



6235 Emerald Parkway  
Dublin, OH 43016

Phone: 614.389.2100  
Fax: 614.389.3816

[www.industryinsights.com](http://www.industryinsights.com)

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Dear John O'Leary and Marie Czenko Kuechel:

The purpose of this letter is to provide the American Society of Aesthetic Plastic Surgeons (ASAPS) with a dermal filler devices adverse events rate, based on the Food and Drug Administration's Executive Summary of Dermal Filler Devices<sup>1</sup> (referred to as "Executive Summary" from this point) and the results of the ASAPS Procedural Statistics Survey (2004 – 2008).

The Executive Summary lists that 930 unique, adverse events reports were filed between January 1, 2003 and September 20, 2008. Of these events, 823 were considered "injuries", and the remaining 107 were identified as "malfunctions" (93)<sup>2</sup> or "other" (14)<sup>3</sup>.

Of the 823 "injuries," 638 reports (77.5%)<sup>4</sup> involved treatments with medication, 94 (11.4%) involved surgical intervention, and 135 reports (16.4%) did not specify treatment. The most common adverse events involved swelling (cited in 40.6% of reports), inflammation (cited in 35.5% of reports), and erythema (cited in 33.4% of reports). Please note, however, that a large number of reports indicated multiple adverse events per patient, so these ailments may have been accompanied by additional adverse events.

Based on the ASAPS Procedural Statistics Surveys, the "Core-Group" of physicians<sup>5</sup> performed a total of 7.6 million dermal filler procedures<sup>6</sup> between 2003 and 2007. To match the Executive Summary's data which stretched to September 20, 2008, the ASAPS Procedural Statistics data from 2006 and 2007 were averaged then extrapolated to reflect the partial year 2008. The extrapolated total is estimated at 9 million dermal filler procedures between January 1, 2003 and September 20, 2008.

Based on the above estimate of 9 million procedures and the Executive Summary's 930 total adverse events reported 0.010% of, or approximately 1 of 10,000, procedures involved an adverse event report. Cases involving "injuries" (823) occurred at a rate of 0.009%, or approximately 1 of 11,000 procedures.

Note 1: The ASAPS Procedural Statistics figure is based solely on the number of procedures performed by the "Core-Group" of physicians and does not include

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<sup>1</sup> *Executive Summary, Dermal Filler Devices: Food and Drug Administration, Center for Devices and Radiologic Health, Office of Device Evaluation, General and Plastic Surgery Devices, Public Advisory Committee Meeting, November 18, 2008.*

<sup>2</sup> 90 reports were related to syringe luer lock problems and needle disengagement. 3 indicated breakage of the syringe.

<sup>3</sup> All "other" reports indicated no patient adverse event as a result of dermal filler injection.

<sup>4</sup> Forty-four reports indicated surgical intervention as well as drug therapy.

<sup>5</sup> The "Core Group" is defined as: Board-Certified Plastic Surgeons, Board-Certified Dermatologists, and Board-Certified Otolaryngologists

<sup>6</sup> Includes: Calcium hydroxylapatite, Collagen, Hyaluronic acid, Poly-L-Lactic Acid, and Polymethyl Methacrylate

other physicians who may perform these procedures. The Executive Summary's figures are based on dermal filler-related adverse events reported by all physician types.

Note 2: The ASAPS Procedural Statistics survey is focused on U.S.-based procedures, whereas the Executive Summary explains that approximately 15-20% of its incidence reports originated outside the U.S.

[Page 25 of the Executive Summary contains an apparent error/mistype. The Executive Summary reads that country of origin is known for 674 reports, of which 739 are from US and 135 outside US. (The sum of US plus outside US totals 874). No further breakdown is provided to explain the difference or to provide guidance about the proportion of incidences that occurred outside the U.S.]

It has been a pleasure working with you. Please let me know if you have any questions and/or if there is anything additional I could do for you.

Sincerely,

A handwritten signature in black ink that reads "Scott A. Hackworth". The signature is written in a cursive style with a large, stylized initial "S".

Scott A. Hackworth, CPA  
Vice President