



Policy for Engaging with Industry

Article 1 - Purpose

The Alport Syndrome Foundation (ASF) is a 501 (c)(3) non-profit organization whose mission is to improve the lives of those affected by Alport Syndrome through education, empowerment, advocacy, and research. The vision of ASF is to 'conquer' this rare genetic disease by finding new treatments to prevent kidney failure and hearing loss for all patients.

To accomplish this mission, ASF has created, and seeks to enhance, a landscape that encourages investment in research into Alport Syndrome by all stakeholders. This includes actively engaging and collaborating with pharmaceutical companies.

ASF has developed this policy to ensure the highest level of ethical conduct is followed in ASF's collaborations with pharmaceutical companies. ASF's goal in engaging pharmaceutical companies is to enable development of therapies to meet patient needs while maintaining independence and neutrality as a patient organization.

ASF's sole priority is the best needs of patients, and no collaborations with pharmaceutical companies will influence ASF's efforts to advocate for accessible, affordable treatments for patients or cause ASF to provide biased information to constituents.

ASF's approach to interacting with pharmaceutical companies was influenced by the consultation with other similarly sized health organizations, including the International FOP Association, the European Federation of Pharmaceutical Industries and Associations (EFPIA) "Code on Interactions between Pharmaceutical Companies and Patient Organizations" and the Pharmaceutical Manufacturers of America (PhRMA) "Principles on Interactions with Patient Organizations."

The principles outlined in this document are intended to guide ASF, including board members, staff, committees and all related parties in engagement with the pharmaceutical industry.

Article II - Company Engagement

ASF seeks mutually beneficial dialogue and information exchange with pharmaceutical companies developing potential therapies for Alport Syndrome according to the following:

1. ASF will actively engage with companies that show interest or activity in drug discovery, preclinical research, or clinical research in Alport Syndrome.

2. ASF will collaborate with companies, at ASF's discretion and in consultation with our Medical and Scientific advisors, which are conducting ethical, high-quality research in a responsible manner, according to industry and international regulatory standards.
3. ASF will seek insight into the company's objectives, plans, and the potential drug being evaluated and will provide companies with community-wide insight and perspective as needed and appropriate.
4. ASF will advocate on behalf of the patient community to make new therapies accessible. Medications can only change lives if patients have access to them.
5. ASF will actively seek the guidance and utilize the expertise of the ASF Medical Advisory Committee throughout the process of working with each company.
6. ASF Board Members and members of the Medical Advisory Committee will disclose any and all relationships with companies with whom ASF engages and will annually sign a statement agreeing to ASF's Conflict of Interest Policy.

Article III - Patient Engagement

ASF encourages and enables direct dialogue between patients and pharmaceutical company representatives for the purposes of promoting disease awareness and sharing patient perspective, according to the following principles:

1. Direct interactions between patients and pharmaceutical companies are best arranged with the involvement of ASF because including a patient organization in these interactions can:
 - a. ensure fairness and transparency within the patient community;
 - b. ensure that the patient community is well and adequately represented to the pharmaceutical company;
 - c. allow for access to experts and professional advisers who can inform the dialogue;
 - d. help avoid misunderstanding in the conversation;
 - e. ensure the protection of patient privacy in any data collection activities;
 - f. allow for the formation of an advisory group, when appropriate
 - g. allow ASF to better understand the needs of both the patient and the pharmaceutical company.
2. Any information learned from these interactions should be shared in an open manner.

3. Personal health data are not recorded by the company without proper informed consent, and that patient identifiers are not recorded at all.
4. For the purpose of raising awareness and providing education about Alport Syndrome, ASF Board Members, staff or individuals representing the Alport Syndrome community may be invited by pharmaceutical companies to speak about Alport Syndrome at internal company meetings, public events hosted by the company, or in meetings with regulatory agencies.
5. To avoid any potential appearance of conflict of interest, Board Members, who have a fiduciary responsibility to ASF and direct the acceptance and use of funds provided by pharmaceutical companies, should not testify at regulatory hearings. Patients and members of the Alport Syndrome community with a connection to the pharmaceutical company, such as relative of an employee or ownership of stock in the company, should also not testify at regulatory hearings.

Article IV - Financial Contributions

All collaboration and communication efforts outlined in this document will be conducted with pharmaceutical companies regardless of their financial support of ASF, or lack thereof. ASF will not operate in any manner as a paid service provider to a pharmaceutical company. However, financial resources are critical for ASF to achieve its mission and vision to improve the lives of all patients affected by Alport Syndrome and therefore, ASF will gratefully accept donations from pharmaceutical companies according to the following principles:

1. Financial contributions from a pharmaceutical company should be initiated by a written request from ASF stating the organization's mission, activities, programs, and reason for the request.
2. A single, unrestricted donation from any given pharmaceutical company in a year is preferable, rather than multiple smaller donations, whenever possible.
3. Donations from pharmaceutical companies must be given in a named manner; ASF does not accept anonymous donations from pharmaceutical companies.
4. Financial contributions should be made either as (1) an unrestricted grant or (2) sponsorship of a specific activity or program initiated by ASF to support its stated mission.
5. ASF Board Members and staff may not receive honoraria to speak on behalf of ASF. Travel expenses incurred to participate in disease-awareness activities may be reimbursed directly to the individual or the organization.

Article V - Clinical Trial and Approved Therapy Communication

ASF will provide information about clinical trials, according to the following principles:

1. ASF shares information about clinical trials with the community to ensure that patients and families are aware of clinical trials and have the opportunity to make informed decisions about participating. The choice to participate in any given trial is an individual one; ASF does not seek to influence that choice, but rather to ensure informed decisions can be made. Patients and families with questions about various trials will be provided with factual information regarding all options and directed to their provider.
2. ASF disseminates accurate, fair and balanced information about clinical trials provided by the pharmaceutical company without additional commentary or opinion that may influence an individual's decision to participate in a clinical trial or that may change the meaning of the information.
3. ASF recognizes that the choice to share information regarding participation in a clinical trial is personal, and does not seek or encourage the sharing of individual clinical trial experiences in social media, email or other means. However, when unsolicited information is shared on ASF's social media platforms, ASF provides pharmaceutical companies with community-wide observations and insight regarding needs and barriers to participation to encourage optimal design and implementation of the trial.
4. ASF board, consultants, volunteers and staff have responsibility to represent ASF in their conduct. Information about clinical trials that is accessible to the community via social media, including in personal blogs or other forms of communication, must adhere to the principles outlined in this document.
5. ASF only provides information about clinical trials that have been approved by appropriate regulatory bodies.
6. ASF does not communicate information in a manner that could be interpreted as advertising or promoting a drug or treatment that has not been approved.
7. When a therapy has received appropriate regulatory approval, ASF disseminates information for educational purposes only and does not promote or encourage the use of any treatment over another. Patients and families with questions about various treatments will be provided with factual information regarding all options and directed to their provider.

Article VI - Patient Privacy

ASF places high value on the privacy of patients. Thus, ASF does not disclose any personal information or information that can identify a patient. The collection of personal health information by a pharmaceutical company for research purposes should be guided by a protocol and reviewed by an ethics committee.

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