LSW
LASIK SURGERY WATCH
www.lasiksurgerywatch.org

October 10, 2009

Donna-Bea Tillman, Ph.D.
Director, Office of Device Evaluation at FDA
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Dr. Tillman:

The members of ***LASIK Surgery Watch (LSW)*** read with great interest an October 14, 2008 letter from FDA scientists and physicians working in the CDRH to Representative John Dingell revealing abuse of the FDA's 510(k) program for clearance of medical devices that have never been clinically evaluated for safety and effectiveness by the agency. LSW was also pleased to learn of your personal effort as Director of the Office of Device Evaluation (ODE) at FDA to address "integrity" problems of the beleaguered 510(k) program.

LSW requests that the ODE review the appropriateness of the 510(k) approval process for the latest technology in LASIK surgery flap creation, femtosecond ophthalmic laser keratomes, which received FDA approval under the 510(K) process - thereby bypassing the rigors and scrutiny of clinical trials. The current IntraLase brand laser keratome was cleared by the FDA on the basis of "substantial equivalence" to a string of a half-dozen or so other Intralase 510(k)'d predicates, beginning in 1999 with a claim of substantial equivalence to a metal blade keratome and an obsolete, dissimilar ophthalmic laser. While the intended use of both blade and laser keratomes is to create a flap in the cornea, technological characteristics of these two devices are not similar as required under 510(k) guidelines.

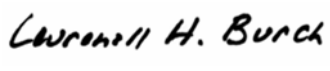
In LASIK surgery, the first step involves cutting a corneal flap with a metal blade called a keratome, or microkeratome. Blade keratomes have been associated with a host of intraoperative complications and serious visual impairment. Newer 'laser keratomes', under the brand names IntraLase, FemTec, and DaVinci, were cleared by the FDA under the 510(k) program. In particular, the IntraLase laser keratome is now widely used by LASIK surgeons to perform LASIK. Like blade keratomes, laser keratomes have never been subjected to the scrutiny of FDA clinical trials. Ironically, the laser keratome ("all-laser LASIK") is now heavily promoted as a safer method of LASIK flap creation with great emphasis placed on its differences from metal blade keratomes.

An obvious omission in the marketing of "all-laser LASIK" or "bladefree LASIK" using laser keratomes is the spectrum of new complications of this technology, which were

never encountered with blade keratomes. Peer-reviewed literature of IntraLase LASIK reveals numerous reports of complications unique to laser keratomes, as well as flap complications similar to those associated with metal blade keratomes[1-3]. The FDA MedWatch database also includes complications associated with laser keratomes, some unique to this device. However, the true incidence of complications associated with the IntraLase is not known due to widespread LASIK surgeon non-compliance with filing of adverse event reports. Unfortunately, most LASIK patients with complications fail to file reports simply because they are not aware of the FDA's voluntary adverse event reporting program.

In light of facts presented here, the FDA was negligent in clearing laser keratomes for LASIK flap creation without rigorous clinical trials. The only remedy available to the FDA to protect public health is to recall these devices until clinical trials are completed. LSW looks forward to an ODE review and response.

Sincerely,



Lauranell H. Burch, Ph.D.
Chair
LASIK Surgery Watch

Matthew Kotsovolos, CPA
Treasurer
LASIK Surgery Watch

Natalie A. Messier
Secretary
LASIK Surgery Watch

cc: **Kathleen Sebelius**
HHS Secretary
U.S. Dept. of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Timothy A. Ulatowski
Director, Office of Compliance
FDA Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20850

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Senator Tom Harkin
Health, Education, Labor, and Pensions Committee
731 Hart Senate Office Building
Washington, DC 20510

David J. Horowitz, J.D.
Assistant Commissioner for Policy
Dept. of Health and Human Services
Office of Policy and Planning
Office of the Commissioner
10903 New Hampshire Avenue
WO1-2217
Silver Spring, MD 20993-0002

Malvina B. Eydelman, M.D.
U.S. Food & Drug Administration
Center for Devices and Radiological Health
Division of Ophthalmic & ENT Devices
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dr. Deborah Carper
Acting Deputy Director
National Eye Institute (NEI)
31 Center Dr., MSC 2510
Building 31, Room 6A03
Bethesda, MD 20892-2510

Diana Zuckerman, Ph.D.
President
National Research Center for Women & Families
1701 K Street, NW, Ste. 700

Judith A. Salerno
Executive Officer
Institute of Medicine
500 Fifth Street NW
Washington, DC 20001

Paul A. Sieving, M.D., Ph.D.
Director
National Eye Institute (NEI)
31 Center Dr., MSC 2510
Building 31, Room 6A03
Bethesda, MD 20892-2510

Andrew M. Pope
Director, Health Sciences Policy
Institute of Medicine
500 Fifth Street NW
Washington, DC 20001

Harvey V. Fineberg
President and Chair
Institute of Medicine
500 Fifth Street NW
Washington, DC 20001

David F. Weeks
Chairman
Research to Prevent Blindness
645 Madison Ave., Floor 21
New York, NY 10022-1010

Clyde J. Behney
Deputy Executive Officer
Institute of Medicine
500 Fifth Street NW
Washington, DC 20001

William Howard Ahmanson
Research to Prevent Blindness Board of Trustee
9215 Wilshire Boulevard
Beverly Hills, CA 90210

Roger C. Herdman
Director, Health Care Services
Institute of Medicine
500 Fifth Street NW
Washington, DC 20001

Jeffrey Shuren, M.D., J.D.
Acting Director, Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Diane S. Swift
President and Assistant Treasurer
Research to Prevent Blindness
645 Madison Ave., Floor 21
New York, NY 10022-1010

The Quaid Foundation
11620 Wilshire Blvd., Suite 460
Los Angeles, CA 90025

John Kusmiersky
Research to Prevent Blindness Trustee
The Brickstone Companies
The Plaza at Continental Park
2101 Rosecrans Avenue
El Segundo, CA 90245-4742

Union of Concerned Scientists
National Headquarters
2 Brattle Square
Cambridge, MA 02238-9105

Citizens for Responsibility and Ethics in Washington (CREW)
1400 Eye Street NW, Suite 450
Washington, D.C. 20005

American Association for Justice
The Leonard M. Ring Law Center
1050 31st Street, NW
Washington, DC. 20007

Talk About Medical Experiences
Pres. & CEO, Dr. J. Talbert
PO Box 6850
Washington, DC. 20020

REFERENCES:

1. Stonecipher KG, Dishler JG, Ignacio TS, Binder PS. Transient light sensitivity after femtosecond laser flap creation: clinical findings and management. J Cataract Refract Surg. 2006 Jan; 32(1):91-4.

2. Bamba S, Rocha KM, Ramos-Esteban JC, Krueger RR. Incidence of rainbow glare after laser in situ keratomileusis flap creation with a 60 kHz femtosecond laser. J Cataract Refract Surg. 2009 Jun;35(6):1082-6.

3. Lifshitz T, Levy J, Klemperer I, Levinger S. Anterior chamber gas bubbles after corneal flap creation with a femtosecond laser. J Cataract Refract Surg. 2005 Nov;31(11):2227-9.