on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Criteria for Members

Persons nominated for membership as consumer representatives on the committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committee on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency’s selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see ADDRESSES) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee’s current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominees receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency’s advisory committees or panels. Self-nominations are also accepted. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

All nominations should include: A cover letter; a curriculum vitae or resume that includes the nominee’s office address, telephone number, and email address; and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations also should specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include a statement that the nominee is aware of the nomination and is willing to serve as a member of the advisory committee or panel if selected.

The term of office is up to 4 years. FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumers organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate the nominee to serve as voting or nonvoting consumer representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

Dated: June 17, 2013.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.
GPR116 Knockout and Conditional Knockout Mice

Description of Technology:

Pulmonary surfactant plays a critical role in preventing alveolar collapse by decreasing surface tension at the alveolar air-liquid interface. Surfactant deficiency contributes to the pathogenesis of acute lung injury (ALI) and acute respiratory distress syndrome (ARDS), common disorders that can afflict patients of all ages and carry a mortality rate greater than 25%. Excess surfactant leads to pulmonary alveolar proteinosis. The NCI investigators created a G-protein coupled receptor GPR116 mutant mouse model and showed that GPR116 plays a previously unexpected, essential role in maintaining normal surfactant levels in the lung.

The mouse model could aid in the development of drug screens to identify agents that can modulate surfactant levels. Alveolar type II cells have also been isolated from the GPR116 wildtype and knockout mice that could be directly used in such assays. The identification of surfactant modulating agents could be important to a number of lung surfactant disorders.

Potential Commercial Applications:

Research materials to study lung surfactant homeostasis and disorders. Competitive Advantages: Not available elsewhere.

Development Stage:

• Prototype.
• Pre-clinical.
• In vitro data available.
• In vivo data available (animal).

Inventors: Bradley Dean St. Croix and Mi Young Yang (NCI).


Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; tongb@mail.nih.gov.

Collaborative Research Opportunity: The Center for Cancer Research Mouse Cancer Genetics Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize GPR116 Knockout and Conditional Knockout Mice. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.