METALS IN IMPLANTS
IMMUNOLOGY DEVICES FDA PANEL MEETING NOVEMBER 13-14, 2019

WHY COMPREHENSIVE LABEL REGULATION IS NEEDED
TO PROTECT PATIENTS FROM AN IMMUNOLOGICAL PERSPECTIVE
SO YOU HAVE THE NEW HIP...

Your body is reacting to the implant metals from Day 1

Is the Implant Manufacturer Label or FDA - UDI going to help your doctor?
PROBLEM

• **MEDICAL DEVICE LABELS ARE NOT COMPREHENSIVE**

• **INCOMPLETE METAL COMPOSITION LABELS POSE A DIRE HEALTH AND PATIENT SAFETY RISK FOR PATIENTS WITH IMMUNE RESPONSES OR ALLERGIC REACTIONS TO METALS IN MEDICAL DEVICES**
I FOUND OUT THE HARD WAY...
MASS CONFUSION CREATED BY MEDICAL DEVICE MANUFACTURER

• WHICH OF THE 4 COMPONENTS ARE YOU REACTING TO ???

• DIFFERENT DOCTORS GET TOLD INCOMPLETE AND CONFLICTING INFORMATION BY THE MANUFACTURER!!
HIP IMPLANT SYSTEM

- **ACETABULAR CUP** (PELVIC CUP)
- **FEMORAL HEAD** (BALL)
- **FEMORAL STEM** (THIGH COMPONENT)
- **ACETABULAR LINER** (LINING THE METAL ACETABULAR CUP)

http://friction.engr.wisc.edu/home/projects/wear-analysis-of-modular-hip-implants
## FDA: Please Step Up the Labeling Requirements...

- **Acetabular Cup** before liner
- **1. Titanium Cup with Titanium Coating**
- **2. Cobalt-Chromium Cup with Titanium Coating**
- **3. Cobalt-Chromium Cup with Cobalt-Chromium Coating**
- **4. Titanium Cup with Cobalt-Chromium Coating**

- **Femoral Stem**
- **1. Titanium Stem with Titanium Coating**
- **2. Cobalt-Chromium Stem with Titanium Coating**
- **3. Cobalt-Chromium Stem with Cobalt-Chromium Coating**
- **4. Titanium Stem with Cobalt-Chromium Coating**

### What is the FULL metal picture?

Current labels fall short!
WHAT METALS ARE IN THE “HIP IMPLANT SYSTEM?”

- Ti cup Ti coating
- Ti cup CoCr coating
- CoCr cup Ti coating
- CoCr cup CoCr coating
- Ti stem Ti coating
- Ti cup stem CoCr coating
- CoCr stem Ti coating
- CoCr stem CoCr coating
JUST THE HIP IMPLANT’S CUP AND STEM PAIRING WOULD BE ANY OF THE FOLLOWING 16 COMBINATIONS!
A HIP IMPLANT MANUFACTURER’S “MIX & MATCH” SYSTEM BECOMES... A DOCTOR & A METAL ALLERGY PATIENT’S NIGHTMARE!

1. Ti cup Ti coating + Ti stem Ti coating
2. Ti cup Ti coating + Ti cup stem CoCr coating
3. Ti cup Ti coating + CoCr
4. Ti cup Ti coating + CoCr stem Ti coating
5. Ti cup CoCr coating
6. Ti cup CoCr coating + Ti stem Ti coating
7. Ti cup CoCr coating + CoCr stem CoCr coating
8. Ti cup CoCr coating + CoCr stem CoCr coating

Labels NEED to show the base metal AND the added coating PER medical device!! Complete labels are needed to help doctors avoid allergy issues - CoCr alloys have Nickel!! According to ATI, Ti alloys Grade 12 also have Nickel.
DOCTORS NEED TO KNOW
PATIENTS NEED TO KNOW
THE MANUFACTURERS KNOW...
THEY MADE IT!

We want YOU> FDA to PROTECT US: Patients and Doctors- Do NOT be complicit in Manufacturer Incomplete Labeling
I AM FACING A REVISION
MY HIP REPLACEMENT WAS MARCH 2019

PLANNING FOR THE REVISION: FIRST PREOPERATIVE NECESSITY: WHAT CHEMICAL COMPOSITION ARE THE COMPONENTS AND COATINGS I NOW HAVE? THE MANUFACTURER TELLS DOCTORS THREE STORIES!

METAL LTT BLOOD TESTS SHOWS Ni High Reactivity, CoCr

IMPLANTING SURGEON TOLD BY MANUFACTURER: CoCr PELVIC CUP, “Ti” STEM

2ND OPINION SURGEON TOLD: “TI SYSTEM”.... DESPITE CoCr evidence rising in blood

3RD OPINION SURGEON TOLD: TI STEM COATED WITH CoCr

Manufacturer information never is the same. They NEED labels for selling & shipping. I NEED them to have a positive outcome for my revision on their brand new implant!
PUT PATIENTS AND DOCTOR SUCCESS OVER MANUFACTURER PROFITS
FDA NEEDS TO DEMAND AND REGULATE COMPREHENSIVE LABELING

Don’t let the Manufacturers hide behind their “I Don’t Knows”
Who regulates who? Industry regulates FDA or FDA regulates industry?

IMPANT some ethics and accountability in the medical device industry
SOLUTION

• FDA needs to enforce strict labeling of metal composition in medical devices with additional labeling for the device coatings.

• Mandate manufacturers provide metal chemical composition sheets for the FDA’s global unique device identification database (GUDID).

• FDA unique device identification (UDI) should require that all manufacturers are held accountable for the complete chemical composition of metals in each device component and include special separate metal chemical composition sheets for the specific coating on each individual device.

• Add black box warnings for low grade titanium with nickel in it and add black box warnings for any component with CoCr or coating with CoCr.

Create safer, more comprehensive medical device metal composition labels for patients with allergies to metals.