EDO Principal Correspondence Control

FROM: DUE: / /

EDO CONTROL: G20010076
DOC DT: 02/08/01
FINAL REPLY:

Carl L. Tommaso
The Society for Cardiac
Angiography and Interventions

TO:

Chairman Meserve

FOR SIGNATURE OF : ** GRN ** CRC NO: 01-0107

DESC:

Request the Appointment of an Interventional Cardiologist to the Advisory Committee on the Medical Uses of Isotopes

ROUTING:

Travers
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Norry
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DATE: 02/14/01

ASSIGNED TO: CONTACT:

NMSS Kane

SPECIAL INSTRUCTIONS OR REMARKS:

For Appropriate Action.

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Date Printed: Feb 13, 2001 16:17

PAPER NUMBER:	LTR-01-0107 **LOGGING DATE:** 02/13/2001
ACTION OFFICE:	EDO
AUTHOR:	Carl Tommaso
AFFILIATION:	
ADDRESSEE:	CHRM Richard Meserve
SUBJECT:	Requests the appointment of an interventional cardiologist to the Advisory Committee on the Medical Uses of Isotopes
ACTION:	Appropriate
DISTRIBUTION:	Chrm, Comrs
LETTER DATE:	02/08/2001
ACKNOWLEDGED	No
SPECIAL HANDLING:	OCM #5372
NOTES:	
FILE LOCATION:	ADAMS
DATE DUE:	**DATE SIGNED:**

5372

The Society for Cardiac Angiography & Interventions

9111 Old Georgetown Road, Bethesda MD USA 20814-1699
(800) 992-7224 Fax (301) 581-3408 e-mail: info@scai.org http://www.scai.org

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Co-Chairman

February 8, 2001

The Honorable Richard A. Meserve, Chairman
United States Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

Dear Chairman Meserve:

In a December 20, 1999 letter, Dr. Arthur Garson, then President of the American College of Cardiology (ACC) wrote to you asking for the appointment of an interventional cardiologist on the Advisory Committee on the Medical Uses of Isotopes (ACMUI). A copy of his letter is attached.

The Society for Cardiac Angiography and Interventions (SCA&I) is a 2000 member organization of interventional cardiologists. We are closely allied with the ACC and have supported their efforts to gain access to the ACMUI. With the approval and proliferation of intravascular radiation, we believe that patients' best interests would be maintained by involvement of interventional cardiologists at each level of regulation and decision-making involving this procedure. We also believe that current iterations of intravascular radiation are first generation tools and significant evolution of this technology will occur.

As I am sure that you are aware, on November 3, 2000 the Food and Drug Administration approved the Novoste Beta-Cath™ System and the Checkmate™ System, intravascular radiation procedures to treat in-stent restenosis. The problem of restenosis is the largest complication of percutaneous coronary intervention since its inception. With the availability of intravascular radiation, there is now a therapeutic modality to attack this problem.

Therefore, in conjunction with the ACC we are asking that you consider the appointment of an interventional cardiologist to the ACMUI. We realize that Manuel Cerqueira, M.D., F.A.C.C. is the cardiology community's representative to the ACMUI; however, he is a recognized expert in nuclear cardiology and board certified in nuclear medicine. The expertise of an interventional cardiologist is different and would be an important addition to the ACMUI particularly in this time of the proliferation and evolution of a new technology.

I hope that you will consider our request on behalf of the SCA&I, and the patients undergoing intravascular radiation.

Sincerely,

Carl L. Tommaso, M.D., F.S.C.A.I.
President, Society for Cardiac Angiography and Interventions

Attachment

cc: Commissioner Nils J. Diaz
Commissioner Greta Joy Dicus
Commissioner Edward McGaffigan, Jr.
Commissioner Jeffrey S. Merrifield
Donald A. Cool, Ph.D.
Catherine Haney
George A. Beller, M.D., F.A.C.C.
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Sincerely,

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President, Society for Cardiac Angiography and Interventions

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	TERENCE CHAN			ALL ASSISTANTS	

REMARKS

	FILE		SEE ME		NOTE & RETURN

FROM (NAME)

FILE LOCATION: ACMUI

G:\MAREK\ROUTE SLIP-CHMOFFICE.WPD

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December 20, 1999

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The Honorable Richard A. Meserve, Chairman
United States Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

Dear Chairman Meserve:

The American College of Cardiology (ACC), a medical society that represents 25,000 cardiovascular specialists, has been an active participant in the revision process of 10 CFR Part 35,"Medical Use of Byproduct Material." We believe that the proposed changes will maintain safety, decrease the regulatory burden and increase public confidence in the regulation of radiation.

The cardiology community has a special interest in the process not only with respect to the use of diagnostic applications such as myocardial perfusion imaging, but also in the evolving field of intravascular radiation for restenosis prevention (intravascular brachytherapy). We believe that this modality has the potential to overcome the biggest problem associated with interventional cardiology procedures: tissue proliferation. As the attached table (Clinical Trials Using Intravascular Brachytherapy for the Inhibition of Restenosis) demonstrates, intravascular radiation for restenosis prevention can be performed in many different ways. We appreciate the fact that the Nuclear Regulatory Commission (NRC) and Part 35 Writing Group have recognized the emerging nature of intravascular radiation for restenosis prevention and acknowledged these changing circumstances in the draft final rule version of 10 CFR, Part 35.1000. Following adoption of a standard protocol, the NRC will address regulatory treatment of intravascular radiation for restenosis prevention.

Over the years, the ACC has been pleased to nominate cardiologists to serve on the Advisory Committee on the Medical Uses of Isotopes (ACMUI). That representation has allowed the cardiology community to provide input into issues related to nuclear cardiology. The ACMUI has a broad composition that represents all the stakeholders in the medical use of byproduct materials. Dr. Manuel Cerqueira, the cardiology community's representative to the ACMUI, has been named to chair that panel. He is a recognized expert in nuclear cardiology and board certified in nuclear medicine. As chair, he will see that all viewpoints are represented fairly.

Dr. Cerqueira does not practice interventional cardiology or have expertise in the emerging technology of intravascular radiation for restenosis prevention. No one presently serving on the ACMUI has either the clinical and technical knowledge or experience sufficient to provide expertise on intravascular radiation. Given the significance of this emerging modality, the ACC believes it is appropriate for an interventional cardiologist to sit on the ACMUI.

An interventional cardiologist with expertise in intravascular radiation for restenois prevention will provide the committee with the unique perspective required to understand the complicated issues involved in the clinical management of patients in the cardiac catheterization

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12/22...To EDO for Appropriate Action...Copy to: Chairman, Comrs, SECY/RAS...99-1084

laboratory where the studies will be performed. The addition of a representative from the interventional cardiology community would assure that the committee receive expert information from practitioners in the field. The cardiology community believes that the addition of an interventional cardiologist is critical to guaranteeing the safety of patients and users.

The cardiology community looks forward to a continuing dialogue with the NRC and the ACMUI on issues related to the medical uses of byproduct material in cardiology procedures. Addition of an interventional cardiologist to the ACMUI would assure that the advisory panel could provide the commissioners the most relevant information on new developments related to intravascular radiation for restenosis prevention.

Thank you for considering the views of the more than 25,000 ACC members.

Sincerely,

Arthur Garson, Jr., M.D., M.P.H., F.A.C.C.
President

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CLINICAL TRIALS USING INTRAVASCULAR BRACHYTHERAPY FOR THE INHIBITION OF RESTENOSIS

Study Name	Principle Investigator	Type of Trial	Trial Design	No. of Patients	Vascular Bed	Lesion Type	Treatment	Isotope	Type of Radiation	Dose or Activity	Delivery Platform	Delivery Method	Centered Source	Results and Status
Venezuela	Condado, et al	Feasibility	Open Label	21	Coronary	De novo	PTCA	^{192}Ir	Gamma	20-25 Gy (actual dose 19-55)	Catheter	Hand	Non-Centered	Completed. Clinical and angiographic follow-up to 24 months demonstrated safety and low late loss. Aneurysm noted in two.
SCRIPPS	Teirstein, et al	Feasibility, Efficacy	Randomized, Controlled	55	Coronary	Restenosis	PTCA and Stent	^{192}Ir	Gamma	8-30 Gy to media by IVUS	Catheter	Hand	Non-Centered	Completed. Significant reduction of restenosis (54% vs 17%) in the irradiated group.
Swiss I	Verin, et al	Phase I	Open Label	15	Coronary	De novo	PTCA	^{90}Y	Beta	18 Gy to lumen surface	Catheter	Afterloader	Centered	Completed. Demonstrated feasibility and safety, but not efficacy (restenosis=40%).
BERT	King, et al	Phase I	Open Label	23	Coronary	De novo	PTCA	^{90}Sr/Y	Beta	12, 14, 16 Gy to 2 mm from source.	Catheter	Hydraulic device	Non-Centered	Completed. Demonstrated feasibility and safety. Restenosis 15%. Late loss index of .4%.
BERT Canada	Bonan, et al	Phase I	Open Label	30	Coronary	De novo	PTCA	^{90}Sr/Y	Beta	12,14,16 Gy to 2 mm from source.	Catheter	Hydraulic device	Non-Centered	Completed. Demonstrated feasibility and safety. Restenosis rate 10%. Negative late loss.
BERT European	Serruys, et al	Phase I	Open Label	30	Coronary	De novo	PTCA	^{90}Sr/Y	Beta	12, 14, 16 Gy to 2 mm from source.	Catheter	Hydraulic device	Non-Centered	Enrollment completed. Data expected Summer, 1998.
PREVENT	Raizner, et al	Phase I	Randomized, Controlled	84	Coronary	De novo or Restenosis	PTCA, Stent	^{32}P	Beta	0, 16, 20, 24 Gy to 1.0 mm into artery wall.	Catheter	Afterloader	Centered	Enrollment completed. Data expected Fall 1998.
WRIST	Waksman, et al	Phase II	Randomized, Controlled	100	Coronary	In-stent restenosis	PTCA, Stent	^{192}Ir	Gamma	15 Gy to 2.0 mm from source	Catheter	Hand	Non-Centered	Enrollment completed.
WRIST SVG	Waksman, et al	Phase II	Randomized, Controlled	120	Coronary	In-stent restenosis in saphenous vein grafts	PTCA, Stent	^{192}Ir	Gamma	15 Gy to 2.4 mm from source	Catheter	Hand	Non-Centered	Enrollment started December 1997

CLINICAL TRIALS USING INTRAVASCULAR BRACHYTHERAPY FOR THE INHIBITION OF RESTENOSIS

Study Name	Principle Investigator	Type of Trial	Trial Design	No. of Patients	Vascular Bed	Lesion Type	Treatment	Isotope	Type of Radiation	Dose or Activity	Delivery Platform	Delivery Method	Centered Source	Results and Status
WRIST LONG	Waksman, et al	Phase II	Randomized. Controlled	120	Coronary	In-stent restenosis in long (36-88 mm) lesions.	PTCA, Stent	^{192}Ir	Gamma	15 Gy to 2.0 mm	Catheter	Hand	Non-Centered	Enrollment started January 1998
BETACATH	Kuntz, et al	Phase II	Randomized Control	1100	Coronary	De novo	PTCA. Provisional Stent	^{90}Sr/Y	Beta	14, 18 Gy to 2 mm from source	Catheter	Hydraulic device	Non-Centered	Enrollment started July 1997
Swiss II	Verin, et al	Phase I	Open Label	160	Coronary	De novo	PTCA	^{90}Y	Beta	9, 18, 32 Gy to Surface	Catheter	Afterloader	Centered	Enrollment started September 1997
GAMMA I	Leon, et al	Phase II	Randomized. Controlled	250	Coronary	In-stent restenosis	PTCA, Stent	^{192}Ir	Gamma	8 - 32 to media by IVUS	Catheter	Hand	Non-Centered	Enrollment started December 1997
CURE	Weinberger, et al	Feasibility and Safety	Open Label	60	Coronary	De novo or restenosis	PTCA , Stent	^{188}Re	Beta	20 to balloon surface	Catheter	Liquid filled balloon	Centered	Enrollment started October 1997.
ARREST	Waksman, et al	Phase II	Randomized. Controlled	700	Coronary	De novo	PTCA and provisional stenting	^{192}Ir	Gamma	8 - 35 to media by IVUS	Catheter	Afterloader	Centered	Enrollment started Spring, 1998.
INHIBIT	Waksman, et al	Phase II	Randomized. Controlled	200	Coronary	In-stent restenosis	PTCA. Stent	^{32}P	Beta	20 to 1.0 mm into wall	Catheter	Afterloader	Centered	Enrollment anticipated June 1998.
IRIS IA	Fischell, et al	Phase I	Open label	32	Coronary	De novo, restenosis	Radioactive stent (Palmaz-Schatz stent)	^{32}P	Beta	Low activity (0.5 to 1.0 μCi	Stent	Catheter	Centered	Completed. Excellent feasibility and safety. Angiographic restenosis ≈31%
IRIS IB	Moses, et al	Phase I	Open label	25	Coronary	De novo, restenosis	Radioactive stent (Palmaz-Schatz stent)	^{32}P	Beta	Activity 0.5 to 1.5 μCi	Stent	Catheter	Centered	Completed. Excellent feasibility and safety. Restenosis data available Summer, 1998
Heidelberg	Hehrlein, et al	Phase I	Open label	15	Coronary	Restenosis	Radioactive stent (Palmaz-Schatz stent)	^{32}P	Beta	Activity 3.0 μCi	Stent	Catheter	Centered	Enrollment completed. No major adverse events at four months.
Milan	Colombo	Phase I	Open label	?	Coronary	De novo, restenosis	Radioactive stent (Palmaz-Schatz stent)	^{32}P	Beta	Activity 6.0 and 8.0 μCi	Stent	Catheter	Centered	Enrollment started January 1998.

CLINICAL TRIALS USING INTRAVASCULAR BRACHYTHERAPY FOR THE INHIBITION OF RESTENOSIS

Study Name	Principle Investigator	Type of Trial	Trial Design	No. of Patients	Vascular Bed	Lesion Type	Treatment	Isotope	Type of Radiation	Dose or Activity	Delivery Platform	Delivery Method	Centered Source	Results and Status
Isostent	Fischell, et al	Phase I	Open label	30	Coronary	De novo, restenosis	Radioactive stent (BX stent)	^{32}P	Beta	Activity 0.7 to 1.5 μCi	Stent	Catheter	Centered	Enrollment started March 1998.
German	Liermann, et al	Feasibility and efficacy	Open label	25	Superficial femoral artery	De novo	PTA and stent	^{192}Ir	Gamma	12 Gy	Catheter	Afterloader	Non-Centered	Completed. Five-year follow-up shows 80% patency. No adverse radiation effects.
PARIS I	Waksman, et al	Phase I	Open label	30	Superficial femoral artery	De novo	PTA	^{192}Ir	Gamma	14 Gy	Catheter	Afterloader	Centered	Completed. Demonstrated feasibility and safety.
PARIS II	Waksman, et al	Phase II	Randomized controlled	300	Superficial femoral artery	De novo	PTA	^{192}Ir	Gamma	14 Gy	Catheter	Afterloader	Centered	Enrollment started June 1998.
Washington Hospital Center	Waksman, et al	Phase I	Open label	11	AV dialysis shunt	De novo, restenosis	PTA	^{192}Ir	Gamma	14 Gy	Catheter	Afterloader	Non-Centered	18 lesions, 40% patency at 44 weeks.
New York Hospital Center	Nori, et al	Phase I	Open label	10	AV dialysis shunt	De novo, or restenosis	PTA	Orthovoltage		8, 12 Gy	External	External beam	Non-Centered	10 patients, 70% patency at 6 months.

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