

FDA Deputy Chief Sharfstein Leaves Agency

BY ELIZABETH MEHCATIE

Dr. Joshua Sharfstein, the Food and Drug Administration's principal deputy commissioner, has left the agency to become Maryland's health secretary.

Dr. Sharfstein was appointed to the FDA position in May 2009 by President Obama after having served as the acting commissioner for food and drugs for

several months. Previously, he had served as the Baltimore city health commissioner, during which time he questioned the safety of over-the-counter cough and cold products in young children. His efforts received national attention and resulted in FDA hearings on the topic and, ultimately, product restrictions.

During his nearly 2 years at the FDA, Dr. Sharfstein gained a reputation as a

tough, intelligent regulator who, alongside Commissioner Margaret Hamburg, sought to restore the FDA's role as an agency whose foremost mission is to protect and promote public health. Their initiatives included expediting responses to product safety issues and manufacturer violations.

Also during his tenure, the agency re-examined its controversial decision to clear a knee repair device, leading to a cur-

rent re-evaluation of the how the FDA reviews medical devices.

John Taylor, counselor to the commissioner, has been asked to serve as the acting principal deputy commissioner for the next 60 days, the FDA said in a written statement. ■

Jessica Bylander of "The Gray Sheet," also published by Elsevier, contributed to this report.



Important Safety Information, continued

Warnings, continued

Hypoglycemia

Hypoglycemia is the most common adverse effect associated with insulins, including Humalog. Hypoglycemia can happen suddenly, and symptoms may be different for each person and may change from time to time. Severe hypoglycemia can cause seizures and may be life-threatening.

Other Side Effects

Other potential side effects associated with the use of insulins include: hypokalemia, weight gain, lipodystrophy, and hypersensitivity. Systemic allergy is less common, but may be life-threatening. Because of the difference in action of Humalog, care should be taken in patients in whom hypoglycemia or hypokalemia may be clinically relevant (eg, those who are fasting, have autonomic neuropathy or renal impairment, are using potassium-lowering drugs, or taking drugs sensitive to serum potassium level).

Important Safety Information, continued

For additional safety profile and other important prescribing considerations, see the accompanying Brief Summary of full Prescribing Information.

Please see full user manual that accompanies the pen.

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Humalog® **KwikPen**™

insulin lispro injection (rDNA origin)



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