

**SUMMARY MINUTES**

**OF THE**

**GENERAL AND PLASTIC SURGERY DEVICES ADVISORY PANEL**

**Open Session**

**March 25, 2004  
Gaithersburg Hilton  
Gaithersburg, MD**

**Attendees**  
**General and Plastic Surgery Devices Advisory Panel Meeting**

**March 25, 2004**

**Panel Chair**

Michael A. Choti, M.D.  
Johns Hopkins School of Medicine

**Voting Members**

Brent A. Blumenstein, Ph.D.  
TriArc Consulting

Phyllis Chang, M.D.  
University of Iowa College of Medicine

A. Marilyn Leitch, M.D.  
University of Texas Southwestern Medical  
Center

Joseph LoCicero, III, M.D.  
University of South Alabama

Michael J. Miller, M.D.  
University of Texas, MD Anderson Cancer  
Center

Amy E. Newburger, M.D.  
Dermatology Consultants of Westchester

**Temporary Voting Members**

Douglas G. Fish, M.D.  
Albany Medical College

Stephen Li, Ph.D.  
Medical Device Testing and Innovations,  
LLC

Michael J. Olding, M.D.  
George Washington University School of  
Medicine

Neal S. Penneys, M.D., Ph.D., M.B.A.  
Ameripath

**Consumer Representative**

LeeLee Doyle, Ph.D.  
University of Arkansas for Medical Sciences  
College of Medicine

**Industry Representative**

Grace T. Bartoo, Ph.D., RAC  
Decus Biomedical, LLC

**Patient Advocate**

Robert J. Munk, Ph.D.  
New Mexico AIDS InfoNet

**FDA Personnel**

Celia Witten, Ph.D., M.D.  
Director, Division of General, Restorative  
and Neurological Devices

CDR Stephen Rhodes, USPHS  
Branch Chief  
Plastic and Reconstructive Surgery Devices  
Branch

David Krause, Ph.D.  
Panel Executive Secretary

David Berkowitz, V.M.D., Ph.D.  
Toxicology Reviewer

Herbert Lerner, M.D.  
Lead and Clinical Reviewer

**Panel Executive Secretary David Krause, Ph.D.**, called the meeting to order at 8:05 a.m. and welcomed the participants. He stated that Douglas G. Fish, M.D., a voting member of CDER's Antiviral Drugs Advisory Committee, and Neal S. Penneys, M.D., Ph.D., M.B.A., a consultant to CDER's Dermatologic and Ophthalmic Drugs Advisory Committee, had been granted temporary voting status for the duration of the meeting by Peter J. Pitts, FDA Associate commissioner for External Relations. In addition, panel consultants Stephen Li, Ph.D., and Michael Olding, M.D., had been appointed temporary voting members for the duration of the meeting by David W. Feigal, Jr., MD, MPH, Director, Center for Devices and Radiological Health.

Dr. Krause then read the conflict of interest statement. Full waivers had been granted for A. Marilyn Leitch, M.D., and Michael J. Miller, M.D., who reported current or past interests in firms at issue but in matters not related to the day's agenda; they could participate fully in the meeting. He then turned the meeting over to **Panel Chair Michael A. Choti, M.D.**, who stated that the purpose of the meeting was for the committee to make recommendations to the FDA on a premarket approval application and he then asked the panel members to introduce themselves.

## **PANEL UPDATE**

**CDR Steven Rhodes, Chief, Plastic and Reconstructive Surgery Devices Branch, Division of General, Restorative, and Neurological Devices**, welcomed the panel and provided an update on the division's activities since the last meeting. In December 2003, FDA approved the PMA for Restylane, and the sponsor, Q-Med, agreed to conduct a postapproval study in people of color to gain more safety data. In January 2004, FDA issued a draft revision of the breast implant guidance document, which updated the February 2003 version. The substantive new recommendations in the revised guidance involve mechanical testing, modes and causes of

rupture, clinical study information, postapproval studies, and labeling. Also in January, FDA determined that Inamed's PMA application for silicone gel-filled breast implants was not approvable. The panel had recommended that the device be approved with conditions in October 2003.

## **OPEN PUBLIC HEARING**

Dr. Choti read FDA's statement on transparency of the device approval process and reminded speakers to disclose any possible conflicts.

**Nelson Virgil, AIDS Treatment Activists Coalition (ATAC) and founding member of *Facial Wasting Report***, stated that ATAC supports approval of the Sculptra facial augmentation product. Facial atrophy can have devastating effects on self-esteem and increase anxiety, affecting the effectiveness of antiretroviral drugs (ARVs). Sculptra has been used in more than 100,000 people in Europe and other regions. Twenty-four percent of patients develop palpable but nonvisible subcutaneous facial nodules. Data demonstrate the effectiveness of poly-L-lactic acid (PLLA). He raised four issues: (1) FDA should approve Sculptra for reconstructive, corrective therapy, not cosmetic procedures. Intended use is important for negotiating with third parties for coverage. (2) For Sculptra and other dermal fillers to yield safe and effective outcomes, they should only be administered by clinicians who have met certain training criteria and have a certain level of experience. (3) Long-term data on safety and efficacy are limited; most data relate to applications of lesser volumes than anticipated for correction of facial wasting. A long-term postmarket study is needed. (4) Third-party payment and reimbursement are of significant importance to ATAC. FDA should require the strictest possible labeling, and Dermik should provide a patient support program.

Dr. Krause read two letters into the record from writers who requested anonymity due to concerns about personal and professional repercussions from testifying in public. The first writer said that the results of Sculptra treatment were “miraculous.” The procedure involved minimal discomfort and no side effects and led to full facial restoration. Business associates have provided numerous unsolicited comments. It is important to approve Sculptra because some people stop taking their medications as a result of facial lipoatrophy.

The second writer urged approval of Sculptra. The writer lost self-esteem, confidence, and the will to fight as a result of facial wasting and received Sculptra through a clinical trial. The writer’s quality of life and outlook have since improved.

**Bradley G. Land, HIV+ Fifth District Commissioner for the Los Angeles County Commission on HIV Health Services**, developed facial lipoatrophy that was devastating to him. He became suicidal. Treatment with Sculptra improved his self-esteem, and people no longer treat him as though he were dying.

A woman who requested anonymity testified that she tested positive for HIV in 1996 and developed facial wasting after drug therapy. By 2002, her lipoatrophy was very bad, and people were concerned that she was very sick. She is concerned about AIDS stigma and does not want anyone but her closest family members to know that she has the disease. But for Sculptra treatments, she would be retreating from professional and personal endeavors.

## **SPONSOR PRESENTATION**

**Kimberley Forbes-McKean, Ph.D., Senior Director, Product Development and Commercialization, Dermik Laboratories**, introduced the sponsor speakers and invited experts and outlined the sponsor’s presentation. The proposed indication for use for Sculptra is to correct

shape and contour deficiencies resulting from facial fat loss (lipoatrophy) in people with HIV disease. The PMA was granted expedited review.

Dr. McKean summarized the product development history and stated that the indication in Europe was expanded to include “large volume corrections of the signs of lipoatrophy.” The product was approved in Europe as New-Fill but will be marketed in the United States as Sculptra. It is currently marketed in 33 countries.

**Marcus A. Conant, M.D., Clinical Professor, University of California-San Francisco and Chair of the Conant Foundation**, noted that he has cared for AIDS patients since 1981 and had the largest practice in the world until 1998. He is a consultant to Dermik and has been conducting a sponsor–investigator protocol for the past 4 months.

Since 1996 and the introduction of highly active antiretroviral therapy (HAART), the major issues in AIDS treatment have been treatment adherence and drug resistance, treatment side effects, diarrhea, and lipodystrophy syndrome. HIV patient management has changed dramatically. Facial lipoatrophy is most troublesome to patients. About 50 percent of patients will have perceptible facial lipoatrophy after starting HAART.

Lipodystrophy syndrome consists of hypercholesterolemia, hypertriglyceridemia, insulin-resistant diabetes, facial lipoatrophy, “buffalo hump,” abdominal obesity, and peripheral fat loss. The etiology of the syndrome is not known. Facial lipoatrophy has become the “scarlet letter” of AIDS. Patients refuse medication until their CD4 count is below 300, and even doctors delay treatment because of side effects. Some patients fly to Mexico and Brazil for Sculptra treatment; other patients discontinue HAART. Sculptra is safe and effective.

**Jeffrey A. Handler, Ph.D., DABT, Director, Drug Safety Assessment and Evaluation, Dermik Laboratories**, summarized the preclinical data on the product. Sculptra is

provided in a vial as a sterile lyophilisate that is reconstituted in 3 mL of sterile water for injection. The product consists of PLLA, a synthetic polymer; the L form was selected for slower degradation. The PLLA microparticles are of irregular shape, and  $d_{50}$  ranges from 28 to 60  $\mu\text{m}$ . PLLA has been used for more than 20 years with excellent safety in devices including sealants, flow restrictors, and fixation screws. It breaks down into  $\text{CO}_2$  and glucose. Sculptra also contains carboxymethylcellulose, a suspending agent; and mannitol, a lyophilization enhancer. Both substances are safe and widely used. After reconstitution, Sculptra is stable for up to 72 hours.

PLLA is hydrolyzed slowly. No evidence of lactic acidosis was found in preclinical and clinical studies. Biocompatibility testing was based on ISO 10993 standards and FDA G95-1 guidance for tissue/bone and duration of more than 30 days. Sculptra passed all tests. In a rat subchronic 90-day study, focal granulomatous inflammation with giant cells surrounding foreign polarizing substances occurred in deep dermis in 5 of 20 animals. In a rabbit implantation study, macrophages and giant cells organized around PLLA crystals. In general, Sculptra is well tolerated in mice, rats, and rabbits. It is nonirritating, nonsensitizing, and devoid of genotoxic potential. No indication of systemic toxicity was found in preclinical testing. Testing did find minimal and expected local tissue response, characterized by foreign body reactions. Sculptra is safe in light of preclinical biocompatibility tests.

**Sharon Levy, M.D., Senior Medical Director, Scientific and Medical Affairs, Dermik Laboratories,** noted that Sculptra has been available commercially since 1999 and is marketed in 33 countries worldwide. More than 150,000 patients have been treated with Sculptra since December 2003, and a total of 251 adverse events have been reported during that time, most commonly injection site nodules (124), induration (36), granulomas (12), and inflammation (12). Other adverse events were reported at a frequency of six or fewer, and six adverse events—one

infection, two allergic phenomena, and three nodules—were termed serious. In the one case of ectropion, biopsy showed foreign body giant cell reaction.

Clinical data are from two pivotal studies involving a total of 79 patients, one in France and one in the United Kingdom. Dermik acquired access to the data after the studies were completed. U.S. supportive clinical data come from one compassionate-use study and two sponsor–investigator IDE studies. The Vega study was a 2-year study in France involving 50 patients who each had three to six injection sessions. Patients were treated to effect and received 1 vial of Sculptra per cheek per session. Outcome measures consisted of total cutaneous thickness (TCT), as measured by ultrasound; photographs; and quality of life, as measured by the Visual Analog Scale (VAS) scale. Patients had to be HIV positive and over age 18; on stable HAART; have a viral load of <5,000 copies/mL; cheek adipose tissue of <2 mm; and able to commit to a 2-year study. Confounding treatments were excluded. Forty-seven of the 50 patients completed 2 years of follow-up. The average age was 45, and just one patient was female.

TCT improved throughout the study, from a mean of 8.2 mm at Week 8 to a mean of 10.0 mm at Week 96. Quality of life demonstrated improvement from baseline at all time points. Photographs demonstrated effectiveness. No clinically or statistically significant changes were observed in blood lactic acid, and no clinically relevant changes were identified in CD4 counts and viral load. Six adverse events unrelated to the device occurred. Thirty-five patients had more than one treatment-related adverse event, most commonly transient bleeding (15 patients), injection site bruising (3 patients), transient edema (2 patients), and nodules (26 patients). The nodules noted by investigators were described as “palpable but nonvisible subcutaneous micronodules.” Most nodules occurred within the first year; five resolved, and the others remained stable. None required treatment. Sculptra is safe and effective.

The U.K. Chelsea and Westminster (C&W) study was an open-label, 24-week trial. Patients were randomized to either immediate or delayed treatment groups. Patients had three injection sessions consisting of one vial per cheek. Outcome measures consisted of ultrasound, anxiety and depression scales, laboratory values, and the VAS. Serial photographs were taken, and follow-up took place at 1.5 years, at which time patients were queried for safety events. Patients had to be HIV positive with moderate to severe lipoatrophy; confounding treatments were excluded. All 30 patients who were treated completed the study, but the PMA data are based on 29 patients because one patient declined the sponsor access to the data. All but two patients were male, and the average age was 41. Significant improvements from baseline were observed in skin thickness, VAS assessment, and anxiety and depression. No statistically significant or clinically meaningful differences were seen in laboratory values (including lactic acid), CD4 cell counts, and viral load. Forty-five treatment-related adverse events occurred in 17 patients. The most common adverse events were transient bruising (11 patients), discomfort/erythema/inflammation (3 patients each), and infected lesion (1 patient). All changes were highly statistically significant in both groups. At follow-up, nine patients had nodules similar to those described in the Vega study. The product is effective out to 2 years, as measured by increases in skin thickness and associated improvements in appearance. Adverse events are generally limited to reactions at the injection site. The product is effective for treating the shape and contour deficiencies resulting from lipoatrophy in people with HIV disease

**Peter Engelhard, D.O., Medical Director, APEX South Beach, Miami Beach, FL,** reviewed the U.S. supportive clinical data. Experience from 1,200 patients in Direct Access Alternative Information Resources, a U.S. nonprofit buyers network, found high patient satisfaction and good toleration of the product. A compassionate use study (APEX 001)

involving 100 HIV-positive men also found high patient satisfaction and low rates of product-related adverse events. The APEX 002 study, a sponsor–investigator IDE study of 100 HIV-positive men with facial lipoatrophy, also resulted in high patient satisfaction and low rates of product-related adverse events (primarily mild swelling and transient soreness). Six percent of patients had small, palpable, nonbothersome subcutaneous nodules. Finally, the Mest/Humble study, a sponsor–investigator study of 86 patients that was similarly structured to the APEX studies, attained results similar to those of the APEX studies. Nine percent of patients had small, nonvisible, subcutaneous nodules. No serious adverse events were reported, and no clinically significant changes in laboratory measurements occurred.

Serial injections with Sculptra are safe, well tolerated, long-lasting, and effective. The product results in high patient satisfaction as well as increased skin thickness. Many HIV-positive patients with facial lipoatrophy would benefit from Sculptra treatment. Because lipoatrophy appears to be strongly related to years with HIV and years on ARVs, the number of patients with significant lipoatrophy can be expected to increase.

Dr. McKean summarized the sponsor presentation. PLLA is a synthetic, biocompatible, biodegradable polymer that is safe and has been used in a broad range of products for decades. Facial lipoatrophy is an emotionally devastating problem for people with HIV disease. The psychological impact may affect the desire to continue HAART. A safe and effective treatment for facial lipoatrophy is needed. Sculptra has a favorable risk–benefit ratio and meets a currently unmet medical need.

## **Panel Questions for Sponsor**

Panel members asked questions concerning the location of skin thickening, changes in skin texture or feel, location and other characteristics of nodules, the frequency with which touchups are needed, the product's mode of action, stability of the Sculptra product once reconstituted, and the possible relation of technique to nodule development. Panel members noted the poor quality of the photographic data and lack of appropriate methodology for using the photos in the studies. They suggested that the sponsor collect data to determine possible correlations between patient response to the product and other variables, such as CD4 count and severity of lipoatrophy. They also noted the need for better data on numerous product characteristics, such as particle size and molecular weight. Sponsor representatives responded to their questions.

## **FDA PRESENTATION**

### **Herbert Lerner, M.D., reviewer, Plastic and Reconstructive Surgery Devices**

**Branch, ODE**, presented the Agency's review of the Sculptra PMA. He reviewed the indication for use and product composition and listed the members of the FDA review team.

**David Berkowitz, V.M.D., Ph.D.**, reviewed the toxicology data. None of the testing raised significant toxicological issues. All essential tests were completed. Sculptra particles range in size from 40 to 63 microns; no more than 2 percent may be greater than 63 microns. Resorption kinetics testing in rats found that at 6 months, subcutaneously implanted PLLA rods were 56 percent degraded. Absorption of Sculptra may be faster in humans because of the much larger surface area.

Dr. Lerner reviewed the clinical data and study methodology. None of the trials were controlled, randomized, or blinded; all were open-label, single-center studies. All studies required that patients be HIV positive and on HAART. In all studies, treatment-related adverse

events were generally mild, and nodules were the main device-related adverse event. Most nodules were reported as mild and nonvisible. No histological data on the nodules are available. The APEX studies are valuable primarily for their safety analysis. Patient satisfaction was high in all studies. The fact that some patients stop taking medications to prevent lipoatrophy was taken into account in deciding to give the PMA expedited status.

Finally, a U.S. study in Hermosa Beach, CA, is ongoing; only 15 of 95 patients have completed 6-month follow-up. Inclusion criteria, treatment regimen, and adverse events are similar to those in the APEX studies. The Hermosa Beach study was designed to evaluate the quantifiable improvement in facial wasting after serial intradermal injections. Caliper skin measurements are taken at treatment sessions and at intervals up to 12 months. The average increase in TCT at 6 months is 5.78 mm. Most treatment-related events are mild and consist mainly of pain, bruising, and swelling at the injection site. Device events generally consist of palpable subcutaneous nodules (up to 50 percent of patients develop nodules). No major adverse events have been reported.

With regard to effectiveness, the Agency has concluded that the Vega and C&W studies document increases in dermal thickness. A review of the studies' photos also suggest effectiveness; however, a masked assessment using a validated severity scale was not performed. Quality-of-life assessments report improvement from the baseline. Changes in ultrasonic measurements of cutaneous skin thickness were taken to be a surrogate endpoint for improvement in facial appearance. A statistically significant increase from baseline in TCT was found at every follow-up through 2 years for the Vega study and through Week 24 for the C&W study. No evidence indicated that the effect of the treatment was related to length of time on HAART, baseline CD4 count, or baseline skin thickness. More change in skin thickness was

observed among patients whose skin was thinner at the outset of the study. The sponsor documented that increased skin thickness was pictorially related to improved appearance.

### **Panel Questions for FDA**

Panel members asked whether the effects of different drug regimens had been examined in relation to Sculptra effectiveness, whether granulomatous disease was a contraindication for the product, and whether the effects of Sculptra on keloid development had been examined. FDA representatives noted that no data were available that could answer those questions. Panel members also asked for data on how patients with healthy immune systems or who used the product for cosmetic purposes might react to the product. They suggested that the animal studies cited by the sponsor might not be an accurate reflection of PLLA degradation in humans. Panel members concurred that the sponsor's characterization of how the material works and how long it lasts was inadequate. No data were provided on ideal particle size, concentration, or reconstitution, and it is not clear why nodules form. Moreover, no data are available on the use of the product in women or people of color. The product appears to be effective, however, and it fills an unmet medical need. Several panel members noted that nodules were more appropriately termed papules. Finally, some panel members speculated on motives for the sponsor's regulatory strategy, and most panel members expressed concern about off-label use once the product reaches the market.

### **FDA QUESTIONS FOR PANEL**

**Question 1: Considering the data in the PMA, please comment on whether there is a reasonable assurance that the device is safe.**

The panel concurred that for the proposed indicated use, there is reasonable assurance that the device is safe. Panel members raised concerns about the need for long-term safety data and data on use in women as well as the need for better characterization of the PLLA used in Sculptra.

**Question 2: Considering the data in the PMA, please comment on whether there is a reasonable assurance that the device is effective.**

The panel concurred that the device is effective, based on face validity. Panel members raised concerns about duration of treatment effect and directions for use.

**Question 3: If you agree that there is enough evidence in the PMA to support the safety and effectiveness of the device, do you feel that a postapproval study to assess the long-term use of this device should be initiated? If so, please advise FDA as to the type of data you feel should be collected and the appropriate duration of follow-up.**

The panel concurred that postmarket follow-up is needed. Panel members suggested collecting data including standardized photos; tissue biopsies on papules; patient weight; patient satisfaction and quality of life; number of touchups needed and effects of multiple treatments; duration of HAART before use of the device; and histological and chemical characterization of the mechanism of action and of adverse events. The panel suggested looking for correlations between papule formation and other variables, including the amount of material and its characteristics, CD4 cell count, and ARV treatment. Data on use of the device in women, minorities, and children are needed. Ideal follow-up should consist of a 5-year randomized controlled trial. The sponsor should anticipate widespread off-label use and should work with the Agency to ensure that the postapproval trial is well designed.

**Question 4: Please advise FDA whether a physician training program is indicated for those wishing to use this device, and if so, what type of training would be appropriate.**

The panel agreed that physicians need some kind of specialized training had mixed opinions as to the specifics of such a program. Many panel members said that hands-on training is important.

Some members noted that plastic surgeons and dermatologists already know how to use dermal fillers, so training is more important for physicians who are not plastic surgeons or dermatologists. Other members emphasized that physicians need to realize that most fillers on the market require filling to complete correction or overcorrection, but Sculptra is different because skin continues to thicken after injection. The patient population has other medical issues; the device should not be used by physicians who are not sensitive to those issues. Training materials should reflect that population.

Panel members expressed considerable concern about off-label use of the device. Sponsor representatives noted that an open IDE is examining cosmetic use in people without HIV disease. The ongoing protocols are continuing to follow patients for extended periods. Dr. Mest is conducting a retreatment protocol. No additional studies have been submitted to FDA for review.

## **OPEN PUBLIC HEARING**

Dr. Choti read FDA's statement on transparency of the device approval process and reminded speakers to disclose any possible conflicts.

**Ziya Saylan, M.D., Dusseldorf, Germany,** noted that Sculptra is composed of diverse sugar products, which are breeding grounds for microbes. He presented data on infections in patients receiving the product. Because of the high potential for infection, Sculptra is not a good choice for people with nonintact immune systems. As with all other facial fillers, bleeding, hematomas, infections, abscesses, damage of nerves, necrosis, and infection of veins may occur. Granulomas are problems with Sculptra. It is also difficult to achieve a consistent mixture of the Sculptra solution.

**Gervais Frechette, M.D., an HIV specialist from New York City,** stated that he has worked with people with HIV for 17 years. For the past 6 years, lipodystrophy syndrome has

been a major concern. He has used Sculptra for several years and has not seen rates of infection like those Dr. Saylan described. He presented results from Sculptra injection in several hundred patients along with several before-and-after photos. No adverse events occurred.

**Jill Follows, Senior Health Policy Fellow, National Center for Policy Research for Women and Families**, raised two concerns. First, clinical trials should reflect the diversity of the population that will use the product. The panel should make it clear that data on people of color and of all genders is expected for FDA approval. Second, the center is concerned about the potential for off-label use and requests a black-box warning noting the lack of data on long-term health risks to patients who are not HIV positive and on effects in women, minorities, and children.

## **VOTE**

Dr. Krause read the voting instructions. The panel voted unanimously to recommend approval of the product with the following conditions:

1. The sponsor must conduct a postapproval study of at least 2 years duration that focuses on the issues the panel raised during its discussion, including long-term side effects; adverse events; use in broader populations, including women and minorities; stratification of histological changes; effects of repeat injections; and effects of injection in other sites.
2. The sponsor should develop a training program that focuses on quality and technique and emphasizes the indications for use.
3. Use of the product should be restricted to HIV patients with lipodystrophy.

4. Product specifications must be more fully developed and specific and should be based on the final injected product. The characteristics of the final injected product, including molecular weight, crystallinity, particle size distribution, and resorption rate, are most important.
5. The sponsor should make the following changes to the labeling:
  - The intended use should state that the product is only for “. . . facial fat loss, lipoatrophy, caused by HIV or its treatment.”
  - The warnings should include a stronger statement about avoiding overcorrection.
  - The labeling should state that safety has been established only in adult male Caucasian populations, and not in pregnant women, infants, or children.
  - Under adverse events, the word “nodules” should be changed to language that is consistent with dermatologic practice.
  - The warning should note that 52 percent of patients have nodule formation and that extreme caution must be exercised in periorbital and perioral areas.
  - The precautions should state that Sculptra should be used only by providers with expertise in correcting defects, and then only after a training program and familiarization of the physician with the product and complete package insert.
  - The labeling should state that performance of Sculptra in patients without HIV disease has not been established and may be hazardous to health.
  - The labeling should state that no studies of drug interactions or of long-term safety and efficacy have been conducted with the product.

## **POLL**

Panel members indicated that their votes were motivated by compassion and the general need of the patient population, not by the strength of the data. The device seems safe and effective for use in the identified AIDS patient population suffering from lipoatrophy, but much more data are needed to support general indications for the general population. They urged the manufacturer to heed the panel's recommendations for additional data collection.

## **ADJOURNMENT**

Dr. Choti thanked the participants and adjourned the meeting at 3:49 p.m.

I certify that I attended this meeting of the General and Plastic Surgery Devices Advisory Panel on March 25, 2004, and that these minutes accurately reflect what transpired.

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David Krause, Ph.D.  
Executive Secretary

I approve the minutes of the March 25, 2004, meeting as recorded in this summary.

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Michael Choti, M.D.  
Chairperson

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Panel on April 20, 2004