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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

BRUCE A. COHEN, *Chief Counsel and Staff Director*
KOLAN L. DAVIS, *Republican Chief Counsel and Staff Director*

May 4, 2011

Via Electronic Transmission

Michael D. Costelloe
Executive Vice President
American Society of Plastic Surgeons
444 East Algonquin Road
Arlington Heights, IL 60005

Dear Mr. Costelloe

In December 2009, I asked for an accounting of industry funding that the American Society of Plastic Surgeons (ASPS) receives from pharmaceutical and medical device companies as well as foundations established by these companies or the insurance industry. I appreciate your response, which I have attached to this letter. I write today to follow up on any efforts by your organization to improve transparency and accountability in its relationships with the pharmaceutical and device industries.

As I stated in my previous letter, I started my inquiry, in part, as a result of accounts documenting the lack of transparency in financial relationships between the pharmaceutical industry and nonprofit health and medical organizations. Specifically, I cited the April 2008 article in *The Wall Street Journal*, which reported that industry representatives, including ten major drug companies, had formed a coalition to promote looser restrictions on off-label marketing.¹ The coalition had asked the National Alliance on Mental Illness (NAMI) to speak in favor of this issue.

In response to my concerns in my April 2009 letter to NAMI, NAMI began to voluntarily disclose to the public any amount of funding exceeding \$5,000 that it received from pharmaceutical companies and foundations on its website. Further, NAMI began to provide a brief description of the purpose of the funding on its website. I commend NAMI for its leadership and had hoped that when I reached out to your organization and 32 others, your organization would follow NAMI's example and begin posting similar funding information on ASPS's website.

As of the date of this letter, it appears that no additional information regarding your organization's industry funding has been posted on the ASPS's website. If ASPS is currently taking steps to enhance the transparency of its financial relationships with the pharmaceutical

¹ Alicia Mundy, "Off-Label Use of Drugs Gets a Push --- Big Pharma Lobbies Washington to Relax Rules on Marketing," *The Wall Street Journal*, April 18, 2008.

and device industries, I would appreciate information regarding those steps. If not, please explain why your organization does not support the disclosure of funding it receives from pharmaceutical and device companies.

The Medicare Payment Advisory Commission (MedPAC) recommended in a report to Congress in March 2009 that Congress require that pharmaceutical and device companies report their financial relationships with physician groups, patient organizations, and others. More specifically MedPAC said the following:

Given the potential benefits of public reporting, we recommend that the Congress mandate the reporting of comprehensive information on industry relationships with physicians and other health care entities and that the Secretary post this information on a public searchable website.²

MedPAC then went on to say in Recommendation 5-1 that:

The Congress should require all manufacturers and distributors of drugs, biologicals, medical devices, and medical supplies (and their subsidiaries) to report to the Secretary their financial relationship with:...physician groups and other prescribers...patient organizations; and professional organizations.³

I look forward to working with you and other health and medical organizations to further increase sunshine on financial relationships.

Thank you for your cooperation and attention in this matter. I would appreciate a response by May 25, 2011. If you have any questions, please do not hesitate to contact Brian Downey for the Committee on the Judiciary at (202) 224-5225.

Sincerely,



Charles E. Grassley
Ranking Member

Attachments

² Medicare Payment Advisory Commission, "Public reporting of physicians' financial relationships," Report to Congress: Medicare Payment Policy, March 2009.

³ *Id.*

Attachment

December 21, 2009

To: The Honorable Charles E. Grassley, Ranking Member
U.S. Senate Committee on Finance

From: Michael F. McGuire, MD
President, American Society of Plastic Surgeons

Re: Response to Your Letter of December 7, 2009

Dear Senator Grassley:

On behalf of the American Society of Plastic Surgeons (ASPS), I am pleased to respond to the questions you asked in your letter of December 7. We appreciate the chance to describe our policies and activities relating to industry funding and disclosure of conflicts of interest. We have compiled the following information and answers to the questions posed in your letter based on our interpretation of each request. Please let us know if there is additional information that we can provide to assist you with this important initiative.

The mission of the ASPS is to support its members in their efforts to provide the highest quality of care and maintain professional and ethical standards through education, research, advocacy and other professional activities. The ASPS works in concert with the Plastic Surgery Educational Foundation (PSEF), which supports research, international volunteer programs and visiting professor programs.

Today, there are flourishing medical innovations being made in plastic surgery, ranging from breakthroughs in nanotechnology to stem cells, from nerve regeneration to face transplantation, that were not even imagined a decade ago. As national organizations, ASPS and PSEF have contributed to these and other significant medical advancements in part because of industry support. ASPS and PSEF solicit and accept support from companies to help our organizations carryout new and ongoing mission-based programs and initiatives. From January 1, 2006, to December 11, 2009, ASPS/PSEF has received \$7,345,886 from pharmaceutical companies, device companies and their related foundations in the form of unrestricted educational grants, research grants, sponsorships for meetings and programs, and fees associated with company supported satellite symposia. This income represents approximately 7 percent of total ASPS/PSEF operating income over the same period.

As requested in your letter, the tables on the following pages summarize the annual amount of industry funding received by ASPS and PSEF for the years, 2006 through 2009. These tables contain annualized funding from each pharmaceutical company, medical device company as well as their related or affiliated foundations. Additionally, as requested in your letter, the tables categorize

the type of funding received by ASPS/PSEF from each corporate entity into the following categories: 1) *Unrestricted Educational Grants* – defined as a company grant received by ASPS/PSEF to support ASPS/PSEF controlled educational programs, 2) *Research Grants* – defined as a company grant received by ASPS/PSEF to support independent ASPS/PSEF sponsored research fellowships or ASPS/PSEF initiated research projects, 3) *Satellite Symposia* – fees received for a company-supported, planned and controlled programs held adjunct to an ASPS/PSEF meeting. ASPS/PSEF does not plan or control the program and, 4) *Sponsorship for Meetings & Programs* – defined as an agreement in which a company provides support for an ASPS/PSEF product, service, or event in order to have the company's name associated with the product, service or event.

2006
(January 1 - December 31)

Company Name	Unrestricted Educational Grants	Research Grants	Satellite Symposia	Sponsorships for Meetings & Programs	Total Amount Received
INAMED	35,000			80,500	\$115,500
Allergan Medical	90,000		10,000	69,500	\$169,500
Artes Medical, Inc.	25,000				\$25,000
ASSI				2,500	\$2,500
BioForm Medical, Inc.	35,000				\$35,000
Biomet Microfixation				2,500	\$2,500
Byron Medical				5,000	\$5,000
Canfield Scientific, Inc.				35,500	\$35,500
Cardinal Health, Snowden-Pencer Products				2,500	\$2,500
Coapt Systems, Inc.			10,000		\$10,000
Cutera				12,000	\$12,000
Dermik Laboratories	25,003		10,000	165,000	\$200,003
Ethicon	60,336			41,500	\$101,836
Integra LifeSciences				20,000	\$20,000
KCI				151,250	\$151,250
La Roche-Posay Laboratoire Pharmaceutique	5,000				\$5,000
LifeCell Corporation	35,000			7,500	\$42,500
Lumenis, Inc.			10,000		\$10,000
Medicis Aesthetics	25,000		10,000	30,000	\$65,000
Mentor Corporation	25,000		10,000	27,000	\$62,000
Merck & Co., Inc.	7,500		10,000	15,000	\$32,500
Micrins Surgical, Inc.				5,000	\$5,000
MicroAire Surgical Instruments				5,000	\$5,000
Patients Unlimited				2,500	\$2,500
Obagi Medical Products		100,000			\$100,000
Shippert Medical Technologies Corp.				2,500	\$2,500
Skin Ceuticals				2,500	\$2,500
Smith & Nephew Wound Management Div.			10,000		\$10,000
Stryker	35,000			2,500	\$37,500
Totals	\$402,839	\$100,000	\$80,000	\$687,250	\$1,270,089

Notes:

Unrestricted Educational Grants - Company grant received by ASPS/PSEF to support an ASPS/PSEF controlled educational program.

Research Grants - Company grant received by ASPS/PSEF to support independent ASPS/PSEF sponsored research fellowships or ASPS/PSEF initiated research projects.

Satellite Symposia - Fees received for a company-supported, planned and controlled program held adjunct to an ASPS/PSEF meeting. ASPS/PSEF does not plan or control the program.

Sponsorship for Meetings & Programs - An agreement in which a company provides support for an ASPS/PSEF product, service, or event in order to have the company's name associated with the product, service or event.

2007
(January 1 - December 31)

Company Name	Unrestricted Educational Grants	Research Grants	Satellite Symposia	Sponsorships for Meetings & Programs	Total Amount Received
Allergan Medical	60,000	150,000	10,000	135,133	\$355,133
Angiotech, formerly Surgical Spec.	2,500			25,000	\$27,500
Artes Medical, Inc.	25,000			7,875	\$32,875
BioForm Medical, Inc.	25,000				\$25,000
Biomet Microfixation				2,500	\$2,500
Black & Black Surgical				2,500	\$2,500
Byron Medical				5,000	\$5,000
Canfield Scientific, Inc.				9,425	\$9,425
Cutera				10,000	\$10,000
Cynosure Inc.			10,000	15,000	\$25,000
Dermik Laboratories	25,000			45,000	\$70,000
DRE, Inc.				2,500	\$2,500
Ethicon	80,525		5,000	55,000	\$140,525
Ethicon Endo-Surgery, Inc.				233,000	\$233,000
Integra LifeSciences	5,000				\$5,000
KCI	15,000			20,000	\$35,000
KLS-Martin L.P.				5,000	\$5,000
LifeCell Corporation	35,000			3,000	\$38,000
Lumenis, Inc.			10,000		\$10,000
Medicis Aesthetics	25,000		10,000	175,000	\$210,000
Mentor Corporation	25,000		15,000	132,198	\$172,198
Merck & Co., Inc.	15,000			142,200	\$157,200
Obagi Medical Products				9,425	\$9,425
Ortho Dermatologics				50,000	\$50,000
Palomar Medical Technologies, Inc.			10,000		\$10,000
PMT/Permark, Inc.				2,500	\$2,500
Sientra				2,500	\$2,500
Sound Surgical Technologies				2,500	\$2,500
Stiefel, a GSK Company				6,500	\$6,500
Stryker	35,000				\$35,000
Tissue Science				2,500	\$2,500
Totals	\$373,025	\$150,000	\$70,000	\$1,101,256	\$1,694,281

Notes:

Unrestricted Educational Grants - Company grant received by ASPS/PSEF to support an ASPS/PSEF controlled educational program.

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Satellite Symposia - Fees received for a company-supported, planned and controlled program held adjunct to an ASPS/PSEF meeting. ASPS/PSEF does not plan or control the program.

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2008
(January 1 - December 31)

Company Name	Unrestricted Educational Grants	Research Grants	Satellite Symposia	Sponsorships for Meetings & Programs	Total Amount Received
Allergan Foundation		35,000		35,000	\$70,000
Allegan Medical	85,000		20,000	235,300	\$340,300
Angiotech, formerly Surgical Spec.				3,000	\$3,000
Artes Medical, Inc.	15,000			57,875	\$72,875
ASSI				2,500	\$2,500
BioForm Medical, Inc.				2,500	\$2,500
Biomet Microfixation				2,500	\$2,500
Black & Black Surgical				2,500	\$2,500
Candela Corp.			20,000		\$20,000
Canfield Scientific, Inc.	5,000			23,000	\$28,000
Cardinal Health, Snowden-Pencer Products				5,000	\$5,000
Cutera				18,800	\$18,800
Cynosure			20,000	8,800	\$28,800
Dermik Laboratories	15,000			70,000	\$85,000
EclipseMed South, LTD				8,750	\$8,750
Ethicon	10,000			97,500	\$107,500
Ethicon Endo-Surgery, Inc.				238,000	\$238,000
Integra LifeSciences	15,000	5,000		15,000	\$35,000
Johnson & Johnson Cons. Prod Co.		150,000			\$150,000
KCI		50,000		110,000	\$160,000
KLS-Martin L.P.				7,500	\$7,500
LifeCell Corporation	40,000	75,000	5,000	2,500	\$122,500
Lumenis, Inc.				8,750	\$8,750
Medicis Aesthetics	20,000		20,000	161,300	\$201,300
Mentor Corporation	20,000	150,000	45,000	208,500	\$423,500
Merz Pharmaceuticals				25,000	\$25,000
Midwest Healthcare, Inc.				2,500	\$2,500
Obagi Medical Products				50,000	\$50,000
Ortho Dermatologics	15,000		20,000	8,800	\$43,800
Palomar Medical Technologies, Inc.				8,000	\$8,000
Sientra		30,000		102,500	\$132,500
Sound Surgical Technologies			5,000	7,500	\$12,500
Stryker				21,500	\$21,500
TEI Biosciences				2,500	\$2,500
Totals	\$240,000	\$495,000	\$155,000	\$1,552,875	\$2,442,875

Notes:

Unrestricted Educational Grants - Company grant received by ASPS/PSEF to support an ASPS/PSEF controlled educational program.

Research Grants - Company grant received by ASPS/PSEF to support independent ASPS/PSEF sponsored research fellowships or ASPS/PSEF initiated research projects.

Satellite Symposia - Fees received for a company-supported, planned and controlled program held adjunct to an ASPS/PSEF meeting. ASPS/PSEF does not plan or control the program.

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2009
(January 1 - December 11)

Company Name	Unrestricted Educational Grants	Research Grants	Satellite Symposia	Sponsorships for Meetings & Programs	Total Amount Received
Allergan Foundation		50,000		35,000	\$85,000
Allergan Medical	85,000		60,000	220,666	\$365,666
ASSI				2,500	\$2,500
Auxilium Pharmaceuticals, IL				47,000	\$47,000
BioForm Medical, Inc.	15,000			2,500	\$17,500
Biomet Microfixation				2,500	\$2,500
Black & Black Surgical				2,500	\$2,500
Canfield Scientific, Inc.				15,500	\$15,500
Clinic Photage				2,500	\$2,500
Contura	20,000				\$20,000
Covidien			25,000		\$25,000
Cynosure Inc.			25,000		\$25,000
Dermik Laboratories	15,000			32,500	\$47,500
EclipseMed South, LTD			25,000		\$25,000
Ethicon				109,000	\$109,000
Ethicon Endo-Surgery, Inc.				112,000	\$112,000
Integra LifeSciences				17,500	\$17,500
Johnson & Johnson Cons. Prod Co.		50,000			\$50,000
KCI		50,000		35,000	\$85,000
KLS-Martin L.P.				7,500	\$7,500
LifeCell Corporation	35,000				\$35,000
Lumenis, Inc.			25,000		\$25,000
Medicis Aesthetics	15,000		50,000	175,000	\$240,000
Mentor Corporation	15,000		25,000	289,080	\$329,080
Merz Pharmaceuticals	25,000				\$25,000
MTI				2,500	\$2,500
Obagi Medical Products				50,000	\$50,000
Ortho Dermatologics	15,000			50,000	\$65,000
PMT/Permark, Inc.				2,500	\$2,500
Santa Barbara Medical Innovations				10,000	\$10,000
Sientra				40,000	\$40,000
Sound Surgical Technologies				2,895	\$2,895
Stryker	15,000			2,500	\$17,500
Suneva Medical, Inc.				5,000	\$5,000
Synovis Surgical Innovations			25,000		\$25,000
Totals	\$255,000	\$150,000	\$260,000	\$1,273,641	\$1,938,641

Notes:

Unrestricted Educational Grants - Company grant received by ASPS/PSEF to support an ASPS/PSEF controlled educational program.

Research Grants - Company grant received by ASPS/PSEF to support independent ASPS/PSEF sponsored research fellowships or ASPS/PSEF initiated research projects.

Satellite Symposia - Fees received for a company-supported, planned and controlled programs held adjunct to an ASPS/PSEF meeting. ASPS/PSEF does not plan or control the program.

Sponsorship for Meetings & Programs - An agreement in which a company provides support for an ASPS/PSEF product, service, or event in order to have the company's name associated with the product, service or event.

1. Please describe the policies for accepting industry funding and whether or not ASPS allows companies to place restrictions or provide guidance on how funding will be spent.

In 2001, the ASPS and PSEF adopted guidelines for engaging in funding relationships with industry. A copy of the guidelines, revised in 2009, immediately follows the response to this question.

A fundamental principle to our Corporate Guidelines is that all interactions with industry must relate to the missions of ASPS or PSEF, and be guided by ASPS/PSEF's educational and ethical standards. In addition to ASPS/PSEF Corporate Guidelines, the ASPS/PSEF adheres to Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, American Medical Association Guidelines on Acceptance of Gifts from Industry and all guidance issued by the Internal Revenue Service. ASPS/PSEF also monitors and supports the codes on interactions with health professionals adopted by the Advanced Medical Technology Association and the Pharmaceutical Research and Manufactures of America. Corporate funding of ASPS/PSEF programs is intended to support the educational, research or member service activities of the organization and will not be used to directly or indirectly promote a company's products. ASPS/PSEF strictly maintains editorial control over any information produced related to the funded program.

ASPS/PSEF may solicit corporate support to help underwrite the cost or partial cost of our programs and initiatives. When ASPS/PSEF determines that it is appropriate to pursue corporate relationships for supporting a particular program or project the ASPS/PSEF Development Office develops a list of potential industry funders that might have an interest in the ASPS/PSEF initiative. Prior to any corporate funding solicitation, the ASPS/PSEF carefully assesses each program's requirements and based on that assessment, the Development Office arrives at an amount of funding appropriate to seek for support. Whenever feasible, ASPS/PSEF seeks funding from a variety of sources. All solicitations for support are coordinated through the Development Office.

ASPS/PSEF will only accept support from corporations if the acceptance of funds does not pose or imply a conflict of interest or impact the objectivity of ASPS/PSEF and its programs. ASPS/PSEF will not enter into a corporate arrangement where the amount of payment by a corporation is contingent upon attendance at an event or other measures of public exposure. All agreements and pledges of support are in writing and signed by both parties. The company is provided with a clear written statement regarding the amount of support, recognition to be provided, required date of receipt of payment, and all other details pertinent to the conditions of contributed support. Furthermore, ASPS/PSEF reserves the right to terminate any arrangement if the sponsor or its representative or agents engage in any conduct which would lead ASPS/PSEF to reasonably determine that its continued participation in the arrangement with a particular company would adversely affect the goodwill and reputation of ASPS/PSEF. Recognition of support is provided according to ASPS/PSEF Corporate Recognition Guidelines. A copy of the Corporate Recognition Guidelines follows the Corporate Guidelines, at the end of this question's response.

In certain circumstances, ASPS/PSEF does accept corporate funds with restricted purposes. Currently, ASPS/PSEF allows for restricted funds to support distinct PSEF research and clinical fellowships, specific PSEF sponsored research projects and visiting professorships.

**American Society of Plastic Surgeons
and
The Plastic Surgery Educational Foundation**

Corporate Guidelines

The mission of the American Society of Plastic Surgeons is to support its members in their efforts to provide the highest quality of care and maintain professional and ethical standards through education, research and advocacy of socioeconomic and other professional activities. The Plastic Surgery Educational Foundation supports its mission through research and public service activities of plastic surgeons.

ASPS and PSEF have mutually beneficial relationships with corporations. The ASPS/PSEF Corporate Leadership Council is an exciting opportunity to work effectively and appropriately with industry in support of our mission. As such, all corporate arrangements must relate to the organization's mission, and are guided by ASPS/PSEF's educational and ethical standards. This document is intended to provide the principles and guidelines that govern these corporate relationships.

General Guidelines

- 1) When appropriate, ASPS/PSEF may pursue corporate relationships to support activities that further the Society's mission. These relationships primarily include grants and sponsorships. Advertising, exhibiting, member service providers and affinity relationships also constitute corporate relationships, and are governed by the policies for those respective programs.
- 2) ASPS/PSEF accepts support from corporations only if acceptance does not pose or imply a conflict of interest and in no way impacts the objectivity of the association and its programs.
- 3) Where appropriate, ASPS/PSEF seeks funding from a variety of sources. Occasions may arise when support of a specific program from a single source is appropriate, but special care will be taken in these circumstances to avoid conflicts of interest or any perception of conflict of interest.
- 4) Solicitation of support (grants, contributions, sponsorships, underwriting, etc.) for the American Society of Plastic Surgeons/Plastic Surgery Educational Foundation and its programs are to be coordinated through the Development Office. Individual members and chairs of programs may work with the Director of Corporate Relations to identify potential grant sources and contact corporate donors.
- 5) Corporations providing support to ASPS/PSEF are regularly recognized in appropriate public forums, including, but not limited to, at the program funded.

- 6) ASPS/PSEF will not enter into a corporate arrangement where the amount of payment by the corporation is contingent upon attendance at an event or other measures of public exposure.
- 7) The ASPS/PSEF name, logos and/or other identifying information may only be used on non-Society materials with the approval and written consent of the ASPS or PSEF Board of Directors or their designees and in accordance with an appropriate license/royalty agreement.
- 8) Where appropriate, ASPS/PSEF will ensure that organizations agree to appropriate indemnification and hold harmless provisions to protect ASPS/PSEF and its officers, directors, employees and agents against any liability that might arise out of the organizations' acts or omissions with respect to a particular arrangement, including but not limited to any acts or omissions relating to the marketing, sale, dissemination, and/or use of a corporate sponsor's products. ASPS/PSEF may also require corporate sponsors to add the Society to the sponsors' liability insurance where appropriate.
- 9) ASPS/PSEF reserves the right to terminate any corporate arrangement if the sponsor or its representatives or agents engage in any conduct, including but not limited to product promotion activities, which would lead ASPS/PSEF to reasonably determine that its continued participation in the arrangement with a particular company would adversely affect the goodwill and reputation of ASPS/PSEF.
- 10) Payment shall be made to ASPS/PSEF under any joint support agreement entered into with a corporation and any other society.
- 11) Only funds contributed directly to ASPS/PSEF or under a joint support agreement shall be applied to membership in the Corporate Leadership Council. Funds contributed to any sister society do not apply to CLC membership.

Grant and Support Policies:

Corporate support may be solicited to help underwrite the cost or partial cost of ASPS/PSEF programs. Support provided to PSEF is usually in the form of a tax-deductible charitable contribution while support for ASPS programs is in the form of a non-charitable sponsorship fee.

- 1) Corporate support of ASPS/PSEF programs is intended to support the educational, research or member service activities of the organization and will not be used to directly or indirectly promote a company's products. Contributed support to the Foundation, beyond normal exhibitor fees, shall not be used as a stipulation for participation in a program.
- 2) Corporate donors and sponsors must represent a product or service that is compatible with the ASPS/PSEF image, its policies and its values.

- 3) All solicitations for support must be coordinated through the appropriate staff. All grants and sponsorships are coordinated through the Development Office, which is responsible for coordination with other appropriate departments.
- 4) In order to be considered final, the Development Office must receive pledges of contributed support in writing. Recognition may be deferred until such time as this written confirmation is received. The donor will be provided with a clear written statement regarding the amount of support, recognition to be provided, required date of receipt of payment, and all other details pertinent to the conditions of contributed support. In cases of significant grants or where the grant substantially underwrites a program and/or the donor is the sole sponsor, a contractual agreement may be required. In cases where recognition exceeds incidental value, the donor will be provided with notice of deductible and non-deductible amount of the payment.
- 5) Pledged support will be payable no later than six weeks prior to the funded program, publication or project start, unless other specific arrangements have been confirmed in writing by ASPS/PSEF.
- 6) Recognition of support will be provided according to ASPS/PSEF Corporate Recognition Guidelines and coordinated through the Development Office. Certain types of recognition may be contingent upon the donor meeting print, publication or other deadlines.
- 7) Recognition shall not include any substantial return benefit other than the appropriate level of recognition for the contribution or sponsorship received. Services or privileges provided to donors within the Guidelines, which do not constitute significant tangible value, are acceptable.
- 8) ASPS/PSEF and the corporate donor will have a signed agreement, maintained by the Development Office, that specifies all terms and conditions of support, including recognition.
- 9) Current donors will be provided with the right of first option for renewal of existing grant or sponsorship support, subject to renewal deadlines.
- 10) ASPS/PSEF will maintain editorial control over information produced related to the program funded. Materials produced by the grantor in relation to announcement of support or the program funded (including promotional pieces, ad copy or artwork) must be approved by ASPS/PSEF before production. The ASPS/PSEF logos may not be used without written permission from the Society.

Contributions in Support of CME Programs

The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. The American Society of Plastic Surgeons, as an accredited sponsor of CME activity, adheres to the ACCME Standards for Commercial Support of Continuing Medical Education and requires corporate donors to CME activities to abide by these standards as well.

Unrestricted Grants and Contributions

Funding received for unrestricted purposes will be accrued to the general operating support of ASPS/PSEF. Such gifts will be recognized as appropriate and in accordance with the ASPS/PSEF Corporate Contribution guidelines.

Equipment Loans for Educational Programs

ASPS/PSEF periodically requests assistance from corporations with loans of equipment or in-kind contribution of materials for lab sessions at educational programs. The following guidelines will apply to the solicitation and use of this material:

- 1) The Development Office shall be informed of the solicitation of loaned equipment or contribution of in-kind materials for all ASPS/PSEF programs. If requested, Development will assist in coordinating such solicitation.
- 2) In soliciting loaned equipment or contribution of in-kind materials, ASPS/PSEF will strive to equitably approach companies active in the necessary specialty. Every effort will be made to provide a range of equipment brands without bias.
- 3) The physical assignment of equipment in the lab session will be the sole responsibility of ASPS/PSEF. Under no circumstances will corporate representatives be permitted to move equipment once space is assigned.
- 4) Attendance during lab sessions by corporate representatives is at the sole discretion of ASPS/PSEF. Under no circumstances may any promotional activity or sales-related activity take place in the educational session.
- 5) Acknowledgement of loan or in-kind support by corporations will be provided in the printed material for the program. If applicable, the value of in-kind contributions will be recognized as such on ASPS/PSEF corporate donor lists.
- 6) Violation of support guidelines or agreements may jeopardize future participation in ASPS/PSEF programs.

Research Support (Fellowships, Basic Grant)

- 1) The review and awarding of fellowship and research grant applicants will be the sole responsibility of the appropriate ASPS/PSEF Committees.
- 2) Support of the Basic Research Grant program may not be designated to a specific award.
- 3) In cases where a fellowship is fully underwritten by a corporation, the fellowship may be designated for a specific area of research, upon agreement between the corporation and the ASPS/PSEF
- 4) Contributions in support of ASPS/PSEF Fellowship or Basic Research Grants do not entitle the donor to input in selection of grant recipients.
- 5) The minimum amount to “name” a fellowship is \$30,000.

Revised 1/09

Definition of Terms Related to Corporate Relationships

Grant or Contribution

Charitable contribution provided to underwrite the cost or partial cost of a program with no expectation of commercial advantage. Donors receive recognition for their contribution in keeping with ASPS/PSEF Corporate Support Guidelines and in adherence with ACCME guidelines where applicable.

Sponsorship

Company pays cash or in-kind fee in return for access to the commercial potential associated with their support.

Advertising

Company pays a fee for the direct promotion of the company or brand through space or airtime bought for that specific purpose.

Service Provider/Affinity Relationship

Company contracts with the organization for the right to market products or service to the society's members.

Licensing

Company contracts with the society for the right to use the society's logo and terminology for resale.

**American Society of Plastic Surgeons
and
The Plastic Surgery Educational Foundation**

CORPORATE DONOR GIFT CATEGORIES AND RECOGNITION GUIDELINES

Donor (\$500 - \$999)

- Listing in appropriate donor category in ASPS/PSEF Annual Report to Members
- Donor Certificate for your booth at the annual meeting
- Appropriate acknowledgement, if applicable, at the specific program funded

Contributor (\$1,000 - \$2,499)

All of the above, plus:

- Listing on the Corporate Donor sign at the entrance to the Exhibit Hall at the annual meeting
- Listing in the appropriate donor category in the *ASPS/PSEF Member Roster*
- Corporate Donor ribbons for exhibit representatives at the program funded, if applicable

Underwriter (\$2,500 - \$4,999)

All of the above, plus:

- One exhibitor bonus point annually for each \$2,500 in contributed support
- Donor logo next to your listing in the annual meeting Official Program
- Donor logo next to your listing on the annual meeting Web site

Sponsor (\$5,000 - \$9,999)

All of the above, plus:

- Corporate name linked visibly with project funded

Patron (\$10,000 - \$24,999)

All of the above, plus:

- Announcement of gift and project in *Plastic Surgery News*®

Benefactor (\$25,000 - \$49,999)

All of the above, plus:

- Invitation to participate on the annual Corporate Leadership Council with ASPS/PSEF/ASMS leadership
- Special major gift society ribbon for exhibit representatives at all meetings at which you exhibit

President's Circle (\$50,000 or more)

All of the above

- President's Circle ribbon

- 2. If ASPS allows companies to place restrictions on industry funding, then please explain all restrictions and/or guidance for each transfer of value from industry. For every transfer of value with a restriction, please provide the following information: year of transfer, name of company, and restriction placed on funding.**

In cases where a fellowship is fully underwritten by a corporation, the fellowship may be designated for a specific area of research or clinical practice, upon agreement between the corporation and the ASPS/PSEF. Contributions in support of ASPS/PSEF research fellowship and clinical fellowship grants do not entitle the company to participate in the selection of grant recipients. The review and awarding of fellowship grant applications is the sole responsibility of the appropriate ASPS/PSEF Committees. In circumstances where a qualified applicant is not selected, the restricted funds may not be used for other purposes without approval from the company providing the support.

In cases where ASPS/PSEF is seeking corporate support for a specific research project or study, a company may restrict the funding to be used only for activities associated with the administration and conduct of the proposed study. While the company can restrict the use of funds to a specific ASPS/PSEF initiated or sponsored research study, the company cannot have input into the research study's design and conduct or data analysis and subsequent publication.

The following table includes information for projects that received restricted funds from pharmaceutical, medical device companies or related foundations during the period January 1, 2006 through December 11, 2009.

Year of Transfer	Company Name	Total Amount Received	Restricted Purpose
2006	Obagi Medical Products	\$100,000	Skin Products Assessment Research Study
2007	Allergan Medical	\$150,000	BREAST-Q – Patient Reported Outcomes Questionnaire Development Project
2008	Allergan Foundation	\$35,000	Research Fellowship – Breast Reconstruction or Facial Aesthetics
2008	Allergan Foundation	\$35,000	Visiting Professorship Program
2008	J&J Consumer Products	\$150,000	FACE-Q – Patient Reported Outcomes Questionnaire Development Project
2008	KCI	\$50,000	Research Fellowship – Wound Healing
2008	LifeCell Corporation	\$75,000	Research Study - Alloderm Research
2008	Mentor Corporation	\$150,000	BREAST-Q – Patient Reported Outcomes Questionnaire Development Project
2008	Sientra	\$30,000	BREAST-Q – Patient Reported Outcomes Questionnaire Development Project
2009	Allergan Foundation	\$50,000	Research Fellowship – Breast Reconstruction or Facial Aesthetics
2009	Allergan Foundation	\$35,000	Visiting Professorship Program
2009	J&J Consumer Products	\$50,000	FACE-Q – Patient Reported Outcomes Questionnaire Development Project
2009	KCI	\$50,000	Research Fellowship – Wound Healing

3. Please explain what policies, if any, that ASPS plans to adopt to ensure transparency of funding in order to provide a greater public trust in the independence of your organization.

ASPS/PSEF supports the goal of facilitating transparency in order to provide a greater public trust. To that end, we are committed to enforcing systems and policies that align with all laws and reporting requirements (i.e., Sarbanes-Oxley and the new IRS 990 filing requirements). Recognizing the evolving landscape of requirements and expectations, ASPS/PSEF continually evaluates best practices and develop systems to meet the fair transparency that the public expects.

In addition to following applicable legal reporting requirements, ASPS/PSEF demonstrates our commitment to providing appropriate disclosure and transparency in a number of areas. As an accredited sponsor of CME activity, the ASPS adheres to the ACCME Standards for Commercial Support of Continuing Medical Education. Additionally, our commitment to furthering the public trust in our operations is reflected in our long standing involvement with the Council of Medical Specialty Societies (CMSS). ASPS/PSEF is active on the CMSS Task Force that is examining medical society interactions with industry. This Task Force has been developed to identify central principles that help foster greater transparency and maintain actual and perceived independence.

Currently, we are carefully evaluating the appropriate and best course of action to take to address these areas: 1) making conflict of interest policies and forms available to all ASPS members and the public, 2) publically disclosing industry support (educational grants, sponsorships, and charitable donations) beyond what is already disclosed in the IRS form 990, and 3) publically disclosing relationships that society officers and members of the board of directors have with companies.

4. Please explain your policies on disclosure of outside income by your top executives and board members.

In 2003, the ASPS/PSEF adopted a policy on conflicts of interest and a disclosure statement applicable to its officers, directors, trustees, committee chairs, senior administrative staff members, the editor and members of the editorial board of the Society's journal, and others holding leadership positions within the ASPS/PSEF. This policy is regularly reviewed and was last updated in 2008. Copies of both our current conflict of interest policy and disclosure statement are attached, at the end of this question's response.

Each year all affected individuals (as indicated above) sign and submit to the secretaries of the ASPS and PSEF disclosure statements. The disclosure statement specifically requires the individual to disclose compensation from any commercial entity engaged in the health care field, including salary, consulting payments, payments for speaking engagements and royalties. Additionally, such individuals are required by the policy to disclose at the onset of each Executive Committee or Board of Directors meeting any conflicts created by the agenda that were not disclosed in the annual written disclosure statement. A summary of the information disclosed by each officer and board member is provided as part of the materials distributed prior to meetings of the Board of Directors and Executive Committee.

The ASPS/PSEF has a specific process for addressing and resolving conflicts as a component of its policy. More specifically, the ASPS President and the Executive Vice President review the conflict of interest disclosure statements, in advance of each Executive Committee and Board of Directors meeting. In situations where a particular member has a conflict, the President may take a number of steps, including having the affected member not be present while the issue is being considered and voted upon.

In sum, the Society and its related foundation have and have had in place since 2003 an all-encompassing and effective policy on the disclosure and resolution of actual or potential conflicts of interest affecting its officers, directors, committee chairs, senior administrative staff, the editor and members of the editorial board of this journal, and others holding leadership positions.

AMERICAN SOCIETY OF PLASTIC SURGEONS
PLASTIC SURGERY EDUCATIONAL FOUNDATION

Policy on Conflicts of Interest

In order for the Society and Foundation to further the purposes for which they are organized and to maintain the excellent reputation in which they are held by the public and the medical profession, it is important that Society and Foundation decisions and actions not be influenced unduly by any special interests of individual members. The Society and Foundation depend upon their members to shape their policies and the actions of those members in shaping such policies must not be inappropriately affected by outside influences. Therefore, it has always been and continues to be important to identify actual or potential conflicts of interest which might improperly affect Society and Foundation activities and decisions. As the professional and business settings and relationships in which Society and Foundation members play significant roles become increasingly varied and complex, informal means of identifying actual or potential conflicts of interest become increasingly inadequate. Accordingly, the Board of Directors of the Society and the Board of Directors of the Foundation have adopted this more formal system for the disclosure and evaluation of possible conflicts of interest.

A. Definition of a Conflict of Interest.

A conflict of interest is defined as an interest held by a member that could influence the member or be perceived as influencing the member to act contrary to the interests of the Society or the Foundation and for the member's own personal benefit or for the benefit of an immediate family member or business associate. For purposes of this policy an immediate family member is defined as a member's spouse, children, parents, siblings and brothers and sisters-in-law.

B. Duty to Disclose Conflicting Interests.

Each officer, director, trustee, committee chair, senior administrative staff member, the editor and members of the editorial board of the Journal and others holding leadership positions in the Society and Foundation shall disclose all actual or potential conflicts of interest which he or she may identify during the course of his or her service to the Society and Foundation. Sources of possible conflicting interests which must be disclosed include the following:

(1) Interests which may affect economic transactions to which the Society or the Foundation is or may be a direct party. An example would be ownership by a Society or Foundation officer of a material financial interest in a company from which the Society or Foundation makes purchases of goods or services. Ownership of a material financial interest shall mean holding an equity interest of \$25,000 or more in any one commercial entity or holding a financial ownership interest which contributes importantly to the individual's income or holding a position as partner, director, managing partner or key employee.

(2) Interests which might cause a representative of the Society or Foundation to abuse a Society or Foundation position in order to achieve objectives which are inconsistent with the purposes of the Society or the Foundation. An example would be a committee chairperson holding a material financial interest in a company that competes with a company whose product is being reviewed by a Society or Foundation committee.

(3) Affiliations, including officer, director, committee and consulting positions, with organizations which have conflicting or dual goals or have competing business and professional interests or activities. Examples would include participation on the Board of a medical specialty society that conducts competing business activities such as coding and practice management workshops or sponsored insurance programs; participation on the board of a pharmaceutical company which advocates a

reimbursement policy conflicting with that of the Society; serving as a consultant to a company that provides goods and services to Society members; or serving in an officer, director, trustee or committee position in another organization whose membership is comprised principally of surgeons certified by the American Board of Plastic Surgery.

(4) The receipt of research grants or similar contributions from commercial entities from which the Society or Foundation or its members obtain goods or services by an officer or director or by the academic institutions or departments or practice groups with which the officer or director is affiliated.

(5) Other personal relationships, activities or interests that may impair an individual's objectivity or may inappropriately influence the individual's decisions or actions in Society or Foundation matters.

The foregoing examples are illustrative and should not be considered the only ones which might give rise to a conflict of interest. If in doubt, one should err on the side of full disclosure in order to permit an objective and impartial determination of the possible conflict by the Society and the Foundation.

Disclosure Statement

Each Society officer, director, trustee, committee chairperson, senior administrative staff member and the editor and each member of the editorial board of the Journal and each Foundation officer, director and committee chairperson will be required to sign and submit to the Secretaries of the Society and the Foundation annual disclosure statements. Attached to this policy statement as Exhibit A is a copy of such disclosure statement. The Boards of Directors of the Society and Foundation may from time to time amend the content and form of the statement.

Resolving Conflicts

A. Recusal

The President and the Executive Director of the Society shall review the conflict of interest disclosure statements in order to be alert to potential conflicts and to resolve conflicts wherever possible in advance of meetings of the Society's Board and Executive Committee. The President and the Executive Director of the Foundation shall similarly review the conflict of interest disclosure statements in advance of meetings of the Foundation's Board.

When any matter comes before the Board or Executive Committee of the Society or the Board of the Foundation that has the potential to create a conflict for a member, the affected member shall make known the potential conflict, whether or not disclosed by his or her written disclosure statement. Disclosure should be made as soon as practicable to avoid any inadvertent harm to the Society or the Foundation. To ensure appropriate disclosure, a summary of the information disclosed by each Board member with specific financial data redacted will be provided to each Board or Executive Committee member at the beginning of each meeting. The member shall respond to any questions that might be asked by other members of the Board or Executive Committee.

The President, with the assistance of legal counsel, may request the member to:

1. remain in the room, participating fully in the discussion involving the conflict but not vote;
2. remain in the room while the matter is being discussed but not speak or vote;
3. provide his or her opinion and leave the room while the matter is considered and voted upon;
4. remain out of the room while the matter is being considered and voted upon.

The President may also make other determinations related to the matter, including insulating the member from documents that might be related.

If the member disagrees with the ruling of the President or does not agree that a conflict exists, the matter will be referred to the Dissociation/Recusal Committee (“DRC”) consisting of the Executive Director, legal counsel, and the immediate past president. If the member continues to disagree with the recommendation for recusal, the matter will be decided by the Executive Committee by a majority vote.

If the conflict of interest affects the President, the President-Elect is empowered to act and to request that the President recuse himself or herself. The same procedures as outlined above will be followed if the President disagrees with the ruling of the President-Elect. For the duration of the discussion and action on the matter, the President-Elect shall preside.

The minutes of the meeting shall reflect the disclosure of the potential conflict and any actions taken in response to the disclosure.

The foregoing procedure shall also be followed by the Editorial Board and Committees of the Society and Foundation except that in the case of Committees, the Committee Chair and Vice Chair shall perform the functions performed by the President and Vice President.

B. Dissociation

Dissociation refers to a member severing a relationship with another organization which has conflicting or dual goals or has competing businesses or professional interests or activities and which, in the opinion of the Society, poses a sufficient conflict of interest to require such action.

Consideration of dissociation for a member with an organizational conflict may be initiated by any member of the Board of Directors. The request will first go to the DRC. After review, the DRC will make a recommendation to the Executive Committee as to whether the member is to sever his/her relationship with the other organization. A simple majority will be

required for the Executive Committee to recommend dissociation. If the Executive Committee recommends dissociation, the matter will be referred to the Board of Directors, where a two-thirds vote will be required. If the Board of Directors decides upon dissociation, the member may appeal the decision to the Trustees where a two-thirds vote will be required. The Trustees will have thirty (30) days after their review to make their decision, and their decision will be binding.

Conclusion

Because proper disclosure by each individual Society and Foundation leader is essential, it is important to approach with the proper perspective the question of what types of circumstances call for disclosure. The purpose of this policy is not to discourage all involvement by Society and Foundation members in outside activities which might produce actual or potential conflicts with interests of the Society or the Foundation. Common sense should guide all decisions about what to disclose. One reasonable test is whether a particular interest or relationship, if disclosed to the full membership of the Society and Foundation would be likely to cause embarrassment for the Society or Foundation and/or the individual involved or evoke suspicion about the motives behind any Society or Foundation action.

**American Society of Plastic Surgeons
Plastic Surgery Educational Foundation
Conflict of interest disclosure statement by an officer, director,
trustee, chair of a committee, senior administrative staff member and the
Editor and members of the Editorial Board of Plastic and Reconstructive Surgery**

(Please fill in shaded area where applicable)

I, _____, hereby acknowledge that for each of the positions I hold with the Society and/or the Foundation, I occupy a position of trust and that I am expected to act at all times in good faith and with loyalty to the Society and the Foundation. I have read the conflict of interest policy of the Society and Foundation and support its intent. I declare that if any interest of mine or of any individual or entity with whom or with which I have a significant relationship conflicts with my duties and responsibilities to the Society or the Foundation or could be perceived as conflicting with those duties and responsibilities, I shall voluntarily disclose that conflicting interest. In furtherance of the foregoing, the following questions have been answered to the best of my knowledge and belief.

1. **OUTSIDE INTERESTS:** Identify any interests that you or a member of your immediate family have in which you hold a position, including but not limited to a board or officer position, or have a material financial interest in any concern from which the Society or Foundation obtains, or might reasonably in the future be expected to obtain, goods or services, or which is, or might reasonably be expected in the future to be, engaged in activities that compete with the existing or anticipated activities of the Society or the Foundation.

2. **OUTSIDE RELATIONSHIPS:** Identify any relationships in which you render directive, managerial or consultative services to any concern that does business with or competes with the Society or the Foundation.

3. **AFFILIATIONS:** List memberships on the board of directors, officer positions, editorial positions, committee positions or status as a paid or non-paid consultant in any health related association or business concern, specifically including professional associations comprised principally of plastic surgeons certified by the American Board of Plastic Surgery and companies providing good or services to plastic surgeons.

4. **INVESTMENTS:** List and describe with respect to you and your immediate family all investments constituting a material financial interest in any outside interest, as described in question 1., above or a material financial interest in any health-related business concern. A “material financial interest” is defined as holding an equity interest of \$25,000 or more in any one commercial entity or holding a financial ownership interest which contributes materially to the member’s income or holding a position as partner, director, managing partner or key employee. For purposes of this disclosure, stock options shall be considered to be the ownership of an equity interest in a commercial entity even if they have not been exercised or are not currently exercisable.

5. **COMPENSATION:** Identify significant support from any commercial or other source, including any publishing, internet or e commerce organization, engaged in the health care field

or from any outside interest as described in question 1., above. Significant support includes salary, stock options, royalty arrangements, or dividends, anticipated to produce more than \$2,500 in annual income, or payment for speaking engagements (exclusive of reimbursable travel costs) in excess of \$2,500 in any twelve-month period. Please identify the range of the significant support e.g. greater than \$2,500, greater than \$10,000, greater than \$25,000, greater than \$50,000, greater than \$75,000 or greater than \$100,000.

6. INSTITUTIONAL GRANTS. List research grants and similar contributions by commercial entities from which the Society or Foundation or its members obtain goods or services to you individually or to the academic institution or department or practice group with which you are affiliated.

7. OTHER: List any other interests or activities in which you or your immediate family are engaged which might be regarded as constituting a conflict of interest or a potential conflict of interest.

I acknowledge my continuing obligation to report to the Secretary of the Society or the Foundation promptly and in writing on any possible conflict of interest which comes to my attention in the future. I agree not to participate in Society or Foundation meetings in which a matter in which I have a conflict of interest is addressed, unless requested to do so by the presiding officer. I further agree to accept and abide by the decision of the presiding officer that a conflict exists and that my participation in a meeting should be appropriately limited. I further

state that neither I nor any member of my immediate family have accepted gifts, gratuities or entertainment that might influence my judgment or actions concerning the business of the Society or the Foundation, nor while serving the Society or Foundation will I or any member of my immediate family accept such gifts, gratuities or entertainment.

The Conflict of Interest Disclosure Statements will be executed using electronic records and electronic signatures. You agree that clicking “I agree” in connection with this Conflict of Interest Disclosure Statement constitutes your signature on said Conflict of Interest Disclosure Statement.

I Agree

I DO NOT Agree

Name

Date

Member ID

***Once this form is complete and is ready to submit, please send to Kristi Chirumbolo at kchirumbolo@plasticsurgery.org no later than Thursday, December 31, 2009.**

****Please save a copy for your own records.**

5. Please provide the disclosures of outside income filed with your organizations by your top executives and board members.

The following table summarizes the outside income disclosed by the 2008-2009 ASPS/PSEF Board of Directors and senior staff. Immediately after the summary table are copies of the 2008-2009 ASPS/PSEF Board of Directors Conflict of Interest Disclosure Statement as well as senior staff.

2008 – 2009 Board Members	Outside Income	
	Commercial Entity	Amount
John W. Canady, MD	None	None
Paul S. Cederna, MD	None	None
Kevin C. Chung, MD	None	None
Richard A. D'Amico, MD	None	None
Gregory Evans, MD	None	None
Roberta Gartside, MD	None	None
Scot Bradley Glasberg, MD	Lifecell Corporation	Between \$50,000 and \$75,000
	Mentor Corporation	Between \$10,000 and \$25,000
	Gerson Lehrman Group	Between \$10,000 and \$25,000
	Leerink Swann/Medacorp	Between \$2,500 and \$10,000
Arun K. Gosain, MD	None	None
Bahman Guyuron, MD	None	None
Phil Haeck, MD	None	None
Brian M. Kinney, MD	Mentor Corporation	Between \$25,000 and \$50,000
William M. Kuzon, Jr., MD	None	None
W. Thomas Lawrence, MD	None	None
L. Scott Levin, MD	None	None
Michael F. McGuire	Col-Bar Life Sciences	Between \$50,000 and \$75,000
Peter C. Neligan, MB	Journal of Reconstructive Microsurgery	Between \$2,500 and \$10,000
	Quality Medical Publishing, Inc.	Between \$10,000 and \$25,000
Michael W. Neumeister, MD	None	None
Malcolm D. Paul, MD	None	None
Malcolm Z. Roth, MD	Gerson Lehman	Between \$2,500 and \$10,000
Renato Saltz, MD	None	None
Kenneth E. Salyer, MD	None	None
David H. Song, MD	Biomet Microfixation	Between \$75,000 and \$100,000
Nicholas B. Vedder, MD	None	None
Charles Verheyden, MD	None	None

2008 – 2009 Executive Staff	Outside Income	
	Commercial Entity	Amount
Paul Pomerantz	None	None
Carol Lazier	None	None
William F. Seward	None	None
Robert A. Micek	None	None
Jennifer M. Krejci	None	None
Lynn Kahn	None	None
Keith M. Hume	None	None
Russ Holbrook	None	None
Carlos Fulcher	None	None