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Chairman John Dingell
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Ranking Member Joe Barton
Committee on Energy and Commerce
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Chairman Bart Stupak
Subcommittee on Oversight & Investigations
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Ranking Member Ed Whitfield
Subcommittee on Oversight & Investigations
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Washington, DC 20515

Dear Chairmen and Ranking Members:

An exposé published over last several days in the Seattle Times (see attached articles) found “a global network of manufacturers who sell unproven devices, and unlicensed practitioners who prey on unsuspecting patients.” It reported a growing practice of exploiting the uncertainty surrounding so-called energy medicine, a type of alternative treatment that manipulates the body’s energy fields to cure disease and improve health, and the desperation of those suffering from chronic and life-threatening illnesses to profit from the use of unapproved and potentially deadly devices.

An article published as part of the Seattle Times series has brought to my attention one particular unproven and potentially dangerous energy-medicine treatment currently being used in my home state of Washington and at least four other states. The so-called the Pap-Ion Magnetic Inductor (PAP-IMI), which has never been approved by the U.S. Food and Drug Administration (FDA), claims to pulse the body with electromagnetic waves, has been marketed as a rapid-healing machine to patients suffering cancer, AIDS, chronic fatigue and allergies, among other health problems.

According to the report, inventors of PAP-IMI were denied FDA approval in 1995, but have exploited the rules governing clinical trials for devices to treat U.S. patients with almost no oversight. The piece described how unlicensed operators used the unproven device on patients, including infants and seniors, during a supposed multi-site clinical trial; how patients were not properly informed and even misled about the device’s safety and efficacy; how two Floridians died just days after getting PAP-IMI treatments in 2002; and, how the head of the PAP-IMI operation, found a second IRB to continue his clinical trial, where he continued to offer for-profit services from an unapproved use of the device for diagnosis and treatment.

This is one of several examples uncovered by the Seattle Times. I fear these may be the tip of the iceberg when it comes to deadly scams aimed at vulnerable Americans who are sick and holding out

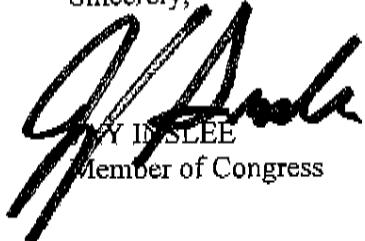
hope for a cure to what ails them. Moreover, I feel that the investigative work started by the Seattle Times raises additional questions about resources for compliance enforcement and oversight at the FDA, oversight of the Institutional Review Boards (IRB) that govern clinical trials for such devices as well as drugs, and oversight and accreditation of unlicensed-medical practitioners.

As a member of the House Energy and Commerce Subcommittee on Oversight and Investigations, which has the responsibility for oversight of FDA, I urge the panel to investigate these troubling claims, especially:

- 1) If FDA has adequate inspection and enforcement tools to locate manufacturing and distribution networks selling and/or operating non-FDA approved devices for various therapeutic outcomes;
- 2) What options does the FDA have to combat overseas exports of unapproved devices, and what legal actions can be pursued against overseas purveyors of devices that flagrantly have ignored FDA's approval standards;
- 3) If rules for clinical trials and IRB's need to be strengthened, particularly with regards to adverse event reporting, FDA oversight of IRB's, and possible statutory or regulatory changes needed to prevent IRB shopping as exhibited in this case;
- 4) If there should be a consolidation of IRB oversight in one office versus splitting it between the Office of Human Research Protections (OHRP) and the FDA as is the case currently;
- 5) If tools for enforcement and oversight of unlicensed professionals need to be increased at the federal and state level, including the accreditation system alternative medicine practitioners;
- 6) If penalties for failing to inform patients about risks or report deaths need to be increased;
- 7) If other unsafe, unproven medical devices are being used on American patients.

Americans with serious or life-threatening illnesses should have the option of turning to alternative or experimental therapies. We must ensure that the FDA has procedures to weed out cases of snake-oil peddlers who recklessly risk the safety and lives of patients. I hope the committee will take immediate action to investigate and protect American patients.

Sincerely,



JAY INSLEE
Member of Congress

Enclosures