

## **California Compliance Law**

ACell, Inc. has established and maintains a Corporate Compliance Program in accordance with the Compliance Program Guidance issued by the Office of Inspector General, U.S. Department of Health and Human Services. Our Corporate Compliance Program is just one attribute that demonstrates our commitment to high standards of corporate conduct and ethical practices. Our Compliance policies and procedures are built upon the various laws, regulations, industry code (AdvaMed Code of Ethics on Interactions with Healthcare Professionals) and other requirements relevant to ACell business. The AdvaMed Code published by the Advanced Medical Technology Association was developed to provide guidance specifically to the medical device industry. The AdvaMed Code is the equivalent to the voluntary Pharmaceutical Research and Manufacturers of America Code (PhRMA code) on interactions with Healthcare Professionals, which was developed to provide guidance to the pharmaceutical industry.

As a part of ACell's Corporate Compliance Program, an annual dollar limit has been established concerning appropriate items covered by the California Health and Safety Code, §§ 119400-119402, that are provided to Healthcare Professionals. Examples of these items include a modest meal while ACell products, indications, efficacy, etc. are presented. ACell's annual dollar limit is \$1,200 per individual Healthcare Professional. This limit is a maximum amount: it is not an average.

Based upon ACell's good faith understanding of the California Health and Safety Code, ACell excludes certain items and payments from its annual dollar limit, as of July 1, 2016, which are listed below.

- Financial support for continuing medical education forums, including independent education
- Financial support for health education scholarships
- Payments for legitimate professional services, and any meals or expenses associated with the provision of such services, that are based on the Fair Market Value of the services provided
- Educational items that are provided to physicians to give to their patients to assist and enhance the patient's understanding or management of their condition

## **Annual Declaration for Purposes of California Health and Safety Code §§119400-119402**

ACell maintains a comprehensive Corporate Compliance Program and declares, to the best of its knowledge and based upon a good faith understanding of the applicable statutory requirements, that the indicated program encompasses the compliance requirements stated in the California Health and Safety Code. ACell further affirms that the program is designed to detect, prevent, and address misconduct appropriately.

As of July 1, 2016, ACell declares that it is in fundamental compliance with the Corporate Compliance Program described above as it relates to the marketing and promotion of our products and the California Health and Safety Code, §§119400-119402. ACell will continue to assess the Corporate Compliance Program and the overall effectiveness of the program at least annually.

#### **Confidential Reporting of Policy Violations and Misconduct**

ACell 's Ethics and Integrity Hotline can be reached by dialing **844-620-0004**. Additionally, you can visit [www.lighthouse-services.com/acell](http://www.lighthouse-services.com/acell). You also have the option to email [reports@lighthouse-services.com](mailto:reports@lighthouse-services.com). **Please note:** You must include the company name with your report.

For a written copy of this declaration or Compliance Program description please call 1-800-826-2926.