Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, August 24, 2020

DUSA Pharmaceuticals To Pay U.S. $20.75 Million To Settle False Claims Act Allegations Relating To Promotion Of Unsupported Drug Administration Process

Massachusetts-based DUSA Pharmaceuticals, Inc. (DUSA), a subsidiary of Sun Pharmaceutical Industries, Inc. (Sun Pharma), has agreed to pay the United States $20.75 million to resolve allegations that DUSA caused physicians to submit false claims to Medicare and the Federal Employee Health Benefit Program by knowingly promoting an administration process for the drug Levulan Kerastick that contradicted the product instructions approved by the U.S. Food and Drug Administration (FDA) and was unsupported by sufficient clinical evidence.

"The department is committed to protecting taxpayer-supported health care programs from fraud and abuse," said Acting Assistant Attorney General Ethan P. Davis for the Justice Department's Civil Division. "We will hold drug manufacturers accountable when they knowingly promote ineffective uses of their products that undermine patient care or waste program funds."

"While this scheme to provide false instructions on the use of its product may have resulted in more sales and bigger profits, it also meant customers endured the frustration of being repeatedly subjected to less effective treatments to try to get their skin lesions to clear," said U.S. Attorney Brian T. Moran for the Western District of Washington. "This investigation seeks to restore money to taxpayers and discourage those who put profits over effective treatment."

"Drug makers that push the inappropriate use of their products undermine the health of patients and the financial integrity of federal health care programs, said Special Agent in Charge Steven J. Ryan of the U.S. Department of Health and Human Services Office of Inspector General. "Our oversight agency, working closely with our law enforcement partners, will continue to thoroughly investigate those who engage in such schemes."

"The OPM OIG will always seek to hold accountable those prioritizing profits over patient health and safety," said Norbert E. Vint, Deputy Inspector General Performing the Duties of the Inspector General, Office of Personnel Management (OPM) OIG. "This settlement demonstrates the commitment of our investigative staff and partners at the Department of Justice to combat health care fraud against the FEHBP."

Levulan Kerastick is a prescription topical solution approved by the United States Food and Drug Administration (FDA) for the treatment of minimally to moderately thick actinic keratosis (AKs) of the face or scalp. At all relevant times, the "Dosage and Administration" section of the drug's FDA-approved instructions described a two-stage process involving application of the topical solution to the target lesions and then, following an incubation period of 14 to 18 hours, illumination of the target lesion with blue light.

The United States alleged that, by January 2014, senior management at both DUSA and Sun Pharma knew that administration of Levulan Kerastick employing short incubation periods ranging from one to three hours resulted in AK clearance rates significantly lower than those achieved in clinical trials using 14 to 18-hour incubation. Nonetheless, between January 2014 and December 2016, DUSA allegedly
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questions from prescribing doctors. The department further alleged that DUSA failed to inform physicians that administering the drug using short incubation periods resulted in significantly lower AK clearance rates than achieved with the longer incubation period described in the FDA-approved instructions, and, in some instances, the company falsely stated that AK clearance rates were the same for the shorter and less effective incubation periods.

As part of the settlement, DUSA and its parent company, Sun Pharma, have agreed to enter into a Corporate Integrity Agreement with HHS-OIG. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

The settlement with DUSA resolves a lawsuit filed under the whistleblower provision of the False Claims Act, which permits private parties to file suit on behalf of the United States for false claims and share in a portion of the government's recovery. The civil lawsuit was filed by Aaron Chung, who formerly worked for DUSA as a sales representative. As part of today's resolution, Chung will receive approximately $3.5 million.

The settlement with DUSA was the result of a coordinated effort among the U.S. Attorney's Office for the Western District of Washington and the Commercial Litigation Branch (Fraud Section) of the Justice Department's Civil Division, with assistance from HHS' Office of Counsel to the Inspector General, FDA's Office of Chief Counsel, and HHS' Office of General Counsel.

The claims resolved by this settlement are allegations only, and there has been no determination of liability. The lawsuit is captioned *United States of America ex rel. Chung v. DUSA Pharmaceuticals, Inc.*, No. 16 cv 1614-JLR.

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