

The Office of the Inspector General (OIG), Department of Defense (DoD) announced today that on December 15, 2000, Lifescan Inc., a Milpitas, CA, subsidiary of Johnson & Johnson, in a plea agreement before Judge Fogel, pled guilty and was sentenced in Federal District Court, Northern District of California, San Jose, CA to pay a criminal fine of \$29.4 million and civil penalties, damages, attorneys fees and restitution to the United States of \$30.6 million. The U.S. Attorney's office charged Lifescan with introducing and delivering for introduction into interstate commerce a misbranded medical device, the SureStep blood glucose monitoring device, failing and refusing to furnish appropriate notifications and information to the Food and Drug Administration and with respect to a medical device, submitting false and misleading reports to the Food and Drug Administration.

The investigation disclosed that Lifescan's SureStep brand blood glucose monitoring system, manufactured and distributed between May 1, 1996 and late 1997, had two defects that would cause SureStep meters to display problematic readings. Lifescan admitted that it failed to describe the two defects in its submissions for U.S. Food and Drug Administration clearance to market the SureStep family of blood glucose monitors, and failed to notify its customers of the defects. Lifescan's SureStep line of blood glucose monitors was marketed commercially throughout the United States. The Government paid a total of \$15,131,628 for the blood glucose monitors and test strips, of which \$4,696,022 was paid by Medicaid, the Veterans Administration and the Department of Defense through its TRICARE program.