Dynamic Chiropractic

Para Tech and Therasys Indicted on 37 Counts

GRAND JURY INDICTMENT INCLUDES CONSPIRACY TO DEFRAUD, ADULTERATED DEVICE SHIPMENTS AND MAIL FRAUD

Editorial Staff

On February 17, 2000, U.S. Attorney Mary Jo White announced charges against Para Tech Industries, Inc., Therasys, Inc., Ernest S. Philpot, and Paul F. Fulk,DC, of Dayton, Ohio. The grand jury indictment was the result of a continuing investigation by the FBI and the FDA. The charges surrounded the defendants' activities regarding the manufacture and sale of Therarm and CTD-Mark I devices "as FDA-approved devices for the treatment of carpal tunnel syndrome" (CTS). According to the indictment, the devices did not have FDA approval.

The defendants are also accused of making additional false claims that in "empirical testing and evaluation, the CTD-Mark I device has proved simple to use and extremely effective in relieving the symptoms of CTS." The indictment goes on to state that from 1995 through 1999, the defendants falsely reported information, ignored an FDA cease-and-desist letter, attempted to conceal their activities and even hid the devices. During this time, they sold these devices to health care providers, along with "instructional material" that included "recommended codes to use in billing health care benefit programs for the use of the CTD-Mark I in the treatment of carpal tunnel syndrome."

While the U.S. Attorney's Office is aware of some of the "medical equipment consumers" who purchased the equipment, there were apparently many who purchased the devices over the four-year period. Unfortunately, many purchasers of the CTD-Mark I were doctors of chiropractic.

If convicted, the defendants face a maximum sentence of five years in prison on the conspiracy charge, three years in prison for each of the 17 adulterated device shipment counts, and five years in prison on each of the 17 mail fraud counts. The charges also carry possible aggregate fines into the millions of dollars.

This indictment is a dramatic reminder of the need to apply great diligence in assessing any device or product offered by a company that purports to benefit patients. As a standard operating procedure, doctors should request documentation of government authorization of the equipment and copies of viable scientific studies published in recognized research journals that attest to its effectiveness.

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