

# Minutes of the Premarin Publication/Presentation Management Meeting

September 13, 2000

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## ***ATTENDEES***

### **Wyeth-Ayerst**

Peter Bodine  
Alice Conti  
Tony DelConte  
Gail Goldsmith  
Harriette Land  
Michelle Mull  
Ramona Richardson-Young

### **DesignWrite**

Karen Mittleman  
Kathy Ohleth

### **Ketchum**

Linda Kanamine  
Justine Stevens

## ***AGENDA***

### **I. JAMA – Call for Abstracts in Women's Health**

- ◆ March publication (if not accepted – JAMA automatically sends to one of their of other journals – no resubmission necessary)
- ◆ Trudy Bush - Breast cancer review article
- ◆ Michelle Curtis - Women's health policy review article
- ◆ Sally Shaywitz/Fred Naftolin - Better oral reading and short term memory in midlife postmenopausal women taking estrogen
- ◆ Roberto Civitelli - Prempro reduces alveolar bone loss research report
- ◆ Martin Scharf - Estrogen and raloxifene on sleep quality

### **II. Premarin Study Tracking Update**

<b>MEETINGS</b>			
<b>Status</b>	<b>Meeting</b>	<b>Investigator</b>	<b>Study</b>
Presented	International Federation of Gynecology and Obstetrics (9/00)	Arnaud (oral)	Estrogen and PTH on bone
		MIICRO/Metz (oral; chairing the session)	Estrogen and cerebral glucose
		Archer (poster)	Bleeding with Prempro
		Pickar (oral)	Delta-8,9-DHES and bone
		Scharf (oral – did not show)	Estrogen and raloxifene on sleep
		Rhoa/Raymundo (poster)	PVC and vaginitis
		Steinberg (oral)	Estrogen and oral health

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Status	Publication	Investigator/Author	Study/Subject
Presented	NAMS (9/00)	Eskin (poster)	Estrogen and bone and NE release in rats
		Civitelli (oral)	Prempro attenuates alveolar bone loss
		Gambacciani (oral)	Low-dose HRT
Presented	ASBMR (9/00)	Lane (poster)	Estrogen and raloxifene on bone microarchitecture
		Arnaud (oral)	PTH and estrogen – 3 <sup>rd</sup> year data
		Ermer (poster)	TSE pharmacology
		Komm (oral; chairing the session)	TSE preclinical data
To be presented	AHA (11/00)	Herrington	Statin use and mortality in HERS
		Shlipak	Estrogen use and mortality
		Rosano (poster)	Low-dose data/MPA data
		Nguyen (oral)	Lipoprotein(a) and estrogen
		Evans (poster)	Estrogen-mediated inhibition of inflammatory gene expression in endothelial cells
		Evans (poster)	Estrogen inhibits inflammatory gene induction in the liver of mice fed an atherogenic diet
Submitted (9/00)	International Society of Gynecological Endocrinology (ISGE) (12/00)	Archer	Low-dose data (HOPE) (vasomotor, lipids, bleeding, endometrial histology)
Submitted (9/00)	ACC (3/01)	Davidson	Zocor/Prempro study
		Rosano	HRT increase in C-reactive protein not related to other inflammatory markers
		Rosano	HRT and atorvastatin on lipids

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PUBLICATIONS			
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Published	<i>Arch Int Med</i> (8/00)	Mosca	HRT and CVD
	<i>Current Athero Reports</i> (7/00)	Mosca	HRT and atherosclerosis
To be published	<i>Am J OB/GYN</i> (date TBD)	Archer/Pickar	Prempro bleeding reanalysis
To be published	<i>Neurobiol of Aging</i> (6/00 – in conjunction with Alzheimer's Assn Meeting)	Maki	ERT on cerebral blood flow and cognition
	<i>Am J Psychiatry</i>	Maki	Enhanced verbal memory in elderly estrogen users
To be published	<i>Int J Fertil</i> (11/00)	Seddon	Eye Diseases and HRT
To be published	<i>Menopause Digest</i> (11/00)	Curtis	SERMs: controversial for managing menopause
To be published	<i>Am J Ob/Gyn</i> (date TBD)	Ansbacher	All estrogens not equivalent
To be published	<i>Microcirculation</i> (date TBD)	Thomas	Premarin and raloxifene on vascular damage and inflammation
To be published	<i>Ann Int Med</i> (date TBD)	Sawaya	Pap smears in HERS
To be published	<i>Circulation</i> (date TBD)	Hsia	Peripheral arterial disease in HERS
Submitted	<i>JAMA Special Issue</i>	Bush	Hormones, breast cancer and criteria for causality
Submitted	<i>JAMA Special Issue</i>	Curtis	Health policy formulation for women's health
Submitted	<i>JAMA Special Issue</i>	Shaywitz	Estrogen and cognitive function
Submitted	<i>JAMA Special Issue</i>	Scharf	Estrogen and raloxifene on sleep quality
Submitted (7/00)	<i>The Female Patient</i>	Nachtigall	Update 2000: HRT and breast cancer
Submitted	<i>Biological Psychiatry</i>	MIICRO/Cooper/Metz	Estrogen and glucose metabolism in the brain
Submitted	<i>Am J Ophthalmol</i>	Seddon	HRT and macular degeneration
Submitted	<i>J Am Medical Director's Association</i>	Maloney	PVC and vaginal pH changes
Submitted	<i>Urology Nurses On-line</i>	Maloney	PVC and UTIs

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Status	Publication	Investigator/Author	Study/Subject
To be resubmitted	<i>J Hyperten</i>	Light	Premarin's effect on vascular resistance and left ventricular mass
To be submitted	<i>NEJM</i>	Arnaud	PTH and estrogen in osteoporosis treatment
To be submitted	<i>Cancer</i>	Boman	Cross-resistance of SERMs in breast cancer model
To be submitted	<i>Menopause</i>	Gambacciani	Low-dose CEE and MPA on symptoms, body weight and metabolism
To be submitted	TBD	Brinton	Raloxifene and estrogen effects on neuronal cells Phyto-estrogen data
Manuscripts in preparation (see binder for further details)	TBD	HOPE Investigators Birge Murphy (2) Lane (2) Eskin	HOPE data (4 manuscripts) Bone in frail women with estrogen Estrogen and brain serotonin Estrogen/raloxifene on bone (rats) Estrogen and NE release

### III. Medical Affairs Update

- ◆ Gambacciani gave an oral presentation on low-dose at NAMS
- ◆ Greendale – Gail and Ramona will follow up to look at original protocol for additional data that may be presented/published
- ◆ Kathleen Light has an additional manuscript to be submitted to *Circulation*
- ◆ Kathy to email Schlipak regarding acceptance of his abstract to AHA
- ◆ Alice will email Kathy Shields for an updated grid of the HERS publications

### IV. WHRI Update

- ◆ Peter will follow up with Barry Komm to find out his interest in submitting to the 8<sup>th</sup> World Congress of the Gynecological Endocrinology
- ◆ It was decided that due to the preclinical nature of WHRI data, there are other meetings more appropriate than ACC for abstract submission

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## V. HOPE Update

- ◆ An abstract was submitted to the 8<sup>th</sup> World Congress of the Gynecological Endocrinology
- ◆ Bone data available in February – Kathy to follow up on International Osteoporosis Foundation meetings
- ◆ Low-dose sub-committee to discuss what can be presented and when

## VI. Publication-related PR Opportunities

- ◆ Ketchum will contact Barry Komm for PR about TSE surrounding ASBMR
- ◆ ASRM publicity planned
- ◆ VNR on tooth loss at the time of ASBMR

## VII. Miscellaneous

- ◆ A back-up plan needs to be in place for when investigators that are not OB/GYNs have to present at OB/GYN meetings (back-up presenter)
- ◆ Data will be resented at ASBMR that refutes the effects of statins on bone