



# Our Corporate Policies

## Corporate Relations Policy

Bridge the Gap - Syngap Education and Research Foundation (“BTG”) will enter into corporate relationships for the sole purpose of providing mission related benefits to its members and the BTG community. The Bridge the Gap - SYNGAP Education and Research Foundation will not accept any corporate donation or enter into any corporate relationship that would create a conflict of interest, or even its appearance, with BTG’s mission, sound science, or board-approved policies. All procedures and formal agreements with corporate donors will be designed to prevent any undue influence upon BTG.

Bridge the Gap - Syngap Education and Research Foundation will perform appropriate and adequate due diligence, with respect to all corporate donors, to insure that the company’s activities, affiliations and business practices do not compromise our mission.

In all relations with external organizations, Bridge the Gap - Syngap Education and Research Foundation will act in ways that will only enhance the credibility and professional recognition of BTG. In order to insure that all corporate donations are in alignment with BTG’s mission and are always for the sole benefit of the BTG community, the Board of Directors has approved the following guidelines and principles in regard to corporate support.

## Types of Corporate Support

- Financial and/or in-kind support in the form of grants and/or sponsorships for educational and communications vehicles (i.e., conferences, videos, podcasts, publications and Community Bridge the Gap - Syngap Education and Research Foundation initiatives).
- Financial and/or in-kind support in the form of grants and/or sponsorships for fundraising purposes.
- Strategic alliances that provide improved services for constituents.
- Cause-related marketing.
- Health message promotion.
- Financial grants and/or professional support for clinical trials and research.
- Vested Corporate Interactions to Avoid
- A vested corporation is one that either makes or offers products/services used by an individual with Bridge the Gap - Syngap Education and Research Foundation.
- Bridge the Gap - Syngap Education and Research Foundation will not endorse any other corporation’s product, service or program.



- Bridge the Gap - Syngap Education and Research Foundation will not lend its name to license products, services or programs of other organizations.
- Bridge the Gap - Syngap Education and Research Foundation will not recognize or certify the quality or standards of a particular company, including its products and services.
- Bridge the Gap - Syngap Education and Research Foundation's name and logo should not be associated with a specific branded product of an external company. References to the Bridge the Gap - Syngap Education and Research Foundation website, phone number and address for the purposes of referral information are an exception to the above.

## General Principles

- Bridge the Gap - Syngap Education and Research Foundation will not endorse any corporation or product nor will it allow a corporation's interest to factor into its decision-making process. All unrestricted educational grants received by BTG will acknowledge and recognize the contributing corporate donor, not the company's product (i.e. specific drug).
- In exchange for contributions, the Bridge the Gap - Syngap Education and Research Foundation will allow standard recognition to include, but not be limited to, items such as signage and acknowledgement in BTG publications. Additional types of recognition will be considered on a case by case basis, based on the type of funding or opportunity presented.
- Bridge the Gap - Syngap Education and Research Foundation will not accept grants that may adversely affect its nonprofit status.
- Revenue generated through corporations will be used to advance the mission of Bridge the Gap - Syngap Education and Research Foundation in accordance with the strategic plan.
- Bridge the Gap - Syngap Education and Research Foundation will maintain complete control of the development and implementation of all content and materials related to educational conferences and materials and all research and clinical trials conducted by BTG.
- Corporations providing sponsorships for advocacy and research conferences or symposia will not influence conference content or selection of speakers.
- Bridge the Gap - Syngap Education and Research Foundation will maintain control and discretion over all corporate funds received and will ensure compliance with related grant agreements.

Adopted August 23, 2019



## **Bridge the Gap - Syngap Education and Research Foundation on Organizational Participation in Food and Drug Administration Hearings and Meetings**

The following information details the Bridge the Gap - Syngap Education and Research Foundation 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 Corporate Relations Policy:

Bridge the Gap - Syngap Education and Research 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 Bridge the Gap - Syngap Education and Research 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, Syngap1 Syndrome 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 Bridge the Gap - Syngap Education and Research 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 our Scientific Advisory Board and the Board of Directors of Bridge the Gap - Syngap Education and Research Foundation. These Committees shall make a recommendation to the Board of Directors regarding whether BTG should testify or take similar action. In the event that the Committees recommend that BTG 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 BTG in an official capacity shall be made by BTG's Board of Directors. If a representative of the Bridge the Gap - Syngap Education and Research 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 CEO from representing the interests of the SYNGAP1 community in a manner that is non-specific to individual drugs, biological products, or medical devices.

Bridge the Gap - Syngap Education and Research Foundation staff will monitor the development of drugs, biological products and devices relevant to SYNGAP1, 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 Bridge the Gap - Syngap Education and Research 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 Chief Executive Officer, together with BTG's Board of Directors, will maintain complete control of the development and use of all content and materials produced or used by the Bridge the Gap - Syngap



Education and Research Foundation related to the dissemination of information concerning the development and regulatory approval of drugs, biological products, medical devices, or programs for the treatment of individuals with SYNGAP1.

Nothing in this policy impedes or discourages individual members of the Bridge the Gap - Syngap Education and Research 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 Bridge the Gap - Syngap Education and Research Foundation.

Approved by the Board of Directors on August 23, 2019.

## **Position Statement on Cannabis and Its Derivatives as a Possible Treatment for Epilepsy**

### **Adapted from that of the American Epilepsy Society**

There are many promising new treatments for epilepsy, and several research initiatives are currently underway. Bridge the Gap - Syngap Education and Research Foundation continues to support both government and private funders to develop and complete well-designed clinical research into all promising treatments for epilepsy. Every case of epilepsy is different. Scientific studies help the entire epilepsy community to understand how and why various treatments work and for whom they are effective.

The term “medical marijuana” is a legal definition referring to the use of cannabis on the recommendation of a healthcare provider in certain states. Given that more than 80 active compounds (called “cannabinoids”) derived from the cannabis plant have been isolated, many with various effects on people (including THC which produces a “high”), it is important that an evidence-based approach be taken to the discovery, development, and clinical application of these compounds.

Recently, important research data emerged from scientifically rigorous, double-blind randomized clinical trials on the use of a pharmaceutical formulation of purified, highly concentrated cannabidiol (CBD) for poorly controlled epilepsy in Lennox-Gastaut syndrome (LGS) and Dravet syndrome. These trials demonstrated that CBD is moderately more effective than placebo in treatment of seizures in LGS and Dravet syndrome, CBD has more side effects than placebo, and CBD has interactions with some other drugs. These results are important to the SYNGAP1 community because some individuals with SYNGAP1 also develop LGS.

Results from these scientifically rigorous clinical trials led the FDA to approve a pharmaceutical formulation of purified CBD to treat persons with epilepsy (Epidiolex®). This drug is a schedule V (five) product available by prescription only and provided by specialty pharmacies. The FDA-approved pharmaceutical formulation of CBD cannot be obtained by a marijuana dispensary. When persons purchase cannabis-based products from a dispensary, it is extremely important to understand the product they select may not contain only CBD but also other cannabinoids such as THC, in addition to pesticides or other dangerous impurities of which the concentrations are unknown. Independent laboratory testing of samples of cannabis products have shown the labels on products in dispensaries claiming to have a certain percentage of CBD or THC are often incorrect.



Bridge the Gap - Syngap Education and Research Foundation is supportive of the clinical research initiatives evaluating the effectiveness and safety of cannabis as a possible treatment for resistant epilepsy. BTG supports review of cannabis' status as a Federal DEA Schedule I (one) controlled substance. BTG's call for consideration of rescheduling is not an endorsement of the legalization of marijuana but is a recognition that the current restrictions on the use of cannabis and its derivatives for research continue to stand in the way of scientifically rigorous research into the development of cannabis-based treatments. Bridge the Gap - Syngap Education and Research Foundation understands first-hand the medical complexity of epilepsy associated with SYNGAP1 and the difficult decisions facing people with epilepsy and their families. BTG urges all people touched by epilepsy to consult with an epilepsy specialist and explore the many existing treatment options, so that they can make informed decisions with their specialist that weighs the risks and benefits of the different treatment options.

Adopted by the Bridge the Gap - Syngap Education and Research Foundation Board of Directors on August 23, 2019