FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

January 20, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Chairman Pitts, and Chairman Stearns:

We are writing to renew our October 12, 2011, request for hearings to examine medical devices that have developed serious defects after being implanted in patients and to propose the Committee seek documents related to the "Lap-Band" weight loss device and urogynecologic surgical mesh. The Committee has failed to schedule the hearing we requested in our October 12 letter, and we remain concerned that the Committee's previous hearings on medical devices have presented a skewed and inaccurate picture of the importance of appropriate medical device regulation. We hope you will reconsider your approach so that the Committee can have a fuller understanding of these critical issues as we prepare to reauthorize the Medical Device User Fees Act.

The "Lap-Band" Gastric Band

The "Lap-Band" is a type of gastric band device that is surgically implanted and wrapped around the upper portion of a patient's stomach to reduce the size of the stomach. When the device is effective, patients feel full more quickly and thus are more likely to eat less and lose weight. FDA approved the "Lap-Band" device for obese patients, but has indicated that the device can pose serious risks including erosion of the band through the stomach wall, stretching the esophagus, stretching the stomach pouch, stomach pain, gastroesophageal reflux disease, difficulty swallowing, nausea, and vomiting.[1] In addition, the FDA has said the device is not a "quick fix" for patients struggling with obesity but instead requires "major, long-term changes" to eating habits.[2]

A study published this week in the *Archives of Surgery* raised questions about the effectiveness of gastric banding, finding that after six years, nearly 50% of patients had either not lost weight or had needed the device to be removed and that over 40% of patients experienced long-term complications.[3] The study echoed research published in the journal's March 2011 edition, which found that 40% of patients who received "Lap-Band" surgery had serious complications and concluded that the surgery had "relatively poor long-term outcomes."[4] Similarly, a study in the *Journal of the American Medical Association* reported that 48% of test group members experienced "adverse events" as a result of the procedure and that nearly 30% required "revisional procedures" to enlarge the stomach above the band.[5] A study in the *Journal of Obesity* found high complication and reoperation rates for gastric banding, with 30% requiring an additional operation and 12% requiring the removal of the device altogether.[6]

Even in the face of these serious medical complications, Allergan, the manufacturer of the Lap-Band, is seeking to expand the use of the device in children and young adults. Allergan is currently seeking FDA approval to market the device to children as young as 14, despite concerns among some physicians that the procedure is too drastic or "extreme" for a young person's developing body.[7] The *New York Times* recently reported that the lure of a seemingly

---

[1] Food and Drug Administration, *Medical Devices: Gastric Banding*, (accessed Dec. 13, 2011)
[2] *Id.*
[3] Dr. Sébastien Romy, et al, *Roux-en-Y Gastric Bypass vs. Gastric Banding for Morbid Obesity*, Archives of Surgery (Jan. 16, 2012)
[4] Dr. Jacques Himpens, et al, *Long-term Outcomes of Laparoscopic Adjustable Gastric Banding*, Archives of Surgery (Mar. 21, 2011)
5 Dr. Paul O'Brien, et al, *Laparoscopic Adjustable Gastric Banding in Severely Obese Adolescents*, Journal of the American Medical Association (Feb. 10, 2010)
[6] Dr. Christine Stroh, et al, *Fourteen-Year Long-Term Results after Gastric Banding*, Journal of Obesity (Dec. 22, 2010)
[7] *Young, Obese, and in Surgery*, New York Times (Jan. 7, 2012)

"easy way out" of losing weight may push young people to undergo "Lap-Band" surgery without adequately considering the risks and the dramatic lifestyle changes that are necessary.[8]

The adverse public health consequences associated with use of this device are exacerbated by aggressive marketing and by the lack of a national registry of implanted medical devices, like those that exist in Europe, which would enable public health authorities to obtain more accurate data on the rates of adverse events and device failures.

The tragic results of aggressive marketing by several Lap-Band surgical centers are particularly evident in recent events in Southern California. In December 2011, FDA issued warning letters to a marketing firm called 1-800-GET-THIN, LLC, and eight surgical centers in California that aggressively market the Lap-Band without adequately informing consumers of the risks associated with the device.[9] According to a series of reports in the *Los Angeles Times*, the use of lap-bands by these surgical centers appears to have been associated with significant harm to the health of a number of Southern California patients, including the deaths of five patients since 2009.[10]

Despite these serious risks, 1-800-GET-THIN and the related surgical centers have marketed the device with ubiquitous roadside billboards, advertising inserts, and radio and television ads that "display the smiling faces of thin people and catchy phrases about the benefits" of the surgery.[11] The ads include phrases such as "DIETS FAIL! The Lap-Band Works!" and "Let Your New Life Begin."[12]

The advertisements either do not mention the risk information, qualifying age and weight requirements for the procedure, and the need for meaningful life style change or they present limited information in lettering the FDA called "so small as to render the information

---

[8] *Id.*

[9] Food and Drug Administration, *FDA Issues Warning Letters for Misleading Advertising of Lap-Band* (Dec. 13, 2011)

[10] *FDA Accuses 1-800-GET-THIN of Using Misleading Lap-Band Ads*, Los Angeles Times (Dec. 13, 2011)

[11] *FDA Accuses 1-800-GET-THIN of Using Misleading Lap-Band Ads*, Los Angeles Times (Dec. 13, 2011)

[12] *Allergan CEO Criticizes Lap-Band Billboards*, Los Angeles Times (Feb. 3, 2011)

illegible."[13] One FDA official said he was "astonished" by the number of billboards advertising the procedure and noted that the ads target "a very vulnerable patient population."[14]

Although Allergan has criticized the advertising campaign and issued voluntary advertising guidelines for the "Lap-Band" in February 2011, these voluntary guidelines have not been effective. It is unclear what, if any, direct action Allergan took to prevent 1-800-GET-THIN or the related surgical centers from advertising the "Lap-Band" in a false and misleading way.[15]

Urogynecologic Surgical Mesh

Urogynecologic surgical mesh implants are permanently implanted in the vaginal wall of patients suffering from conditions such as pelvic organ prolapse and urinary incontinence in order to repair weakened or damaged tissue.[16] These mesh devices were permitted on the market under the 510(k) clearance process, meaning that the devices had to demonstrate that they were "substantially equivalent" to one or more devices already on the market. Although clinical data can be required under this clearance process, many submissions are cleared without such data. FDA did not require original clinical studies before clearing urogynecologic surgical mesh through the 510(k) process.[17]

Beginning in October 2008, FDA began to respond to rising reports of complications associated with the surgical mesh by issuing a Public Health Notification calling the transvaginal placement of the mesh "an area of continuing concern."[18] In the three years before the notification, over 1,000 adverse events related to the mesh had been reported to FDA.[19] Over

---

[13] Letter from Steven Silverman, Director, Office of Compliance, Center for Devices and Radiological Health, FDA, to Robert Silverman, Esq., 1-800-GET-THIN, LLC (Dec. 12, 2011)
[14] *FDA Accuses 1-800-GET-THIN of Using Misleading Lap-Band Ads*, Los Angeles Times (Dec. 13, 2011)
[15] *Lap-Band Maker Issues Own Advertising Guidelines*, Los Angeles Times (Dec. 13, 2011)
[16] Food and Drug Administration, *Urogynecologic Surgical Mesh Implants* (Jan. 4, 2012)
[17] FDA Obstetrics and Gynecology Devices Advisory Committee Meeting, Executive Summary, *Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence*, (Sep. 8, 2011)
[18] Food and Drug Administration, *FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse* (July 13, 2011)
[19] *Id.*

the next three years, the number of reported complications rose to more than 2,800, driving FDA to issue an update on the "serious complications" associated with the device in July 2011.[20]

In 2010 alone, nearly 300,000 synthetic vaginal meshes were implanted in American women.[21] The most common complication associated with the device is erosion through the vagina, which can be potentially debilitating for some women and require multiple surgeries to correct.[22] Even with multiple surgeries, some women are never able to recover from the damage.[23]

After years of reports of serious complications associated with use of the device and amid a rising chorus of academic and clinical concern, FDA just last week announced that it was considering reclassifying vaginally implanted surgical mesh as a high risk Class III medical device.[24] The agency ordered 33 manufacturers of the device to conduct postmarket safety studies of the device.[25]

It is unclear when the manufacturers of this device became aware of the serious health risks associated with the device. It is also unclear if the manufacturers and the FDA have taken appropriate steps to protect patients.

Conclusion

We believe the Committee should hold hearings to examine whether FDA device regulation has been ineffective in protecting the public from dangerous medical devices like the Lap-Band and intravaginal mesh. We also believe we should hold hearings on the brain stents and metal-on-metal hip implants mentioned in our October 12 letter.

We further ask that the Committee seek documents relevant to both the Lap-Band and intravaginal mesh devices. In the case of the Lap-Band, we urge you to request documents from Allergan, 1-800-GET-THIN, LLC, and the eight surgical centers named in the FDA's warning letters to learn the degree to which these entities cooperated in the marketing of the Lap-Band,

---

[20] *Id.*
[21] *J&J, C.R. Bard Must Study Safety of Vaginal Mesh, FDA Says*, Bloomberg News (Jan. 5, 2012)
[22] Food and Drug Administration, *FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse* (July 13, 2011)
[23] *Id.*
[24] Food and Drug Administration, *Urogynecologic Surgical Mesh Implants* (Jan. 4, 2012)
[25] *Id.*

what steps were taken to minimize the risks the aggressive marketing campaign posed to patients and children in particular, and to obtain additional information regarding their knowledge of and response to device failures and adverse events. In the case of the intravaginal mesh, we ask that the Committee seek documents from the manufacturers of surgical mesh to ascertain when they first learned of the safety issues associated with certain uses of the device and what, if any, actions they took to limit risks for patients.

As the Committee approaches reauthorization of the Medical Device User Fee Act, we need to understand the safety of devices on the market, the tactics device manufacturers and others use to market these devices, and the extent to which these tactics may increase risks. It is also vital that we understand whether device manufacturers and the FDA are taking appropriate steps to keep hazardous devices from the market and to protect patients from marketed devices that are later discovered to be dangerous.

The Committee's reauthorization of the Medical Device User Fee Act is an important opportunity to improve the efficiency of the FDA's review process while at the same time strengthening assurances of safety and efficacy. Obtaining information about devices like the Lap-Band and intravaginal mesh will be critical to informing members of the Committee on an issue that has thus far been absent from the Committee's record.

Sincerely,

Henry A. Waxman
Ranking Member

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

John D. Dingell
Member of Congress