

Letter to the Editor: The Pundit Speaks

By Randolph M. Howes, M.D., Ph.D.

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“Dietary Supplements Under Federal Investigation”

The Justice Department indicted USP Labs and says it is a "wake up call" for the industry. Indictments have been for mislabeling and making false claims about products. U.S. consumers spend an estimated \$40 billion per year on dietary supplements, noted Acting Deputy Director J. Reilly Dolan of the Federal Trade Commission. "Many deliver what they have promised, but some are nothing more than 21st century snake oil," Dolan said. Up to 50% of Americans are believed to take herbal/dietary supplements. The DOJ announced indictments against Dallas-based workout and dietary supplement maker USP Labs and four of its executives for criminal conspiracy to mislabel and market potentially dangerous products. Subsequently, shares of nutritional-supplement companies tanked. Hardest hit were shares of GNC Holdings Inc., which traded down 27% early and closed down 6.4%, followed by Herbalife LTD, Vitamin Shoppe Inc and Nu Skin Enterprises Inc. The head of the Justice Department alleged that certain USP Labs products had been labeled as being derived from natural plant extracts when they were 100% synthetic. Dolan said the FTC also took action against Sunrise Nutraceuticals for selling a \$75-a-bottle herbal remedy falsely claiming to alleviate the pain of withdrawal for opiate addicts. USP Labs products contributed to an outbreak of liver injuries, with some consumers experiencing jaundice and some requiring liver transplants. The USP Labs indictment is at the center of a yearlong federal investigation into the dietary supplement industry, resulting in a "widespread crackdown on more than 100 companies accused of selling tainted or misleading products." SK Laboratories Inc., which makes supplements for USP Labs, was also charged in the case. USP Labs sold a supplement, OxyELITE Pro, linked to a 2013 outbreak of liver disease that killed one person and sickened 97 people. According to a criminal complaint, USP Labs was directed by the FDA to recall its OxyELITE Pro product in 2013, and while it told the agency it would stop distributing it, it instead began a "surreptitious, all-hands-on-deck effort to sell as much OxyELITE Pro as it could as quickly as possible." Now, however, diet supplement manufacturer USP Labs is stopping nationwide distribution of the diet pill OxyELITE Pro in lieu of a staggering number of liver failure cases associated with the supplement. The FDA warned earlier this year against supplements containing demethylamylamine (DMAA), including OxyELITE Pro, after it was linked to cases of serious illness and even deaths. OxyELITE Pro was sold all over the United States, but all of the known recent hospitalizations have occurred in Hawaii.

In the America that I love, please be very careful with all dietary supplements. Dr. William Lee, University of Texas Southwestern, said, "He would discourage anyone from using an herbal/dietary supplement."

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