



1227 25th St., NW
Washington, DC 20037-1156

Combination Products Coalition

Principles and Mechanics

Mission

The Coalition's Mission is to improve the regulatory environment for combination products. To that end, the Coalition focuses on developing and advocating policy positions on issues affecting combination products.

Principles

With membership in the Coalition come certain rights and privileges. Among those rights and privileges is the right to have a say in all decisions made by, and activities undertaken by, the Coalition. Specifically:

1. Membership control. The decisions and activities of the Coalition will be controlled by the members of the Coalition. No policy decisions will be made or activities undertaken without agreement of the Coalition.
2. Operation by consensus. In most cases, we will seek unanimous agreement on decisions and activities to be undertaken by the Coalition. Any move to allow decision-making by majority rule will require agreement of the Coalition members.
3. Diverse viewpoints. The Coalition is founded on the belief that development of sound policies on combination products requires the unique perspectives of each of the component areas: Drug, device and biologic. With that in mind, the Coalition includes a diverse group of member companies with diverse viewpoints. This diversity is encouraged, and is what differentiates the Coalition from other industry organizations.
4. Meetings. The Coalition typically will meet by teleconference to discuss issues and business pending before it. When appropriate, the Coalition may meet in person at a convenient location. Every effort will be made to schedule meetings during times when the majority of Coalition members are available



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to participate. Notice of teleconferences and in-person meetings typically will be provided by e-mail. Between such teleconferences and meetings, the

Coalition will conduct its business through e-mail and oral communications, unless the Coalition agrees otherwise.

5. Coordination. Bradley Thompson will be responsible for coordinating all Epstein Baker & Green, PC and EBG Advisor services involved in representing the Coalition, including all communications with members of the Coalition.

6. Leaving the Coalition. Any Coalition member is free to leave the Coalition at anytime, for any reason. If at any point your company decides to leave the Coalition simply let us know. Your company will not be billed for the following month, or from that point forward.

Fees

The budget for Coalition activities is developed and managed by the Coalition. As a general matter, the Coalition divides costs of maintaining its activities among member companies. To cover the Coalition's costs, each member company is billed a monthly fee, based on the size of the company:

- Companies over one billion dollars in sales--\$2,000 per month.
- Companies between \$50 million and one billion dollars in sales—\$1,000 per month.
- Companies under \$50 million in sales--\$300 per month.
- Start up companies--\$100 per month

In addition to fees, member companies may be responsible to pay a share of disbursements and certain other expenses incurred in support of the Coalition. Those expenses typically are allocated equally among member companies; they will only be charged to Coalition members if agreed upon by the Coalition.

How to Join

For more information, or to join the Coalition, call Bradley Thompson, (317) 514-5008.