibility study that led into the larger

1 published studies, which I'll talk more about.

2 I'm also going to be going through some of the  
3 other controlled published studies. These had various  
4 study hypotheses. Some of them had retrospectively  
5 selected patients. Others used normal volunteers and  
6 assumed that they would have angiographically-defined  
7 negative disease, although these normal volunteers did not  
8 undergo angiography. These were smaller studies. There  
9 were nine other published studies that had a wide variety  
10 of hypotheses but still supported the idea of using N-13  
11 ammonia to define coronary perfusion.

12 Also in my review I included myocardial blood  
13 flow quantification algorithm papers, much as what was  
14 summarized by Dr. Udo earlier.

15 The two studies I'll focus in on are Gould,  
16 published in 1986, which is a feasibility study, and Demer,  
17 published in 1989 as the follow-up larger study to the  
18 Gould study.

19 Other controlled studies are listed here:  
20 Schelbert, Di Carli, Gerwitz, and other supportive studies  
21 are listed in alphabetical order. You see them here and  
22 on the next slide.

23 The quantification algorithms are listed here,  
24 three studies that I really will not be talking about, but  
25 they're included in the review for completeness.

1           In terms of the first study we'll spend some  
2 time on, Gould in 1986 published this from the University  
3 of Texas Medical Center. It was a feasibility study for  
4 diagnosing coronary artery disease with rubidium and  
5 ammonia N-13 using rest and stress testing with IV  
6 dipyridamole and hand-gripping. Now, 23 of the 50 subjects  
7 received ammonia in this study, and these people were  
8 presenting for work-up of chest pain. They were being  
9 evaluated status post-MI. Some of them were pre- and post-  
10 angioplasty patients. Some of them were pre- and post-  
11 plasmapheresis for cholesterol control patients. So a  
12 variety of types of patients were in the study.

13           It was a prospective study, and it compared  
14 angiography results to PET results. The image protocol  
15 involved masking. PET images were re-read three times  
16 using three presentations. There was gray-scale  
17 presentation, a tri-color presentation, and an isocount  
18 color format which ended up to be what the investigators  
19 felt most correlated between PET and angio results. The  
20 isocount color format had defects defined by the color  
21 format and the continuum of changing count densities being  
22 reflected in hue gradations in each of five primary colors  
23 corresponding to steps of about 3 percent maximal counts at  
24 rest and stress images.

25           The dosage of N-13. People got between 10 to

1 20 millicuries two times, at rest and at stress, of either  
2 N-13 ammonia or rubidium. It depended on what was  
3 available from the generator. X-rays were digitized and  
4 allowed for the measurement of stenosis dimensions and  
5 allowed for calculation of coronary flow reserve. That was  
6 scored between zero to 5, zero being no flow and 5 being  
7 normal. They defined having a significant coronary flow  
8 reserve problem as less than 3.0 on the angiography, and  
9 this was defined prospectively. There were 22 patients  
10 that met this definition of having significant coronary  
11 artery disease. There were 9 patients without coronary  
12 artery disease defined as greater than or equal to a score  
13 of 4, and there were 13 patients with mild disease, between  
14 3 and 4.

15           The paper stated in a caption that the percent  
16 isocount reduction on PET was proportional to the percent  
17 decrease of coronary flow reserve. So I'm making the  
18 assumption that this is the equation in terms of relating  
19 coronary flow reserve and PET scores.

20           The sensitivity of this study showed 21 out of  
21 22 patients who were identified as having significant CFR  
22 picked up by PET, and a specificity of 9 out of 9 who were  
23 disease-free were picked up as PET-negative. The  
24 qualitative comparison of N-13 ammonia and rubidium-82 was  
25 just stated in the study to be comparable. There was no

1 separate stratified data on how each of these agents  
2 performed.

3           The Demer study also came out of the same  
4 university as a follow-up to the Gould study. The specific  
5 objective was to look at accuracy of N-13 ammonia in  
6 evaluating coronary artery disease using rest and stress  
7 testing compared to coronary angiography. The sample size  
8 included 111 patients who received ammonia. The remaining  
9 patients received rubidium. There was a total of 193  
10 patients, of which 174 were analyzed. Nineteen patients  
11 were excluded from the analysis, and the reason stated was  
12 the infarct-related stenoses they had had undergone acute  
13 revascularization, and they were excluded because residual  
14 stenosis severity would not be comparable to perfusion  
15 defect on PET.

16           The inclusion criteria were all patients who  
17 were undergoing catheterization, and this included the  
18 population suspected of having the disease, and including  
19 some that were disease-free. There were 143 men, 50 women.  
20 They included people undergoing work-up for chest pain,  
21 abnormal stress test results, thrombolytic therapy. They  
22 were being evaluated for renal transplant. There was also  
23 a cholesterol lowering program involving coronary  
24 angiography and PET testing, and these patients were also  
25 enrolled.

1           The design of the study was comparing stenosis  
2 flow reserve, which resulted from digitized angiograms that  
3 allowed calculation of SFR, and they defined SFR as the  
4 intersection of flow at maximum coronary vasodilatation  
5 relative to rest flow. They compared this score to PET  
6 defect scores.

7           The endpoints were continuous scales. SFR was  
8 measured from zero to 5, and I have here 5 being normal,  
9 but it's actually greater than or equal to 4 being normal,  
10 less than 3 being significant coronary artery disease. The  
11 PET defect scores were also zero to 5, but going in the  
12 reverse direction, 5 being severe perfusion defect, zero  
13 being normal, 1 being possible, 2 being probable, 3 being  
14 mild, and 4 being moderate. So significant coronary artery  
15 disease was defined as a PET score of greater than 2 and an  
16 SFR of less than 3.

17           The image protocol involved masked readers.  
18 They were independent in reading. Each image was re-read  
19 twice. The rest and stress images were read side-by-side  
20 using the isocount format. Scores for PET were averaged.  
21 This study talked about tracking inter-observer variation.  
22 Dispute resolution was described for eight cases. These  
23 cases were re-read, and either there was an agreement in  
24 two cases or they averaged the scores in six cases.

25           The dose and administration section of the

1 study was supplied, and the results were presented as a  
2 Spearman correlation coefficient of 0.77 per patient,  
3 scores with the most severe PET score and SFR score. What  
4 that meant was for each patient, regardless of the location  
5 of the vessel that was being considered, the most severe  
6 score for PET and for SFR was correlated. So these may not  
7 be of the same regions in the testing modalities.

8 Also, per-vessel analysis done by 243 stenosis  
9 defect pairs was correlated, to have a Spearman correlation  
10 coefficient of 0.63. In terms of rubidium and ammonia use,  
11 the study stated the following concerning the two agents:  
12 "Images obtained with rubidium-82 and N-13 ammonia tracers  
13 were qualitatively similar." There was no breakdown in  
14 data of how rubidium performed relative to ammonia, but  
15 there was some information in terms of the total enrolled  
16 patients of 193. There were two false-positives, of which  
17 one was from rubidium, one was from ammonia, and there were  
18 seven false-negatives, of which two were from rubidium and  
19 five were from ammonia.

20 This 193 and the two false-positives and seven  
21 false-negatives was not the actual data set they analyzed,  
22 which, if you recall, was 174, because they excluded 19.  
23 So in trying to use the data that was presented, I know Dr.  
24 Links was hoping FDA would move away from sensitivity and  
25 specificity. Nevertheless, we moved towards it in this

1 study, to trying to use Figure 3 in the study, which I'll  
2 show you in the next slide, which is a graphical  
3 representation that does permit some estimates of N-13  
4 ammonia PET sensitivity and specificity using the data of  
5 the plot versus mean stenosis flow reserve score versus  
6 subjective PET defect severity score.

7 So if you go to the next slide, I think it's  
8 kind of hard to see but it is included in your review. The  
9 upper representation is the per-vessel analysis. If you  
10 total the N's here, it deals with 243 vessels. I'm going  
11 to first talk about the lower representation, which is the  
12 per-patient analysis, which, if you totaled all the N's  
13 here, comes to 174 patients.

14 I'm going to orient you. This is the PET score  
15 severity, zero to 5, zero being no disease or PET-negative,  
16 and a score of 2 or more being significant artery disease  
17 as defined by PET. So a PET-positive score is 2 to 5. So  
18 all these people here are PET-positive. These are the  
19 numbers of the people and their average scores. These are  
20 the error bars associated. There are 106 patients here in  
21 the study that were defined as PET-positive. Over on the  
22 right-hand side, these are the PET-negative people. There  
23 are 68 patients here defined as PET-negative.

24 Now, if you go on this axis, stenosis flow  
25 reserve score, it's the reverse, where zero is severe



1 disease and 5 is considered non-disease. Here a score of 3  
2 or less is considered significant disease based on the  
3 angiography results. So this box of people are considered  
4 disease-positive based on this gold standard of angiography  
5 stenosis flow reserve, and the people below a score of 3 on  
6 SFR are considered normal.

7           So what we have here is the making of a 2x2  
8 table, except that there are some overlaps. The number  
9 here is 4, and there is some overlap in that probably two  
10 out of four of these patients are false-negatives, meaning  
11 that the PET score is less than 2 but their stenosis flow  
12 reserve score is greater than 3. We also have patients  
13 here who are false-positive, where their PET score is  
14 greater than 2, meaning they're PET-positive, but their  
15 angiography results are less than 3, meaning that they're  
16 not diseased according to angiography.

17           So what you have is the makings of the 2x2  
18 table, and if we advance one slide we have the totals based  
19 upon that graphical representation. We have one degree of  
20 freedom, in that if I fill in one box, everything else must  
21 add up. So if I fill in one box, I'm obligated to come out  
22 with the totals on the end. What I've done is I've  
23 estimated that error bar that was a false-negative, two out  
24 of four, putting the 2 here as a false-negative score,  
25 meaning that the PET score was less than 2 but the stenosis

1 flow reserve was less than 3, signifying disease.

2 Based on that 2x2 table, we get a sensitivity  
3 of 98 percent and a specificity of 85 percent. This is the  
4 per-patient analysis.

5 Now, if we go back to the graphical  
6 representation, I've done the same thing also for this per-  
7 vessel analysis, using this corner as the PET-  
8 positive/disease-positive cell for my 2x2 table. This  
9 would be my PET-negative/angiography-negative cell in my  
10 2x2 table, and the offsetting two boxes would be my  
11 discordant cells, meaning PET-positive/angiography-  
12 negative, and here would be PET-negative/angiography-  
13 positive.

14 Using an estimate of the error bar here, saying  
15 that that's about two out of the five total patients, if  
16 you go forward two slides, I've put in two here, and again  
17 with one degree of freedom, all the other cells fill in,  
18 and I can estimate a sensitivity of 99 percent and a  
19 specificity of 74 percent. So if you advance one more  
20 slide, these are the numbers that we got with the  
21 confidence intervals figured in. For patients, 98 percent  
22 sensitivity with a 95 percent confidence interval between  
23 92 to 99.7, a specificity of 85 percent with a confidence  
24 interval between 75 to 92 percent.

25 The strengths of the Demer study were that the

1 inclusion criteria were rather broad and allowed for  
2 diseased patients and non-diseased patients to be entered  
3 in. The images were read by two readers independently.  
4 They were masked to the angiography results. Inter-  
5 observer differences in PET readings were tracked and  
6 analyzed. There was graphical data with enough detail to  
7 look at the sensitivity and specificity. Dispute  
8 resolution was defined. There was detailed information on  
9 readers' performance, on the reader variability, and there  
10 was a relatively large number of patients.

11 In terms of weaknesses, we do not actually have  
12 a stratified study of rubidium versus ammonia results. We  
13 have some indication from the false-negative and false-  
14 positive of the total 193 patients what false-positives and  
15 false-negatives did occur. We know that in terms of sex  
16 and age distribution, age was not presented. There were  
17 certainly more men, 143 compared to 50 women. Nineteen  
18 patients were excluded from the analysis, so this was not  
19 an intent-to-treat analysis.

20 In terms of other controlled studies, these  
21 were more variable in their hypotheses. Their patient  
22 populations were selected retrospectively at times. There  
23 were small numbers in sample size. Normal volunteers were  
24 selected to represent coronary artery disease-free patients  
25 in some of the studies. Schelbert in 1982 from the

1 University of California-L.A. published a study to try to  
2 correlate angiography and N-13 ammonia PET results. It was  
3 a very small study of 32 patients who had coronary artery  
4 disease on angiography, and there were 13 normal volunteers  
5 who underwent PET imaging, rest and stress testing, but who  
6 didn't undergo angiography, and they were assumed to be  
7 normal in terms of disease-free for angiography.

8           Eleven patients with coronary artery disease  
9 did also have stress thallium testing as a small sub-study.  
10 There were two readers reading through consensus. They  
11 were masked to the findings of the angiography. The  
12 agreement of these readers were tracked. We have dosage  
13 and administration, as well as acquisition information from  
14 the study.

15           The results show a sensitivity, based on a  
16 percent stenosis of 50 percent or more, of 97 percent, 31  
17 out of 32 patients, and a specificity of 13 out of 13  
18 patients.

19           The major weakness in this study was that it  
20 was a retrospectively selected study population, and it  
21 really didn't test how the diagnostic test is going to be  
22 used in a clinical population. The same size was very  
23 limited, but nevertheless it was a study that could be  
24 viewed as providing information on proof of concept.

25           Di Carli in 1994 from the University of

1 California at L.A. School of Medicine published an article  
2 on the relationship of collateral flow, wall motion, and  
3 viability as defined by metabolism of F-18 FDG. The sample  
4 size was 42 consecutive patients, with a total of 78  
5 vessels, with coronary artery disease defined by  
6 angiography with LV dysfunction. This was a comparative  
7 study of PET viability patterns and the severity of  
8 perfusion defects between three groups of angiographic  
9 collateral flow grades.

10 The findings were that there seemed to be  
11 separate information provided by angiography from PET and  
12 that they were contributing different types of information  
13 about flow. Fifty-eight percent of patients that had  
14 collaterals on angiography had decreased N-13 flow, and 50  
15 percent with no angiographic collaterals had N-13 flow.  
16 This study was included in the review as providing  
17 information on this aspect of microperfusion that is above  
18 and beyond what angiography can provide, because  
19 angiography will not be imaging vessels less than 100  
20 meters in diameter.

21 The next study was in 1994 by Gerwitz from the  
22 MGH in Boston, and it was to try to determine a minimum  
23 level of myocardial perfusion, and this I think was  
24 referred to earlier in discussions about is there a flow  
25 rate beyond which viable myocardium cannot be sustained.

1 This looked at 26 patients with chronic MI referred for  
2 thallium and PET testing. It compared wall motion in the  
3 PET FDG study with N-13 ammonia perfusion.

4 The results of this study showed that perfusion  
5 correlates with wall motion and that in patients with  
6 chronic myocardial infarction, myocardial viability is  
7 unlikely when a basal regional myocardial blood flow was  
8 less than 0.25 ML's per minute per gram. Again, this  
9 information, although the study was small, provided proof  
10 of concept of how to use N-13 ammonia as opposed to  
11 anatomical definition that's traditionally looked at from  
12 angiography.

13 Other studies that were reviewed -- and I don't  
14 intend to really go into detail because these also were  
15 wide-ranging in their hypotheses. Some of them were  
16 uncontrolled. Some of them had very small sample size. In  
17 some of them, experimental intervention was the goal of the  
18 study, and PET testing and angiography results were part of  
19 looking at how well intervention worked for the patients.  
20 Most of these studies were retrospective in nature.

21 The results of these studies talked about  
22 either how angiography correlates with PET or, in severely  
23 diseased patients, how PET detects microperfusion when  
24 angiography is negative.

25 Beanlands in 1995 from the University of

1 Michigan Medical Center studied myocardial blood flow  
2 reserve and angiography and did a correlation in terms of  
3 lumen diameter and flow rates. There was detailed patient  
4 information in this study.

5 I know I'm going to slaughter many people's  
6 names here. Dr. Czernin in 1995 from the University of  
7 California School of Medicine studied myocardial  
8 perfusion's response to conditioning, exercise  
9 conditioning. There were 13 volunteers, of which four had  
10 coronary artery disease, and there were eight non-  
11 randomized, non-concurrent controls that were normal  
12 volunteers. This study showed an improved flow in cardiac  
13 endpoints with conditioning. What this study allowed us to  
14 do was to look at the pressure heart rate product and  
15 exercise as a reflection of flow and microperfusion as a  
16 functional comparison.

17 Di Carli in 1994 from the University of  
18 California Los Angeles School of Medicine used PET and  
19 angiography to try to predict survival. Ninety-three  
20 consecutive patients with severe left ventricular  
21 dysfunction were studied, but this was not a randomized  
22 assignment in terms of 50 getting medical treatment, 43  
23 getting revascularization. Rather, treatment was based on  
24 the referring physician who was aware of the PET results.  
25 Management decisions in terms of how the referring

1 physicians used PET to change patient management was not  
2 tracked, but the results in terms of survival were tracked.

3 The next study by Gould in 1994 from the  
4 University of Texas Medical School was of 15 patients with  
5 greater than 50 percent stenosis to try to assess perfusion  
6 after a cholesterol reduction program, and they were  
7 randomized to three 90-day programs to decrease  
8 cholesterol. It was a treatment-control sequential trial,  
9 and PET was correlated with better cholesterol results,  
10 better exercise capacity.

11 Gould in 1995 published in JAMA his randomized  
12 clinical trial of 20 patients who received active risk  
13 modification for coronary artery disease, along with 15  
14 patients who received usual care. Quantification of PET  
15 and angiography results were done initially, and then after  
16 five years, and there was a correlation of PET results in  
17 terms of size and severity of defect and angiography  
18 results in terms of percent stenoses, absolute lumen area,  
19 and SFR.

20 Haas in 1997 from the University of Munich,  
21 Germany, published a study to assess PET's correlation with  
22 outcomes of CABG decisions. This again was a retrospective  
23 study. It was non-randomized in terms of treatment. There  
24 were 76 patients, of which 35 were selected to undergo a  
25 CABG based on angiography, and 34 of 41 underwent CABG



1 based on angiography and PET results. This study also  
2 tracked survival.

3 Laubenbacher in 1993 from the University of  
4 Michigan published a study involving 29 patients with  
5 coronary artery disease on angiography and 23 controls to  
6 evaluate automated analysis of 3-D myocardial blood flow  
7 algorithms. ROC curves were generated from this study.  
8 Agreement of software and observers' interpretation also  
9 resulted.

10 Sambucetti in 1995 from Pisa, Italy, studied  
11 myocardial perfusion in collaterals. There were 19  
12 patients with coronary artery disease, 13 normal patients.  
13 PET results were compared to angiography at rest and  
14 stress, and the results of this study again supported that  
15 angiography and PET provide different information when it  
16 comes to collaterals, that collateral-dependent myocardium  
17 maintains a residual blood flow reserve at stress not  
18 appreciated by angiography at rest.

19 Soufer in 1995 from the West Haven VA Medical  
20 Center studied reverse redistribution in thallium studies.  
21 A new or increased defect was defined as reverse  
22 redistribution after thallium stress testing. Basically,  
23 the study results of the 32 patients with coronary artery  
24 disease and reverse redistribution contributed information  
25 on PET wall motion and microperfusion correlations. There

1 were 50 segments with reverse redistribution. Thirty-six  
2 of the 50 -- that's 72 percent -- were PET-positive for a  
3 perfusion mismatch, and after a mean follow-up of 14  
4 months, 50 percent with cardiac events had reverse  
5 redistribution and PET viability -- that's 5 out of 10 --  
6 compared to 9 percent, 2 out of 22, who didn't have a  
7 cardiac event.

8 We've talked about the weaknesses of the  
9 literature. In the ammonia data set, the studies were  
10 certainly a lot smaller than the ones that were reviewed  
11 for FDG oncology, and also in terms of consistency, there  
12 was much more variability than for FDG in myocardial  
13 hibernation that Victor reviewed. The data set was much  
14 smaller, and the hypotheses were much more variable in  
15 terms of supporting myocardial perfusion.

16 Nevertheless, some of the data did suggest  
17 support for the intended use to assess myocardial  
18 perfusion. These findings were consistent with the  
19 perfusion indication not only from an anatomical point of  
20 view but also from a microperfusion point of view for  
21 functionality. The studies were done in diverse  
22 populations. We were able to calculate sensitivity and  
23 specificity based on the larger Demer study, and we did  
24 have information not only on blood flow as defined by  
25 anatomical blood flow but also functional blood flow in

1 terms of microperfusion.

2 The safety information has been discussed by  
3 Dr. Udo. A small amount of ammonia is introduced to the  
4 body, with known metabolism and excretion, a very short  
5 half-life. Dosimetry information was given to you earlier.

6 So in my preliminary conclusions, I would  
7 invite the advisory committee to help us in terms of  
8 discussion of effectiveness to assess myocardial perfusion  
9 in the evaluation of coronary artery disease for patients  
10 with known or suspected CAD. Again, this is not a  
11 screening test. This is done specifically in a diagnostic  
12 population, people with symptoms or people with known CAD.

13 Thank you very much.

14 DR. RAMSEY: Thank you, Dr. Houn.

15 I think we'll go on to the next presentation,  
16 and this is Dr. Jamshid Maddahi from the University of  
17 California in Los Angeles. This is part of the open public  
18 hearing portion of the program.

19 By the way, we will not take up tomorrow's  
20 program today. That will be presented tomorrow. Thinking  
21 ahead while we set up, we probably will not take all day,  
22 probably just the morning. We should be done by noon. I  
23 imagine so, but obviously you can never predict. But that  
24 would be what we're looking at, without holding me to that,  
25 please.

1                   But nonetheless, Dr. Maddahi. Thank you.

2                   DR. MADDAHI: Thank you very much for the  
3 opportunity to be here. I thought that I would show some  
4 case examples of how this test is used at our clinical PET  
5 center at UCLA and how we make patient management decisions  
6 based on this. Also, I thought that, as Dr. Ed Coleman  
7 drew cases from last Wednesday, I'll draw cases from  
8 several years ago because I wanted to show you how these  
9 tests actually help the prognosis of patients as well, in  
10 addition to diagnosis.

11                   The first case that we'll be looking at --  
12 could we please have the slides on? This first case is a  
13 58-year-old physician, a radiologist actually, who was  
14 admitted with severe resting anginal pain, and myocardial  
15 infarction was ruled out in the hospital. On the resting  
16 electrocardiogram, there was some T-wave inversions in ADL.  
17 In order to find out whether this pain is cardiac, the  
18 patient had an exercise test, did very well, went for 10  
19 minutes with a good heart rate response, good blood  
20 pressure response, no chest pain, but there was some  
21 questionable ST segment depression on the treadmill test.

22                   Because of the fact that the patient did have a  
23 recent onset of angina and had some questionable ECG  
24 changes, then the decision was that we needed some more  
25 information, at least non-invasively, as to whether this

1 patient has coronary artery disease.

2 I'm going to show you in two different formats  
3 the slices. These are all the slices that we get, and I'll  
4 reorient them in the short axis. The red is the myocardium  
5 that is perfused from apex to the base of the heart in the  
6 resting condition and stress condition, and vertical long  
7 axis the same way, and axial cut. In order to appreciate  
8 what the abnormalities are, these are the selected cuts in  
9 the vertical long axis at the time of stress and rest,  
10 short axis stress and rest, and axial stress and rest.  
11 That shows normal myocardial perfusion in this patient,  
12 absence of stress-induced ischemia.

13 Based on the data that you already heard from  
14 Dr. Houn that the specificity and sensitivity of the test  
15 is quite good based on several published literature,  
16 although they used different criteria, here you obviously  
17 cannot, based on a negative study, you cannot ever on a  
18 non-invasive test draw the presence of coronary disease  
19 with 100 percent, but the sensitivity of the test is in the  
20 95 percent range, and the specificity is in the same ball  
21 park. Therefore, we were quite confident that the  
22 likelihood of coronary artery disease in this patient is  
23 quite low.

24 Treating this patient was not very easy. For  
25 those of you who have had physician patients, you'll

1 appreciate my comments. So the patient insisted on having  
2 an angiogram also, as a gold standard, just to see what's  
3 going on. And sure enough, my arms were twisted to refer  
4 him for coronary angiography, which actually turned out to  
5 be completely normal, to confirm that the results were  
6 okay.

7 This patient actually has done quite well.  
8 This study was done in 1992, I believe, and he's done quite  
9 well for these past seven years and has not had any  
10 problems.

11 We'll go to the next patient.

12 I'd like to point out before we go to the next  
13 patient that we do actually do quantitation with a polar  
14 map approach. This is the flattened-out myocardium. If  
15 you imagine the myocardium being like a semi-open umbrella,  
16 a cone-shaped structure, we're opening it up, looking at  
17 the entire myocardium, with the apex at the center, and  
18 then the atrium ventricular group in the periphery, and the  
19 different colors indicate different degrees of uptake of  
20 ammonia in this case, which is entirely normal, except for  
21 the apex, which has a normal pattern of apical thinning  
22 that we see in patients.

23 The next patient is a younger gentleman. He is  
24 about 48 years old. He also presented to the emergency  
25 room, also with a similar kind of scenario, with several

1 hours of chest pain, and the myocardial infarction was  
2 ruled out, and a subsequent rest and stress PET study was  
3 done. Here I'm showing it to you in black and white. This  
4 is the way we analyze these images. They're either in the  
5 gray-scale color or in color scale. Here you can see again  
6 that there's a normal perfusion throughout the myocardium,  
7 and everything was normal at rest and during pharmacologic  
8 stress.

9 Here is the representation of the color slices  
10 of the same patient, showing normal myocardial perfusion,  
11 and the polar map display quantitation shows again some  
12 apical thinning and normal perfusion in the myocardium.

13 This patient agreed that he's not going to have  
14 an angiogram. He took the suggestion that this is a low  
15 likelihood of having coronary disease. Even more  
16 importantly, this is a low likelihood of having coronary  
17 events in the future. This patient has been now for five  
18 years after the study and he has not really had any  
19 coronary events or any problems. He is one of 173 patients  
20 that we have followed for a period of about two and a half  
21 to seven years now, with negative studies, and we were  
22 curious to know what the prognostic indication or the  
23 prognostic significance of a negative study is in these  
24 patients, and we found in the 173 patients that there was  
25 no mortality in these patients. The event rates were quite

1 low, about a quarter percent per year, which is a 0.28  
2 percent per year event rate in patients with a negative  
3 test.

4 Now, we know from nuclear cardiology, from  
5 thallium testing, and from the sestamibi testing literature  
6 also, that the event rate in patients having an entirely  
7 normal study is quite low, is in the less than 1 percent  
8 range. This, in fact, appears to be slightly better,  
9 meaning that it is more predictive of lack of events in  
10 these patients.

11 The way we would use this information,  
12 obviously, is that we could, based on the strong negative  
13 predictive value of the test, which is over 99 percent --  
14 when we're talking about a quarter percent event rate per  
15 year, we're talking about a negative predictive value that  
16 exceeds 99, is 99.7 percent negative predictive value.  
17 This becomes a very, very powerful test in patient  
18 management. I think we have avoided coronary angiography  
19 in many patients who have had negative studies, even though  
20 they have presented with symptoms that were suspected of  
21 having coronary artery disease, and they have had good  
22 prognosis.

23 Here is an example of another individual who  
24 has had some pain, and his physician, with repeated  
25 treadmill testing over a period of time, he has only seen a



1 very slight and insignificant ST segment depression on the  
2 treadmill, and he wasn't convinced that this patient's  
3 chest pains are cardiac and has been assuring him that his  
4 pains are not cardiac, until he insisted that he needs  
5 another step beyond treadmill testing to find out what's  
6 going on with him.

7           Here you're looking at the stress perfusion  
8 with pharmacologic stress and the resting ammonia  
9 distribution. The resting study is normal, as you can see,  
10 a complete doughnut-shaped pattern in the short axis and  
11 the horseshoe pattern in the vertical long axis and axial  
12 planes, but there is a significant reduction of perfusion  
13 in the lateral wall that extends to the inferior wall. It  
14 involves approximately 30 percent of the myocardium. This  
15 was interpreted as indicating the presence of a very severe  
16 proximal disease in this patient. The patient subsequently  
17 went to coronary angiography and was found to have 95  
18 percent proximal stenosis, which then subsequently  
19 underwent angioplasty, and that resulted in the resolution  
20 of this patient's chest pain.

21           Now, whether we need to do a prospective study  
22 of whether these defects, if they are left alone, would  
23 cause more events, I think this goes back to another issue  
24 that was brought up earlier today, that although ideally we  
25 want to have prospective randomized studies to evaluate the

1 effectiveness of various prognostic indicators, I believe  
2 that we have learned enough in the field of PET, and  
3 perhaps even with some other agents, that it becomes  
4 increasingly difficult and perhaps unethical to conduct  
5 prospective studies and randomize these type of patients.  
6 If I was a patient who had such a defect, I would not want  
7 to be randomized to no treatment in order to provide data  
8 to support that this kind of an abnormality is associated  
9 with higher incidence of death or myocardial infarction.

10 So I'd like the group to keep in mind that we  
11 have a dilemma as researchers, that we cannot actually  
12 conduct in certain areas randomized studies anymore because  
13 of the fact that the knowledge is out there and it has  
14 become unethical to conduct these types of studies.

15 Here the polar map display also shows very  
16 nicely that a big chunk of the myocardium, one-third of the  
17 myocardium is severely hyperperfused during stress, while  
18 the resting perfusion is normal, indicating that this  
19 patient has not suffered prior infarction, but these are  
20 all areas that become hyperperfused during stress,  
21 indicating coronary disease.

22 I'd like to move on to another challenging  
23 case. This was a patient who presented after acute  
24 myocardial infarction. The first three cases that I  
25 discussed with you were cases who were suspected of having

1 coronary disease but they did not have known coronary  
2 artery disease. But the role of the myocardial perfusion  
3 imaging with PET and ammonia goes beyond this group of  
4 patients and extends into patients with known coronary  
5 artery disease.

6 This is an example of a patient with a prior  
7 known anterior myocardial infarction, and he was  
8 complaining of chest pain about two weeks after an acute  
9 myocardial infarction. He was a patient who presented with  
10 his MI with sudden death. So he was resuscitated at that  
11 time. He is now complaining two weeks after resuscitation  
12 and after acute myocardial infarction with chest pain. The  
13 question was whether something should be done about this  
14 patient.

15 The patient went to coronary angiography first,  
16 and what was seen was a single 80 percent lesion in the  
17 left anterior descending coronary artery. This is when I  
18 think most cardiologists, especially the catheterizing  
19 cardiologists -- I may say these things because I'm a  
20 cardiologist myself, so I'm sure they will not be taken  
21 wrong by anybody -- they may go by this reflex that we call  
22 the occluding dilating reflex, that they see stenosis and  
23 they want to dilate the stenosis. They think that this  
24 will cure the problem.

25 Now, in this case they asked my opinion of what

1 should be done, and as a consultant I decided that we need  
2 some functional information in this patient to know whether  
3 that 80 percent stenosis is supplying viable tissue, that  
4 by opening that stenosis up, we're going to help this  
5 patient. There's 80 percent stenosis. Is this supplying  
6 dead tissue or viable tissue?

7 Here, looking at the resting, first we looked  
8 at the viability pattern with FDG and ammonia. The resting  
9 ammonia shows a big hole in the distribution of the left  
10 anterior descending coronary artery. We no longer see the  
11 doughnut-shaped pattern, and the apex and the anterior wall  
12 is missing, and you can see a match to defect. That was  
13 the pattern that was discussed earlier today with FDG.  
14 There's a match to defect in exactly the same area, with  
15 almost absence of perfusion and absence of FDG uptake.

16 This indicated to me that there's really no  
17 viable tissue within this area that would benefit from  
18 opening up that artery.

19 Another question that may come up in this  
20 situation is that these are all resting images. Do we know  
21 whether we're going to make other portions of the left  
22 anterior descending coronary artery ischemic during stress?  
23 So we proceeded to do also the protocol of stress/rest  
24 study. The resting study is the same one that you saw  
25 before, and then we did pharmacologic stress, and we see

1 absolutely no change in the pattern of perfusion. These  
2 were quantified, and the size of the perfusion abnormality  
3 was identical to the resting size of the perfusion defect.

4 The conclusion here was that not only is there  
5 no viable tissue within the infarct zone, but there's no  
6 stress-induced ischemia in this patient, so the patient  
7 really would not benefit from angioplasty, and I resisted  
8 that. Now it is about four years after this test and the  
9 patient is doing quite well. There is no problem with that  
10 stenosis.

11 Now, where did the chest pain come from? It  
12 turns out that after a while we did some x-rays of the  
13 chest, and we found out that during the initial  
14 resuscitation, the patient had a fractured part of the  
15 junction, and it was the reason for the patient's chest  
16 pain, not myocardial ischemia.

17 I'm going to show you two more cases. The two  
18 more cases are again patients with known coronary artery  
19 disease, and the orientation, now that you are quite  
20 familiar with what these look like, I'm going to show you a  
21 whole row of data. Here the resting study is on the top  
22 and the stress study is on the bottom. We're looking at a  
23 patient here -- perhaps this is the clearest view, the  
24 vertical long axis, that shows an area of severe decrease  
25 of activity in the anterior wall and apex, which is normal

1 at rest. Here you can see the same thing, that the apex  
2 that is missing during stress is normal at rest.

3 This is a patient who has had angioplasty of  
4 the left anterior descending coronary artery, and because  
5 it was a high-risk angioplasty, meaning that the lesion was  
6 quite complex and statistically there was a high chance of  
7 recurrence, the physician who did the angioplasty was quite  
8 concerned that this patient would have a high likelihood of  
9 re-stenosis. But the patient was asymptomatic, so the  
10 dilemma was whether there's anything we can do to evaluate  
11 this patient non-invasively rather than doing another  
12 angiogram, and we proceeded to do a PET study.

13 As you can see clearly, there is evidence of  
14 significant stress-induced ischemia in the left anterior  
15 descending coronary artery territory. Here are the polar  
16 maps at rest, resting perfusion, and stress perfusion,  
17 which is significantly worse than the resting perfusion in  
18 the left anterior descending coronary territory.

19 We also see that even resting perfusion is not  
20 entirely normal, indicating that perhaps during the first  
21 angioplasty the patient had suffered a non-transmural  
22 myocardial infarction, perhaps as a result of dislodgement  
23 of the plaque distally. There is a small apical  
24 myocardial infarction in this patient as well.

25 This led to a repeat angiogram in this patient

1 that confirmed that there has been significant re-stenosis  
2 in this patient.

3 Another case is a patient who has had bypass  
4 surgery already and comes about four years after bypass  
5 surgery with a chest pain episode that again statistically  
6 puts the patient in the category that, knowing from the  
7 literature that vein grafts may close, about 50 percent  
8 chance of closure about five years out after bypass  
9 surgery. This patient is in an intermediate likelihood of  
10 having one of the vein grafts having a problem and is  
11 presenting with chest pain.

12 Doing a nuclear evaluation with PET ammonia,  
13 resting images are shown on the top, and stress images are  
14 shown on the bottom. At first glance things look to be  
15 okay, except for a very, very small area here in the  
16 posterior lateral wall that is a non-reversible defect.  
17 I'll show it on the polar maps. There's a very, very small  
18 area of lack of perfusion at rest that remains unchanged  
19 during stress.

20 This patient had a known occlusion or  
21 infarction in the distribution of a branch of the  
22 circumflex coronary artery, which is the second obtuse  
23 marginal branch, and that correlates perfectly well with  
24 that old known small myocardial infarction that did not  
25 even show on the resting electrocardiogram. But it was

1 known that the patient had a second marginal branch  
2 occlusion. But beyond that, we don't see any evidence of  
3 stress-induced ischemia in this patient, and this was a  
4 reassurance that this patient was in a low-risk category  
5 for development of events.

6           There is, again, nuclear data, not necessarily  
7 with ammonia, but rest and stress perfusion has been  
8 excessively used in the single photon arena. I've shown  
9 this concept that the negative test after revascularization  
10 is indicative of good prognosis in these people, and  
11 currently data with PET is accumulating in order to  
12 establish the prognostic significance of these findings,  
13 similar to what we know from the single photon data in the  
14 PET data in patients following acute myocardial infarction  
15 or in patients who have had bypass surgery.

16           Thank you very much for your attention.

17           DR. RAMSEY: Thank you very much.

18           I want to thank all the presenters this  
19 afternoon.

20           Now we are in open discussion and the question  
21 and answer period. Specifically, I'd like to ask if the  
22 FDA individuals have any specific questions or any specific  
23 things you want addressed.

24           DR. HOUN: I'd like to hear the committee's  
25 comments on their evaluation of effectiveness. I mean, I



1 think the studies that I've presented are certainly smaller  
2 in sample size, very diverse in their hypotheses, but as a  
3 whole I'm just interested in hearing the positives and  
4 negatives about the group of studies reviewed and how  
5 people are feeling in terms of effectiveness for perfusion  
6 with N-13 ammonia based on the data.

7 DR. CHOYKE: Can I just begin with a technical  
8 question, because I'm perplexed by it. Perhaps you can  
9 address it.

10 You have an agent with a 10-minute half-life,  
11 and I'm trying to figure out how you can do rest and stress  
12 and do all these things while the decay is happening. How  
13 technically demanding is this study, and is it really  
14 reserved for a sophisticated center, or could an average  
15 center do it?

16 DR. RAMSEY: I have a corollary to that, too.  
17 That is, I also don't do cardiac imaging, so coming from  
18 lack of knowledge here, how often is it done? Who does it?  
19 Where is it done? How many cases per year or per week or  
20 whatever?

21 DR. MADDAHI: I think these are all very  
22 important questions. It is a technically demanding type of  
23 study. It requires certain things. One is that the  
24 cyclotron that produces ammonia has to be on site. Unlike  
25 FDG, that has a future and is currently being used as

1 having regional cyclotrons that can ship FDG to remote  
2 sites within a two-hour distance from the sites, with N-13  
3 ammonia, we cannot do it that way. The cyclotron has to be  
4 on site. Because of that, it creates a technical  
5 difficulty there.

6 The second thing is that timing is very  
7 important. We have pneumatic tubes that connect the  
8 cyclotron directly to where the patients are being imaged.  
9 We're in contact with them to know when the ammonia is  
10 introduced, and then we will just have the patient ready to  
11 inject. So it is technically demanding as well.

12 At the present time, there are not many studies  
13 being done because of these technical difficulties. But  
14 whether there will be more of them done in the future, I  
15 would guess that the use of -- this is not going to be the  
16 type of procedure that would be done 5 or 10 a day or  
17 anything like that. I think that this is going to be  
18 perhaps much more limited than that, and the reason is not  
19 that the disease is not common. We all know that coronary  
20 artery disease is very common, and centers that do non-  
21 invasive evaluation of coronary disease with other  
22 techniques such as single photon imaging, they often do 10  
23 patients a day, 15 patients a day.

24 But here I think that we're not going to be  
25 getting to that. I think that for centers that have access

1 to both ammonia and to other agents, the first choice would  
2 remain those that are more practical, and then ammonia  
3 would be perhaps reserved for a very specific type of  
4 patient population, perhaps those where attenuation  
5 correction is very important. We know that one of the  
6 sources of artifact with imaging is breast attenuation in  
7 women and diaphragmatic attenuation in both women and men.

8 Attenuation means that the activity that is  
9 coming from the heart going through the tissue would  
10 register on the camera as being an area that has decreased  
11 activity, and the more tissue it goes through, the less  
12 activity would show. So it becomes confusing at times to  
13 interpret. So I think that perhaps is one of the fortes of  
14 this technique. But I think that the use of it is not  
15 going to be very widespread because of these technical  
16 limitations.

17 DR. CONTI: Can I interject?

18 DR. RAMSEY: Yes, please.

19 DR. CONTI: This is Peter Conti from USC. I'd  
20 also like to just mention that, of course, we do rubidium  
21 in the field, which has a shorter half-life, and also is  
22 technically challenging. So this is not necessarily  
23 something that's novel to the PET community. I would also  
24 add that the technologies that we currently use for  
25 stress/rest are not necessarily that technologically

1 undemanding either. It requires a fair number of visits to  
2 the scanning suite, the studies are more protracted, and  
3 when the systems are down, they can actually be quite  
4 simple with 13 ammonia, as long as there's a reliable  
5 delivery system in-house.

6 DR. RAMSEY: Any other questions or comments?  
7 Jonathan?

8 DR. LINKS: Just one point of clarification.  
9 When you do a stress and a rest, it's two administrations.  
10 So you're not trying to fit two different imaging protocols  
11 into a 10-minute half-life.

12 DR. CHOYKE: Could we maybe change the subject  
13 a little bit back to your question? I'll pose it back to  
14 you a little bit, because I was confused about what is the  
15 ideal gold standard in these tests. I mean, you've  
16 reviewed all the literature, and I was confused. I mean,  
17 if you had to design the ideal study, what would it be, and  
18 how far away are we from those ideals?

19 DR. HOUN: I think that for N-13 ammonia, it's  
20 been studied in the literature according to a variety of  
21 standards because the indications that these investigators  
22 were studying were of a wide variety. Some of these  
23 investigators were focused in on correlating N-13's use in  
24 terms of revealing anatomic information. In that case,  
25 coronary angiography was used. In other cases,

1 investigators were trying to look at N-13's ability to  
2 detect microperfusion where people would be  
3 angiographically negative, and they compared microperfusion  
4 as detected by N-13 ammonia to other kinds of functional  
5 standards, such as exercise endurance. They looked at wall  
6 motion by echo or ventriculography.

7 So I guess there are a variety of standards  
8 used because the hypotheses about what this agent is trying  
9 to indicate, what it's trying to be used for are varied.

10 In my review, I wanted to try to encompass both  
11 types of indications, an anatomical indication, which is  
12 certainly supported by the Demer paper, as well as a  
13 functional indication that's supported by the various  
14 studies that used wall motion, exercise endurance, and  
15 those other kinds of standards.

16 Now, perhaps I'm stretching too much. If  
17 people are more comfortable with an anatomical description,  
18 I'd like to hear that. If people feel that the stretch is  
19 okay, I'd like to hear that too. But that is the struggle,  
20 you're right. I do think this agent is able to do more  
21 than just anatomical information, and I'm just wondering  
22 whether the studies support the microperfusion and  
23 functional indications.

24 DR. KONSTAM: Maybe I can comment. First of  
25 all, I think that this, with the caveats that we discussed

1 this morning about not having an NDA before us, I think  
2 that this application is extremely strong. I actually  
3 favor the wording that you've used very much.

4 I think that in terms of an ultimate gold  
5 standard of what you would want, I guess what we're seeking  
6 is something resembling clinically relevant abnormalities  
7 of myocardial perfusion. I guess that's sort of what we're  
8 trying to capture. There is no gold standard of that, as  
9 far as I know. Actually, I think if you look through the  
10 literature, there are many places where the combination of  
11 N-13 ammonia and FDG has been used as the gold standard for  
12 that. So what gold standard do we have outside of that? I  
13 think we don't really have one. So what do we know?

14 I mean, we know that this agent follows  
15 myocardial perfusion based on other markers of myocardial  
16 perfusion in experimental models and in patients. So I  
17 don't think that there would wind up being any doubt about  
18 that. The next thing you get to, and that's really the  
19 analysis that you focused on in your review, is how does it  
20 relate to abnormalities in the epicardial coronary  
21 circulation, and the answer is pretty well. So even if you  
22 sort of set that up as what you're after to identify  
23 anatomic large-vessel coronary artery disease, I think it  
24 does pretty well at that, and that's useful because there's  
25 a lot we know about the clinical importance of epicardial

1 coronary disease.

2           So if that was all it did, I think that would  
3 be okay, and I think getting beyond that, again in the  
4 absence of any external gold standard for clinically  
5 relevant myocardial perfusion abnormalities, which is not  
6 provided by the coronary angiogram really, I think the next  
7 thing you get into is outcome studies. For whatever  
8 reason, there has not been -- and Dr. Maddahi touched on  
9 this -- there has not been randomized data to really look  
10 at outcome information in the best possible way, but  
11 there's been a wealth of cohort analyses looking at  
12 clinical outcomes of patients who have undergone  
13 revascularization versus those who have not, and looking at  
14 it in cohort analysis, this agent, often together with FDG,  
15 tends to mark those patients who are better served by  
16 bypass surgery than not, within the caveats of the cohort  
17 analyses.

18           So, I don't know. I think without a sponsor  
19 doing a large amount of other work in this area, I think  
20 it's a pretty strong indication.

21           DR. RAMSEY: Dr. Herscovitch?

22           DR. HERSCOVITCH: I would agree, and although I  
23 don't vote, I'm not voting, I would not vote yes on this  
24 application with this wording. I understand your  
25 reservations about the literature review and the fact that

1 perhaps some of these papers weren't as extensive in terms  
2 of the patient population as the earlier ones, but I still  
3 think there's a tremendous amount of supporting data that  
4 you presented.

5           But there's another whole body of data that I  
6 might suggest be considered in this type of application,  
7 and that is the use of animal data or clinical research  
8 studies to show that in this case, it's an effective agent  
9 for myocardial perfusion, and this speaks to the more  
10 general issue of how the FDA in the future will study  
11 radiopharmaceuticals, not just PET radiopharmaceuticals, in  
12 which the indication has at least a partial functional  
13 basis, and that is for virtually all PET  
14 radiopharmaceuticals, there usually is a rather large and  
15 often very well done literature with basic studies in which  
16 the measurement being made has been validated against  
17 another gold standard, and also various physiologic  
18 manipulations have been made to show that whatever it is  
19 you're measuring with the agent varies appropriately.

20           I would suggest, or urge almost, the FDA to  
21 include in their evidence for proposals such as this not  
22 only the clinical studies but also the basic physiology  
23 studies. In this case, there is a large literature going  
24 back 15 or 20 years on the suitability and the limitations  
25 of N-13 ammonia as a myocardial perfusion agent.



1                   There is perhaps another caveat. If you had  
2 trouble selecting appropriate papers to include in your  
3 review as a surrogate for NDA-type protocols, selecting  
4 appropriate research papers might be even more difficult  
5 but not at all insurmountable. So again, I would just urge  
6 you to look at animal studies which have been done with  
7 most PET agents to validate the physiological function of  
8 these tracers. In fact, on page 13 of the guidance -- it  
9 says "Draft," so I don't know if I'm allowed to quote from  
10 it, but really there's a very nice paragraph, the second  
11 paragraph, which shows how animal data might and even  
12 should be used in applications such as these.

13                   DR. HOUN: The animal data and preclinical data  
14 reviews are included in the pharm/tox and biopharm reviews.  
15 So that has been considered.

16                   In terms of putting them as part of the  
17 clinical effectiveness review, usually the human studies  
18 are looked at at that point. But certainly the animal data  
19 is considered in terms of the overall package for the drug.

20                   DR. HERSCOVITCH: Peter Herscovitch again. I  
21 might add, though, that there is considerably more data  
22 supporting the use of ammonia as a myocardial perfusion  
23 agent than was addressed in this package, and I guess we'll  
24 discuss this tomorrow, but the O-15 water package had  
25 really minimal, if any, animal data supporting the use of

1 O-15 water as a cerebral perfusion agent. Again, if part  
2 of the indication is based on the function of the  
3 radiopharmaceutical, I would suggest that those data be  
4 included, not to the exclusion, of course, of the clinical  
5 data, but to buttress or lend further support to the  
6 clinical evidence.

7 DR. KONSTAM: I don't know if I take a little  
8 bit of issue with what you're saying. I mean, I think  
9 that, to me, a clinical application has to be supported by  
10 the clinical data, period, except that I think that the  
11 mechanism by which an agent works or a drug works can be  
12 very important in going beyond the clinical data and  
13 saying, well, where else might it work, are there concerns  
14 we might have about what's the population? I think it's  
15 very helpful. But, to me, I think that a clinical  
16 application really stands on the clinical data.

17 I mean, I agree with everything you say, but it  
18 doesn't surprise me that we wouldn't spend a lot of time on  
19 it.

20 DR. HERSCOVITCH: Just two things. First of  
21 all, I'll quote Lou Sokoloff, who is the developer of the  
22 deoxyglucose method, which went on to FDG. Taking a purely  
23 clinical approach -- and I hope nobody will be offended by  
24 this word, but it wasn't my invention -- one could, in  
25 fact, using radioactive shoe polish, and showing it has a

1 certain sensitivity and specificity, but without a firmly  
2 based understanding of how the tracer behaves, you're only  
3 doing a correlational work and specificity and sensitivity.  
4 Understanding how the tracer behaves not only supports an  
5 indication which says here, "Imaging of myocardial  
6 perfusion," but it also helps you understand those  
7 conditions or diseases where the tracer may or may not be  
8 valuable.

9           For example, with FDG, it's been shown not to  
10 be particularly valuable looking at brain metabolism in  
11 ischemia, for a lot of theoretical reasons which have been  
12 experimentally justified. So knowing how the tracer  
13 behaves I think will not only buttress the clinical  
14 indications but also help support certain caveats as to how  
15 the tracer may or may not be used in certain diseases or  
16 when you have physiological or pathological variance, such  
17 as diabetes. The whole concept of why one should even look  
18 at diabetes and blood sugar came from an understanding of  
19 how deoxyglucose and fluorodeoxyglucose behaves, issues  
20 which one wouldn't be concerned about if one were only  
21 looking at radioactive shoe polish.

22           DR. LINKS: To follow up on this a little bit,  
23 I think we have to be careful about the phrase "clinical  
24 indication," because basically what we have here is a set  
25 of four categories of clinical indications, and assessment

1 of myocardial perfusion falls under one of those categories  
2 as intrinsically, now, a "clinical indication." It seems  
3 to me that if that's going to be the case, then the  
4 challenge is to expand our thinking on what it means to  
5 validate it. For me, if I want to know if this agent  
6 measures perfusion, I'll do microspheres. I'm going to  
7 have a hard time doing that study in humans, but that to me  
8 would be an obvious study to do. Of course, it's been  
9 done, and it does track with microspheres.

10 So I think if we're going to expand what we  
11 mean by a clinical indication, we have to correspondingly  
12 expand our willingness to accept all sorts of very  
13 different types of data than we have in the past when  
14 clinical indication was more narrowly defined.

15 DR. KONSTAM: I guess I'd respond to that by  
16 saying -- and I sympathize, and I agree with almost  
17 everything you said. So I sympathize with the concept.  
18 But I guess I'd respond to what you said by saying that if  
19 I did a microsphere study in rats with the agent and found  
20 that it was a good marker of myocardial perfusion, that  
21 would not be sufficient for me to support a clinical  
22 indication. When I say clinical indication, I'm talking  
23 about an indication in patients. That's what I mean.

24 Now, I understand the nuance of saying that an  
25 indication can be, in the case of tracers, let's say,

1 physiologically based, if we can identify something that  
2 would fit into that category. But nevertheless, I'd like  
3 to at least know that in patients.

4 DR. RAMSEY: I'd just like to ask for  
5 clarification since I think we're getting to where we have  
6 to vote on Question 3. Dr. Herscovitch, you said you would  
7 vote against it. I think I heard you say why, but could  
8 you say why you would vote against it again?

9 DR. HERSCOVITCH: Perhaps I was being too smart  
10 by half. I was saying that I'm not allowed to vote, but my  
11 non-vote would be yes, and I strongly support this  
12 application as it is worded.

13 DR. RAMSEY: I totally misunderstood you. Boy,  
14 am I glad I asked that question.

15 DR. HERSCOVITCH: I apologize.

16 DR. RAMSEY: Any others? Mr. Hammes.

17 MR. HAMMES: If you were to draw up a lecture  
18 and describe the ideal human radiopharmaceutical to do  
19 perfusion imaging, you would probably describe ammonia.  
20 You have an endogenous substance, you have a very favorable  
21 energy in the particle, you have a high specific activity,  
22 and you have a short half-life so you can do repeat  
23 studies. The only limitation is that you need the  
24 cyclotron there.

25 I mean, we are looking at what we will consider

1 the gold standard in the future, I think. The only real  
2 limitations are with the instrumentation and what you can  
3 image. So in terms of the drug, I think this is the  
4 biggest no-brainer in terms of approval you're ever going  
5 to run into. What its use will be I think is going to be  
6 determined by the requirement that you have the cyclotron  
7 right there. But I think we're looking at the gold  
8 standard.

9 DR. HERSCOVITCH: I just have a question of  
10 clarification. The first presenter gave a table of  
11 dosimetry which also included pediatric patients, and that  
12 just led me to think will there be any guidance or  
13 discussion of the use of this agent or the other agents in  
14 the pediatric population.

15 DR. HOUN: None of the studies reviewed had  
16 pediatric population in them. So the indication would be  
17 supported by the literature for adults. I guess in terms  
18 of the pediatric section of the label, we would indicate  
19 that no information is available from the literature review  
20 that we did.

21 DR. RAMSEY: Dr. Conti?

22 DR. CONTI: Let me just address this issue of  
23 dose. This actually is available, this material, in N-13,  
24 FDG, and water. So I think we can get that for the label.

25 DR. RAMSEY: I'm not sure I heard the answer

1 there. It's available for adults or children?

2 DR. CONTI: For children.

3 DR. RAMSEY: Or both?

4 DR. CONTI: For children and adults. There's a  
5 scale, basically, that's available for reducing the  
6 injected dose based on radioactive exposures for children  
7 for all those isotopes.

8 DR. RAMSEY: But that's extrapolated data, or  
9 it's been done in children?

10 DR. CONTI: We do it every day in the clinic.  
11 I mean, it's done. It's based on doses, radioactive doses.  
12 So this material is available.

13 DR. RAMSEY: Thank you.

14 DR. MALCOLM: But I think the question is, I  
15 think the review had no children in the studies. That's  
16 what we're asking. There are no children.

17 DR. CONTI: That actually doesn't matter. It's  
18 the radioactive material that's given and how much exposure  
19 the child gets versus the size of the child. It's not a  
20 dose of ammonia per se. It's a dose of the radioactive  
21 material.

22 DR. MALCOLM: I understand extrapolation. I  
23 don't have a problem with that. But what I'm saying is, I  
24 think what the FDA is saying is that the studies that they  
25 reviewed and what we're approving, from the information, is

1 in adult patients. It's not in children. So I think the  
2 question is, are we going to use this material in children?  
3 I think that's the question.

4 DR. HOUN: I think the question for approval  
5 does not include children, and certainly if there is more  
6 information, it can be submitted as a supplement to get  
7 pediatric labeling. But at this point in time, the  
8 literature doesn't comment on its effectiveness in  
9 children.

10 DR. CONTI: Well, let me be the child's  
11 advocate in this case. There's no reason for it not to be  
12 applicable in a child with ischemic heart disease. What is  
13 the difference between a child with ischemic heart disease,  
14 Kawasaki's disease, which we study all the time, with  
15 conventional nuclear isotopes, which give a higher  
16 radiation dose, and with N-13 ammonia?

17 DR. RAMSEY: I'll jump in here on that. As a  
18 neuroradiologist, the myelographic concentrations were  
19 utilized for a long time and approved only for adults. We  
20 used it in children all the time, but it was not approved.  
21 I think that's the same thing we're looking at here.

22 Correct me if I'm wrong from the FDA side.

23 DR. HOUN: There's a labeled indication, and  
24 how physicians want to use the drug in their practice is up  
25 to them.



1 DR. CONTI: This would apply, then, to all the  
2 radiotracers we're discussing today as well. But I will  
3 tell you again that radiation information is available.

4 DR. RAMSEY: Thank you.

5 Yes?

6 DR. MADDAHI: I just want to make sure that I  
7 haven't misled the committee here about the complexity that  
8 I spoke about. I think the issue of complexity that I  
9 referred to was the issue of the need for an on-site  
10 cyclotron. But I just want to tell you that in our  
11 experience of thousands of these perfusion studies that we  
12 have done of rest and stress, even in the pediatric  
13 population, I don't recall any study that we couldn't read  
14 because it was technically unreadable or it was not good  
15 quality. These are excellent images, excellent studies,  
16 although it requires, obviously, technical ability of the  
17 people who work with this technique, like anything else.

18 The complexity I was talking about is the  
19 instrumentation complexity, not the agent itself, and not  
20 the quality of the images that we get.

21 DR. RAMSEY: Thank you.

22 Any other questions or comments?

23 (No response.)

24 DR. RAMSEY: Okay. I think we'll move to the  
25 question, then. This is Question 3.

1 "Based upon the presented literature reviewed,  
2 do you think ammonia N-13 injection is safe and effective  
3 in positron emission tomography (PET) imaging of the  
4 myocardium under rest or physiological stress conditions to  
5 evaluate myocardial perfusion in patients with suspected or  
6 existing coronary artery disease (CAD)?"

7 I think we'll again follow the vote, your vote  
8 and your comments.

9 Dr. Herscovitch.

10 DR. HERSCOVITCH: Yes, and I think I've made  
11 all the comments that I have to make. Thank you.

12 DR. TATUM: I would also say yes, mainly  
13 because I do think the data does show it's safe, and it's  
14 quite effective. But in addition, there's been a lot of  
15 discussion of gold standard, and it's probably the most  
16 likely candidate for now for giving us something that's  
17 quantitative, which is a badly needed tool in the approved  
18 arena for other reasons. So I would definitely support it.

19 DR. KONSTAM: Yes.

20 MS. BEAMAN: Yes.

21 MR. HAMMES: Yes.

22 DR. HERTZBERG: Yes.

23 DR. TULCHINSKY: Yes.

24 DR. CHOYKE: I'd just like to be a little more  
25 wordy. I think I'm a little hesitant about the data,

1 frankly, because I saw it all over the place, ranging from  
2 99 percent to 50 percent correlations. But even in that  
3 range, it seems like we definitely have some kind of  
4 correlation, that it is a meaningful agent. It may very  
5 well be that the gold standards that are used in the test  
6 are just not adequate to measure this, and that's supported  
7 I think by the animal data, or what we hear of the animal  
8 data. It's certainly a harmless agent.

9 So for those reasons, I'm voting yes.

10 DR. MALCOLM: My answer is yes, and I  
11 completely agree with Pete's comment.

12 DR. RAMSEY: Yes.

13 DR. PONTO: Yes.

14 DR. AMENDOLA: Yes.

15 DR. ZIESSMAN: Yes.

16 DR. LINKS: Yes.

17 MR. MADOO: We have a total agreement on the  
18 committee, 12-0.

19 One other comment. Dr. Love, when we leave,  
20 are you comfortable with us keeping our materials on the  
21 desk in a locked room, or --

22 DR. LOVE: Yes.

23 MR. MADOO: Okay. That's probably relevant to  
24 people. You don't have to tote your stuff.

25 DR. LOVE: All of these data are publicly

1 available.

2 DR. RAMSEY: Any other questions or comments?

3 (No response.)

4 DR. RAMSEY: Okay. I want to thank the  
5 presenters all for coming in. I know sometimes it's hard  
6 to get here. I really appreciate your coming and sharing  
7 your information. I want to thank all of you for  
8 participating.

9 We will begin tomorrow sharp at 8:00 in this  
10 room, where we will have the presentations regarding  
11 nitrogen N-13. Am I right? No. Presentations on water O-  
12 15 beginning at 8:00 tomorrow morning. So I'll see you  
13 here. Thank you all.

14 (Whereupon, at 4:40 p.m., the meeting was  
15 recessed, to reconvene on Tuesday, June 29th, at 8:00 a.m.)

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