



## **Summary of Expertise, Experience and Affiliations and Interests for the Scientific Advisory Panel on Bioequivalence Requirements for Gender-Specific Drug Products (SAP-GSDP)**

### **Purpose of the Summary**

The following summarizes the information about expertise or experience, affiliations and interests relevant to the Scientific Advisory Panel on Bioequivalence Requirements for Gender-Specific Drug Products (SAP-GSDP) mandate declared by committee members. Health Canada considered these declarations as part of the selection process. The Health Products and Food Branch has made this summary available as part of its commitment to be transparent about the membership of its advisory bodies.

### **Assessment of affiliations and interests prior to each meeting**

Prior to each committee meeting, Health Canada assesses members' affiliations and interests, including direct financial interests, as they may apply to agenda items for discussion. Depending on the nature of the member's affiliations or interests, the Chair of the committee in consultation with the members, may limit the participation of a member in the meeting or ask him/her to make a verbal statement of affiliations and interests at the beginning of the meeting. Members' affiliations and interests are reviewed on an annual basis and updated as required based on changes in the status of their affiliations and interests.

In accordance with the Health Products and Food Branch Review of Regulated Products: Policy on Public Input and Guidance on Advisory Bodies, a person with a direct financial interest in the outcome of a review of a regulated product may be a member of an advisory body whose broader mandate encompasses matters of policy, management, or program development. However, such a member would not be asked to participate in any discussion, formulation of advice, or recommendations to Health Canada relating to that review.

### **Indicated Sector/Perspective and Expertise/Experience**

#### **Sector/perspective:**

- Health professional
- Research
- Academia

#### **Expertise/experience:**

- Pharmacokinetics
- Obstetrics
- Pharmacology

#### **1. Direct financial interests**

- a. Current employment, investments in companies, partnerships, equity, royalties, joint ventures, trusts, real property, stocks, shares or bonds, with the regulated industry.

## 2. Indirect financial interests

- a. Within the past five years, payment from regulated industry for work done or being done, including past employment, contracts or consulting; or financial support including research support, personal education grants, contributions, fellowships, sponsorships, and honoraria.<sup>1</sup>
- b. Within the past five years, materials, discounted products, gifts, or other benefits, or attendance at meetings where all or part of the travel and accommodation costs were provided by the regulated industry.<sup>2</sup>
- c. Within the last three years, grants or other funding from the regulated industry to any of the organizations where you are currently employed or participate in internal decision making.<sup>3</sup>

## 3. Intellectual interests

- a. Within the last five years, any formal advice or opinion to industry, a government organization or a non-government organization on a matter of relevance to the SAP-GSDP.
- b. Within the last five years, any published or publicly stated point of view on issues of relevance to the SAP-GSDP mandate.
- c. Current professional or volunteer affiliations such as membership of professional societies, lobbying, public interest or advocacy groups, of relevance to the SAP-GSDP.

## 4. Other

- a. Any other affiliations and interests or potential circumstances that might give a well-informed member of the public reasonable grounds for concern regarding the integrity and objectivity of your participation.

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<sup>1</sup> other than from present employer

<sup>2</sup> other than from present employer, over \$1,000

<sup>3</sup> “participate in internal decision making” means as a board member, or as an executive or non-executive director

Name and Indicated Sector/Perspective and Expertise/Experience		Summary of Response							
Jake J. Thiessen	Perspective/ Sector Academia  Expertise/ Experience Pharmacology and Pharmacokinetics	1a) No	2a) Yes	2b) No	2c) No	3a) Yes	3b) Yes	3c) Yes	4a) No
		<b>Comments:</b> Received payment as a consultant in scientific, business and regulatory issues for several companies. Since 2005, has been the Chair for Health Canada's Scientific Advisory Committee on Bioequivalence and Bioavailability. Provided expert testimony to the Tax Court of Canada. Has published several articles on Bioequivalence and Bioavailability. A member of the Canadian Society of Pharmaceutical Scientists and the American Association of Pharmaceutical Scientists.							
Daniel Sitar	Perspective/ Sector Academia  Expertise/ Experience Pharmacokinetics and Bioequivalence	1a) No	2a) Yes	2b) Yes	2c) No	3a) Yes	3b) Yes	3c) Yes	4a) No
		<b>Comments:</b> Has received research grants and partial reimbursement costs for a podium presentation from pharmaceutical companies. Provided formal advice as a member of Health Canada's Scientific Advisory Committee on Bioequivalence and Bioavailability as well as a past member of the Scientific Advisory Committee on Bioequivalence Requirements for Fentanyl Transdermal Delivery Systems. Participated in a Health Canada mediation panel. Acted as a consultant to a biotechnology company regarding development of a diagnostic screening test for cancer. Has published several manuscripts, reports, and scientific papers relating to Bioequivalence and Bioavailability. Is a member of several Pharmaceutical and Pharmacological Societies and Associations. Is a member of the Editorial Board of Clinical Pharmacology and Therapeutics and the Board of Regents of the American College of Clinical Pharmacology and acts as Editor in Chief for the Journal of Clinical Pharmacology.							
Robert J. Herman	Perspective/ Sector Health Professional  Expertise/ Experience Internal Medicine, Pharmacology and Bioequivalence	1a) No	2a) No	2b) No	2c) No	3a) Yes	3b) No	3c) Yes	4a) No
		<b>Comments:</b> Volunteered as a member of Health Canada's Scientific Advisory Committee on Bioequivalence and Bioavailability and Alberta Blue Cross/Alberta Health and Wellness Expert Committee. Participated as an expert witness for a drug product legal challenge. A member of the Canadian Hypertension Society (CHEP) Guidelines Taskforce and participates as Chair for the Sub-Committee on Treatment of Hypertension in Adults Without Confounding Indications for Specific Agents.							
Scott Walker	Perspective/Sector Health Professional  Expertise/ Experience Pharmacokinetics, Pharmacodynamics	1a) No	2a) Yes	2b) No	2c) Yes	3a) Yes	3b) Yes	3c) No	4a) No
		<b>Comments:</b> Received Research and financial support from various pharmaceutical companies as well as grants or funding for the department of Pharmacy at Sunnybrook Health Science Centre. A member of the Committee to Evaluate Drugs for the Ontario Ministry of Health and Long Term Care. Has received payment for advice, primarily in the areas of bioequivalence, pharmaceutical equivalence and the suitability of blood glucose strip accuracy and reproducibility. Made numerous public statements on the topic of bioequivalence. A member of the Canadian Society of Hospital Pharmacists and the Canadian Association of Pharmacy in Oncology.							

William Racz	Perspective/Sector Academia  Expertise/ Experience Pharmacology, toxicology, bioavailability and bioequivalence	1a. No	2a. No	2b. No	2c. No	3a. Yes	3b. No	3c. Yes	4a. No	<b>Comments:</b> Volunteers as a member of Health Canada’s Scientific Advisory Committee on Bioavailability and Bioequivalence. Receives payment to provide formal advice as a member of the Ontario Drug Programs Committee to Evaluate Drugs and as Chair of the Appeal Committee to Reconsider a proton pump inhibitor drug. Newsletter editor and member of the Society of Toxicology of Canada. Member of the Pharmacological Society of Canada.
Elaine Jolly	Perspective/ Sector Health Professional/ Academia  Expertise/ Experience Obstetrics and Gynaecology	1a. No	2a. Yes	2b. No	2c. No	3a. Yes	3b. No	3c. No	4a. No	<b>Comments:</b> Scientific and Clinical advisory board member for various pharmaceutical companies. Principal Investigator for several clinical trials. Receives honoraria for speaking and participating in advisory boards. Provided formal advice or opinion within advisory boards.
Heather Shapiro	Perspective/ Sector Health Professional  Expertise/ Experience Obstetrics and Gynaecology	1a. No	2a. No	2b. No	2c. No	3a. No	3b. No	3c. No	4a. No	<b>Comments:</b> None.