

Advisory Committee For Pharmaceutical Science  
CDER Advisory Committee Conference Room  
5630 Fishers Lane  
Rockville, MD  
September 23-24, 1999

*Exposure-Response Introduction/Overview*

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**CENTER FOR DRUG EVALUATION AND RESEARCH**  
**FOOD AND DRUG ADMINISTRATION**

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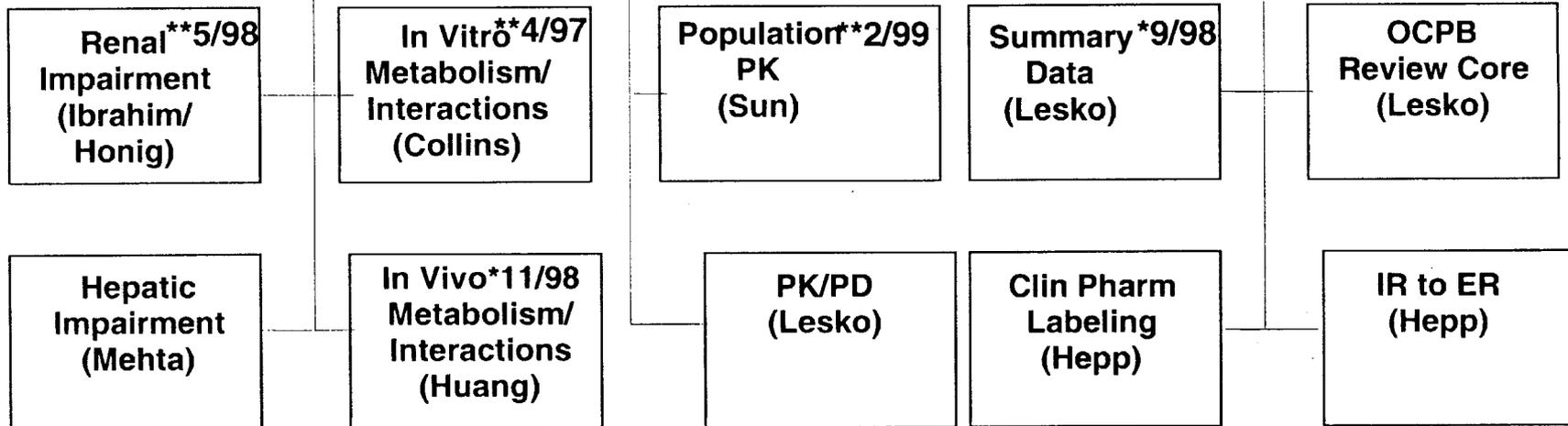
# CDER Medical Policy Coordinating Committee

Co-Chairs: Temple, Williams

## Clinical Pharmacology Section

Chair: Lesko  
Facilitator: Williams  
Exec Sec: Huang  
Proj Tracking: Taira

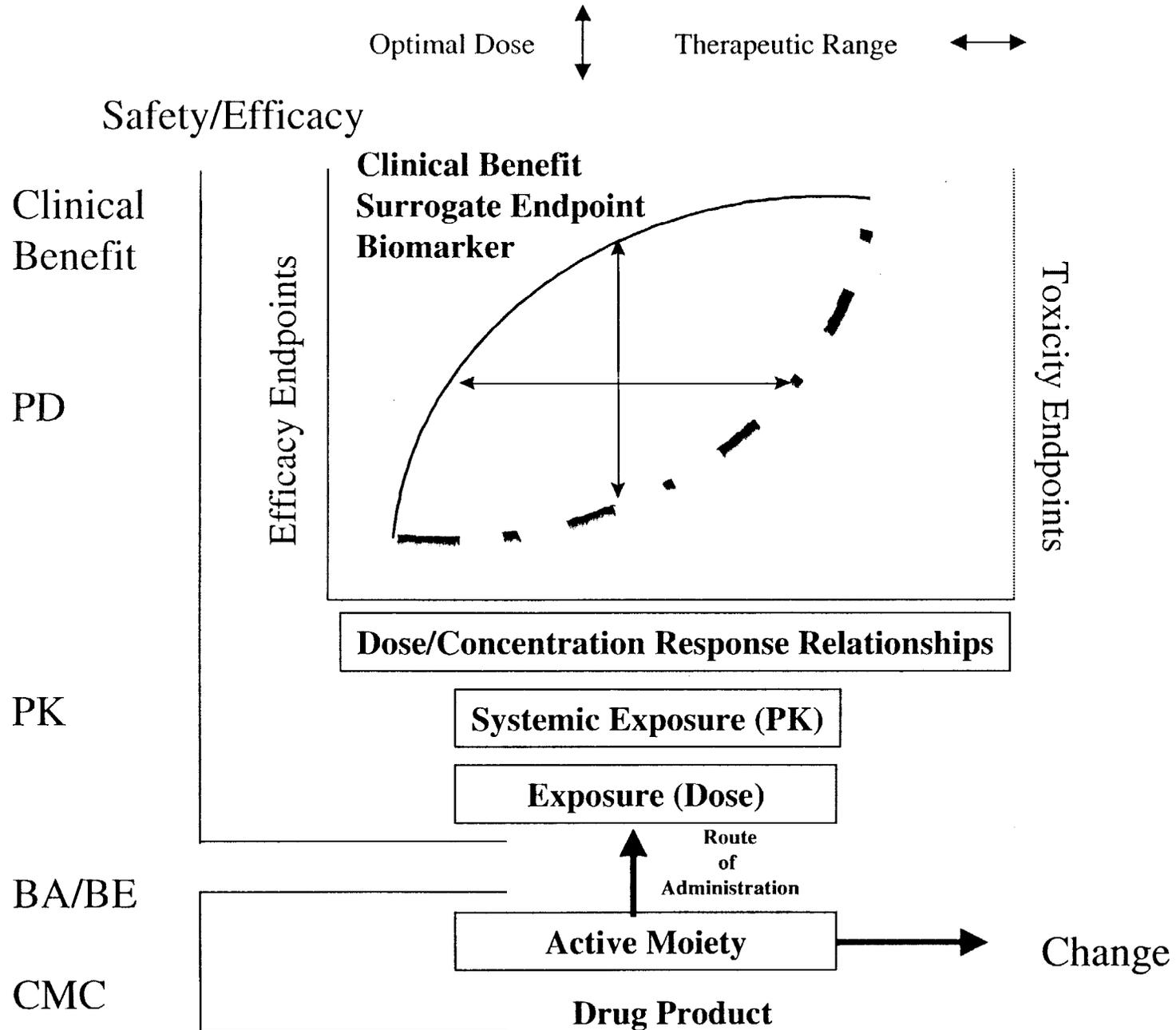
Members: Honig, Karkowsky,  
Senior, Kobayashi,  
Cavaille-Coll, Wilkin,  
Green



\*\* = final guidance published

\* = draft guidance published [http://www.fda.gov/cder/guidance/index.htm]

# ICH CTD Modules



# Questions/Approaches/Documents

Information	Phase	Questions	Policy
Key Papers	Nonclinical	What Does One Need to Know? How Certain Does One Need to Be? What Is One Willing to Assume?	1. Phase 1 Guidance
Workshops	1 Learn	<p>Response/Surface</p>	2. Phase 1 Workshop (ASCPT)
Seminars			3. OCPB/Core Studies
Other	2A Confirm		4. OCPB Labeling
	2B Learn/? Confirm(?)		5. Prognostic Factors Elderly (E7) Pediatric Gender Ethnic Factors (E5) Disease States (renal/hepatic)
	3 Confirm/ Learn	Efficacy/Safety	6. Methods Drug-Drug Interactions Dose/Response (E4) PK/PD IR to ER
	4 Learn	Post Marketing	7. Population PK/PD 8. E1, E9, E10
			9. ADR Reports (E2)

Efficacy: While ordinarily substantial evidence consist of data from 2 or more such clinical investigations, where the Secretary determines that is appropriate, the Secretary may find that substantial evidence consists of data from a single adequate and well controlled clinical investigation

Y axis: Response

X axis: Dosage regimen

Z axis: Adjust dosage regimen for  
Intrinsic/Extrinsic factors

“Confirmatory” Evidence

Adequate and well-controlled

2 or more

1

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