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NEWS RELEASE

American Health Care, Inc. and its President Edward Letko agreed today to resolve allegations by the United States that they misled consumers in the sale of diabetic test strips, announced United States Attorney Zane David Memeger. A proposed Consent Decree, which awaits Court approval, prohibits American Health Care and Letko from placing stickers over – or otherwise obscuring – language on the outside of test strip boxes that limits the geographic location where the boxes are to be sold (e.g., language that states that the boxes are “Not for Sale in North America”).

Diabetic test strips are small, flat plastic medical devices. A test strip user places a drop of his blood on the test strip, which he then inserts into a meter. The meter measures blood glucose levels. Test strips are essential in diabetic care. They help a diabetic determine how much insulin he may need to regulate the glucose in his blood.

“Consumers of medical devices must have access to all the information they need to ensure that they know exactly what they are buying, how to use it safely, and what to do if there are problems with it,” Memeger said. “The defendants here took steps to make it difficult for diabetics to be sure that the test strips they were using were effective. Today’s settlement is an important step towards ensuring that diabetics can be confident in the products they buy to help them manage their chronic disease.”

Manufacturers produce test strips in plants around the world. Not all test strips are intended for sale in the United States. Each batch of test strips manufactured at the same time and in the same plant is assigned a unique lot number. Lot numbers become vitally important in the case of any problem with the test strips. If there is a problem with test strips, manufacturers and government agencies will notify the public by referencing the lot numbers.

Test strip boxes intended for sale outside of the United States do not share lot numbers with test strip boxes intended for sale within the United States. If there is a problem with test strips intended for sale outside of the United States, manufacturer’s web sites and toll free telephone numbers meant to inform United States consumers may not list the lot numbers for the problematic test strips.

There is a gray market for diabetic test strips. The gray market exists, in part, because the price for diabetic test strips is higher in the United States than it is in foreign countries. In the gray market, distributors purchase genuine diabetic test strips that are intended for sale outside of the United States. The distributors then ship the test strips to the United States and re-sell them, often to wholesalers or other distributors, at prices lower than those the purchaser would have to pay to obtain test strips meant for sale in the United States.

As part of its business, American Health Care purchased diabetic test strips, not intended for sale in the United States, in markets overseas and then imported the test strips into the United States. American Health Care then sold those test strips to purchasers in the United States.

The United States alleged in a Complaint filed today that, in selling gray market test strips within the United States, it was a practice of American Health Care to place stickers or labels on boxes of test strips to obscure language on the boxes stating that the test strips were not meant for sale in the United States. Should there be a problem with or recall of the lot numbers associated with the test strips that American Health Care sold with such obscuring stickers or labels, the consumer in the United States would find it difficult if not impossible to learn about that problem or recall. The lot numbers associated with the test strips he had purchased likely would not appear on the manufacturer's United States web site. What is more, the toll-free number that would come with some of the test strips meant for sale outside the United States would only work outside of the United States. And, even if the United States consumer reached the manufacturer – using a United States telephone number – he might not get the answers he needs. The United States operator might not be aware of any problems with the lot numbers associated with the test strips he purchased; those lot numbers were not meant for United States consumers after all.

The Consent Decree, to which American Health Care and Letko have agreed, prohibits them from altering any box of diabetic test strips in such a way as to obscure material information on that box. By executing the Consent Decree, American Health Care and Letko have also agreed, going forward, that they will not knowingly put into the stream of commerce any box of diabetic test strips that hides language stating that the box is not meant for sale in the United States. The United States has filed a motion with the Court asking that it approve the Consent Decree.

The case was investigated by the Federal Bureau of Investigation and the Food and Drug Administration's Office of Criminal Investigations, and the Pennsylvania State Attorney General's Office. It is being prosecuted by Assistant United States Attorneys Judy Goldstein Smith and Michael S. Blume.

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