



## **LGS Foundation Policy on Organizational Participation in Food and Drug Administration (FDA) Hearings and Meetings**

The following information details the LGS Foundation's official policy on organizational participation in Food and Drug Administration (FDA) hearings and meetings regarding the regulatory approval of drugs, biological products, and medical devices in accordance with its above-stated Corporate Relations Policy:

- The LGS Foundation will not generally provide testimony or submissions in its name in direct support for or against any drug, biological product, or medical device approval application. However, the LGS Foundation may on occasion provide testimony, submissions, or participate in open or closed FDA meetings in its name to provide information about, or relevant to, LGS or related diseases, including information (e.g. evidence of community need, what constitutes evidence of clinical benefit, endpoints, etc.), which may be relevant to regulatory decisions regarding an application under FDA review or a product under development.
- Any request for the LGS Foundation to provide testimony, statements, or opinions either supporting or opposing specific drugs, biological products, or devices in FDA or regulatory approval proceedings shall be reviewed by the Accelerate Research Committee, the Communications Committee, and the Executive Committee of the LGS Foundation Board of Directors. These Committees shall make a recommendation to the Board of Directors regarding whether the LGS Foundation should testify or take similar action. In the event that the Committees recommend that the LGS Foundation should provide testimony, statements, or opinions either supporting or opposing specific drugs, biological products, or devices in FDA or regulatory approval proceedings, final determination of the course of action to be taken by the LGS Foundation in an official capacity shall be made by the Board of Directors. If a representative of the LGS Foundation testifies before the FDA, that person will clearly disclose any conflict of interest prior to testimony or submission as is required at all FDA meetings and hearings. Nothing in this section prohibits the Executive Director or Director of Research from representing the interests of the LGS community in a manner that is non-specific to individual drugs, biological products, or medical devices.
- LGS Foundation staff will monitor the development of drugs, biological products, and devices relevant to LGS, including the pendency of applications for FDA or other regulatory approval of such treatments, and provide this information to its members and the general public.
- In the dissemination of information concerning the development of treatments, officers and staff of the LGS Foundation will comply with the Corporate Relations Policy and refrain from taking any action that can be seen as endorsing any corporation's product, service, or program, except as provided above.
- The Executive Director, together with the Executive Committee of the LGS Foundation Board of Directors, will maintain complete control of the development and use of all content and materials produced or used by the LGS Foundation related to the dissemination of information concerning the development and regulatory approval of

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drugs, biological products, medical devices, or programs for the treatment of individuals with LGS.

- Nothing in this policy impedes or discourages individual members of the LGS Foundation, or its Professional or Corporate Advisory Boards from participating in or testifying before the FDA or other regulatory panels, provided they make clear that they are not acting as a representative of the LGS Foundation.