KING & SPALDING LLP

1730 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706
Fax: 202/626-3737
www.kslaw.com

Edward M. Basile
Direct Dial: 202/626-2903
ebasile@kslaw.com

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VIA HAND DELIVERY

PRIVILEGED AND CONFIDENTIAL: SUBJECT TO ATTORNEY-CLIENT PRIVILEGE AND ATTORNEY WORK PRODUCT DOCTRINE

Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2003P-0530: Silicone Gel-filled Breast Implants (November 19, 2003)

To Whom It May Concern:

This letter is filed on behalf of Inamed Corporation ("Inamed") in response to a Citizen Petition filed by Marlene Keeling, President of Chemically Associated Neurological Disorders ("petitioner"). The petition requests that FDA delay approval of any and all premarket applications ("PMAs") for silicone breast implants ("SBIs"). Specifically, the petition requests that FDA stay any action on the PMA for Inamed's McGhan silicone breast implants until the PMA is amended to meet petitioner's conditions.

There is no basis for FDA to stay its review of Inamed's PMA or issuance of a decision on this PMA. The Food, Drug and Cosmetic Act ("FDCA") gives FDA the ultimate role of assessing the safety and effectiveness of medical devices.[1] The statute also specifies procedures for third-party participation in the process at the time of the advisory panel meeting and *after* an order approving or denying a PMA has been issued by FDA.[2] Rather than following the procedures mandated by Congress, petitioner incorrectly assumes that 21 C.F.R. § 10.35 allows her to step into the role intended for FDA and to compel an applicant to respond to her own assessment of the PMA's adequacy. For these reasons, further discussed below, FDA should deny this petition and proceed to make its own determination of the safety and effectiveness of Inamed's SBIs.

[1] *See* 21 U.S.C. § 393(b)(2)(C) (2003).
[2] *See* 21 U.S.C. 360e(g); 360e(c)(2)(B) (2003).

2003P-0530 C1

I. Introduction

All contentions raised in this petition were presented over two days to the General and Plastic Surgery Devices Panel, October 14 and 15, 2003 ("Panel"). These issues were thoroughly discussed and considered by the Panel, which thereafter voted 9 to 6 to recommend approval (with conditions) of Inamed's SBIs. The petition simply seeks to reargue positions rejected by the panel in order to delay consideration of this PMA and to encumber the statutory PMA evaluation by substituting petitioners' views for those of FDA's PMA reviewers.

II. Following The Failure to Persuade the Panel, Petitioner is Attempting to Usurp FDA's Decision-Making Power.

Petitioner and other SBI opponents already have presented their concerns at the appropriate point in the PMA process. Ms. Keeling had opportunity to present her views on the first day of the Panel meeting.[3] In addition, the FDA gave opponents of SBIs every opportunity to express their viewpoint to the Panel. This included the reading of statements for seventeen individuals who never appeared at the hearing. There were also numerous opponents of SBIs who borrowed time from other speakers who did not appear at the hearing. The net result of these opportunities is that the opponents of SBIs consumed approximately twice as much of the public session as those speakers in favor of SBIs, demonstrating FDA's exceedingly fair in treatment of SBI opponents.

The Panel ultimately found their position unpersuasive. Having failed to persuade at the designated time, and in apparent fear of an outcome contrary to their wishes, the petitioner now seeks to usurp the function of the Office of Device Evaluation ("ODE") by having FDA substitute her analysis of the issues for ODE's, and thereby forestalling a final decision on the PMA.

We believe that ODE and the Center for Devices and Radiological Health ("CDRH") are fully capable of objective PMA evaluation and should be allowed to proceed without further delay. The interruption of the PMA process sought would be unprecedented and would portend poorly for the future. If allowed to succeed, this attempt to derail the legal process would simply encourage competitors and interest groups to obstruct the PMA process in the future. FDA should not allow petitioner to disrupt the orderly and reasoned PMA consideration that the FDCA provides. Petitioner

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[3] *See* Transcript, Oct. 14 at 180. In addition, Ms. Keeling has presented her views on SBIs to FDA on numerous occasions, including: a meeting on November 18, 1997 with Audrey Sheppard, Acting Director of the Office of Women's Health; a statement at CDRH's Stakeholders Meeting, August 18, 1998; a statement at the FDA Modernization Teleconference, June 6, 1999; a meeting on August 31, 1999 with Audrey Sheppard and Dr. David Feigal, Jr., Director of CDRH; a meeting on December 13, 1999 with Audrey Sheppard; and a Citizen Petition filed in November of 2000 seeking "Revocation of Silicone Gel Implants from the Market."

and others opposed to SBIs already have taken full advantage of their opportunity to influence the process, and perforce must await ODE's decision.

A. Petitioner Lacks Standing to Inject Herself into the PMA Process at This Point.

There is no legal basis, cited in the petition or elsewhere, for the relief sought. The regulations cited in the petition are purely procedural. Procedures governing a petition process do not create authority for the relief sought. The lack of substantive authority for a stay coupled with further data submission desired by third parties makes good sense. The statute contemplates FDA evaluation of the PMA at this point—nothing more and nothing less. To stay PMA evaluation based on a claim of public interest, when it is still unclear what final action will be taken and how that might affect the public, is as illogical as it is unauthorized.

B. Applicable Regulations Do Not Contemplate a Stay of the PMA Process and Reflect that Petitioner Cannot Request PMA Amendment.

Petitioner is mistaken if she believes 21 C.F.R. § 10.35 supports her request for a stay of the PMA process. Part 10 of the C.F.R. includes general, procedural provisions that apply only to the extent that they do not conflict with other provisions of Title 21.[4] In the instant matter, these sections conflict with PMA implementing regulations at 21 C.F.R. § 814, and it is these regulations that govern administration of § 515 of the FDCA.[5]

Congress intended to create an orderly PMA review process and prescribed the sequence and conditions for that review. Applicable PMA regulations specify that prior to decision on a PMA, amendments may (a) be submitted at the applicant's initiative, or (b) be requested by FDA.[6] Petitioner has requested that Inamed's PMA be amended according to her own recommendations, but there is no authority for any third-party involvement at this stage of the process. Other applicable regulations address the involvement of the public before PMA approval, viz., at the advisory panel stage, prior to the issuance of the panel's report and recommendation to FDA.[7]

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[4] 21 C.F.R. § 10.1(b) (2003).
[5] 21 U.S.C. § 360e (2003).
[6] 21 C.F.R. § 814.37 (2003).
[7] 21 C.F.R. § 814.44 (2003); *Implementing* 21 U.S.C. 360e(c)(2)(B) (2003).

C. Any Interested Person May Seek Review After FDA has Approved or Denied a PMA.

The FDCA sets out in great detail the administrative procedures pertinent to the PMA process. These provide opportunity for interested parties to raise concerns at designated points in the process. When the FDCA permits interested parties to challenge actions on PMAs, it does not provide for a concomitant stay of the administrative process.[8] Under accepted rules of statutory construction, the creation of a detailed statutory scheme giving specific remedies negates resort to alternative remedies, unless persuasive evidence of a contrary legislative intent is shown.[9] The legislative history here confirms Congress' intent to maintain the PMA process without disruption.[10]

The FDA's regulations correctly implement Congress' intent by creating orderly procedures through which third parties can participate—public comment before FDA's decision, and challenge to the decision by interested persons once the decision has been made.[11] Thus, certain third parties may seek recourse from a PMA approval order. Pursuant to 21 C.F.R. § 814.44(d), FDA will give public notice of the order of approval, and of the opportunity for "any interested person"

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[8] The present circumstances are far different from those in *Bracco Diagnostics, Inc. v. Shalala*, 963 F.Supp. 20 (D.C.D.C. 1997). In *Bracco*, the court granted a preliminary injunction preventing PMA approval until 10 days after FDA responded to the merits of a citizen petition based on a claim "that the FDA ha[d] failed to treat similarly situated products in the same fashion, and that such conduct is arbitrary and capricious." *Bracco* at 31; 5 U.S.C. 706(2)(A). PMA approval was not at issue, and § 515(g) did not apply; plaintiffs were not seeking review of the PMA or trying to stop approval based on its safety and effectiveness, but rather addressing a claim of disparate treatment. *Id.* In contrast, petitioner directly address issues of safety and effectiveness, and uses procedural methods not provided by statute in derogation of those specified for PMA actions under § 515(g). The *Bracco* plaintiffs were seeking review of a final agency decision for which there was no applicable review provision in the FDCA. *Id.* at 30. FDA already had made a final decision to treat one product as a new drug, while treating a competitor's similar product as a device, and there was no statutorily created method for the plaintiffs to seek review. *Id.* at 30. In the present circumstances, FDA has not made a final decision, and the FDCA includes a detailed scheme, which is intended to provide review only for *final* decisions on PMAs.

[9] "When a statute limits a thing to be done in a particular mode, it includes the negative of any other mode." *Transamerica Mortgage Advisors v.Lewis* 444 U.S. 11, 20, 100 S.Ct. 242, 247 (1979); *Botany Mills v. United States*, 278 U.S. 282, 289, 49 S.Ct. 129, 132, 73 L.Ed. 379. See *Amtrak,* 414 U.S., at 458, 94 S.Ct., at 693; *Securities Investor Protection Corp. v. Barbour*, 421 U.S. 412, 419, 95 S.Ct. 1733, 1738, 44 L.Ed.2d 263; *T. I. M. E., Inc. v. United States*, 359 U.S. 464, 471, 79 S.Ct. 904, 908, 3 L.Ed.2d 952.

[10] House Committee Report on Medical Device Amendments of 1976, § 515(g) at 33-34.

[11] 21 C.F.R. § 814.44 (b) and (d)(1) (2003).

to request review under § 515(d)(3) of the FDCA which directs such persons to seek review under § 515(g).[12] Such an interested person may request either a hearing under the Administrative Procedures Act ("APA"), or review by an advisory committee.[13] Through this statutory provision, Congress created recourse for "interested persons" with good cause to seek review of actions on application for premarket approval after the PMA is approved or denied.[14]

D. The Limited Review of PMA Orders Provided by the FDCA is Not Intended to Delay the Process.

Congress has spoken to the precise question of the role of third parties in the PMA process, and FDA "must give effect to the unambiguously expressed intent of Congress."[15] In addition to the creation of a specific method for interested persons to seek *post*-decision review, the legislative history of the statute teaches that such challenges were not intended to stall the PMA process. The House Committee Report on the Medical Device Amendments of 1976 states that while two potential avenues for review are created under § 515(g), *"[n]either form of administrative review operates to stay the contested action under review."*[16] Congress intends that challenges to actions on PMAs not preclude the discharge of FDA's mandate—to make a determination on the reasonable assurance of the safety and effectiveness of medical devices.

II. FDA Should Fulfill its Congressional Mandate by Rendering Its Decision and Providing a Long-Awaited Resolution.

Congress did not bifurcate decision-making power for determining the safety and effectiveness of medical devices. It recognized that FDA's expertise places the agency in the best position to make these determinations. The orderly process for PMA approval does not leave the public unheard or unprotected—rather, it is designed to provide the best information possible, accommodating those members of the public who wish to be involved prior to the recommendation of the panel, and allowing interested parties to request review of actions on PMAs.

The PMA process in § 515 of the FDCA is well-designed to support FDA's evaluation of medical devices, allowing a determination to be made based on science, without disruption at an illogical point or by a method that would set a dangerous precedent of interference with FDA function by parties not contemplated by Congress.

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[12] 21 U.S.C. 360e(g) (2003).
[13] FDCA § 515(g)(1) or (2) (2003); *See* 5 U.S.C. § 554 (2003).
[14] We do not concede that Ms. Keeling or her organization would be "interested parties" or have good cause to seek review under FDCA § 515.
[15] *See Chevron U.S.A. v. National Resources Defense Council, Inc.*, 467 US. 837 (1984).
[16] House Committee Report on Medical Device Amendments of 1976, § 515(g) at 33-34 (emphasis added).

FDA's final decision on whether to approve the PMA for Inamed's SBIs will be the culmination of an 11-year process, and will provide a long-awaited resolution. FDA ran a fair and orderly Panel meeting, giving those with various perspectives on the issues the opportunity to voice their opinions and concerns. FDA's actions demonstrate adherence to its mission of protecting the public health, by considering the safety and effectiveness of Inamed's SBIs in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, and others.[17]

As noted above the opportunity for presentation at the Panel meeting by those opposed to SBIs was more than fair.

The concerns raised in this petition are precisely those raised before and rejected by the Panel. This petition is an effort to manipulate and halt the review process until petitioner's conditions are met. We believe the process should proceed as Congress intended, not as petitioner dictates.

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We respectfully request that in accordance with the FDCA, the petition be denied, that no stay be granted, and that ODE proceed with its review and decision regarding Inamed's PMA.

Sincerely,

Edward M. Basile

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[17] 21 U.S.C. § 393(b) (2003).