Docket No. FDA-2011-N-0661-0001

Metal on Metal Hip & Joint Implants
FDA-CDRH Request for Comments – Effective Date of Requirements for Premarket Approval for Two Class III Preamendments Devices

by Dwight Schrag - Chemical Engineer
Patient Advocate

KEY RECOMMENDATIONS FOR HHS/FDA IMMEDIATE IMPLEMENTATION & ACTION

I. Adopt most restrictive State Standards for Cobalt Toxicity blood serum safety levels of hip implant patients (e.g. California). Due to severe, even fatal health risks of Metallosis poisoning, infections and disabilities of all-metal implants, standards must apply to all patients, not just those who are now symptomatic.

II. Commence Cancerous tumor studies immediately. High incidence of tumors at implant sites (wrongfully referred to as pseudo-tumors) is extremely serious considering recent animal studies reported to FDA-CDRH.

III. Require device manufacturers to immediately establish a "Trust Fund" of Forty to Sixty ($ 40 to $60 B) Billion dollars for healthcare reimbursement of failed implants, such as tobacco and asbestos trusts of similar magnitude.

IV. Set revision surgery standards. Orthopedic Surgeons are operating without sufficient guidelines while further risking the lives and health of patients.

V. Restrict any further (discontinue immediately) use of all-metal implants in women patients; those of child-bearing age; and any and all use for pediatrics/children whose bone formations years are underway.

VI. Require device manufacturers fund work, fully cooperating with CDC, NIH, universities and other independent research organizations to conduct long-range studies of complex bone formation degradation (bone destruction) which impacts hip joints of many/most implant patients with all-metal joint. Especially women and children.

VII. Expand research with patient studies of medical complications resulting in deep-seated infections originating at patient implant sites of all-metal devices. Lack of understanding; severity of infections demands solutions; as do serious medical complications requiring lifetime antibiotics treatment (or fatalities).

cc: U.S. Senators Patty Murray & Maria Cantwell – Senate Office Bldg.
cc: Honorable Kathleen Sebelius – HHS Administrator

Comments: Metal-on-Metal Class III Medical Devices
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Hundreds of medical journals, research studies and toxicology documents have been published since early 1980's clearly and conclusively showing extreme and unwarranted risks of Metal-on-Metal hip implants. Toxic metals used in manufacture have severe impacts on vital organs (heart, brain, lungs, liver, kidneys, thyroid) and create disabling bone destruction, metallosis and deadly infections.

Wrongfully negligent HHS/FDA-CDRH 510(k) Clearances for faulty, improperly tested Metal-on-Metal (M-o-M) hip implants with poor designs have extremely high device failure rates, placing up to forty (40) percent of implant-patients at risk of serious disabilities and death. Total U.S. M-o-M implants number approximately 750,000 hip patients by conservative estimates.

Such a dismal, failed track record borders on gross negligence, proof that HHS/FDA has done nothing substantive to protect patient health and safety; nor will they act responsibly to properly regulate use of Metal on Metal implants as Federal laws require them to do.

FDA's highly questionable policies, seeking inputs "for comment" is no improvement over previous pathetic red herrings used by HHS/FDA to delay or confuse required regulatory actions. The agency has used similar misleading statements dating back more than three (3) decades in asking for "more scientific data".

For example:
Prior to 1982 HHS/FDA was fully aware of deadly risks in use of toxic metal device failures for these implants. But the agency irresponsibly failed in its primary Mission; and continued to allow massive proliferation with full FDA Clearance for marketing, unfettered by oversight. HHS/FDA is not acting in good faith or with responsible intent; nor are they using ethical standards in regulation. Their miserable track record for Metal on Metal implants speaks for itself.

Such negligent, immoral regulatory oversight has already created deadly toxic poisoning dangers for tens of thousands of U.S. implant victims. Around the world, healthcare tracking registries have highlighted these tragedies. Forced product-recalls of U.S. manufactured, "FDA cleared" implants have been implemented abroad. U.S. Consumer advocacies have also begun to uncover extent of human harms for this national tragedy.

Co-Inventor Testified He Would Not Use DePuy's ASR Hip Implant
Source: Brandi Law Firm April 8, 2013

During an ongoing trial in Chicago, Carol Sturm vs. DePuy (Johnson & Johnson), orthopedist and co-inventor orthopedic surgeon Thomas P. Schmalzried, who helped develop the DePuy ASR metal on metal device, testified under oath in a Chicago courtroom that he had to revise 15 out of 66 insertions (23% failure rate) which he said is an unacceptable failure rate. In a separate news report, April 2, 2013, Dr. Schmalzried further testified that he would not use the ASR and that the benefits do not outweigh the risk. "I would not implant the ASR XL today," he stated. His testimony was in his role as first witness called by the defense (In Re DePuy ASR Hip Litigation, No. 10-L-10506, Cook County Circuit Court). – ***End quote****.*

Tragically, deplorably this is the same device HHS/FDA-CDRH provided full market clearance for in 2005 without properly, professionally reviewing DePuy's application documents. About 34,000 of these faulty M-o-M devices were used in the U.S. HHS/FDA's negligent and unscientific procedures and policies in regulating such Class III all-metal implants dates back several decades:

A ***1982 Orthopedic Device Classification Panel*** *recommended that while general controls alone were not sufficient, sufficient information existed to establish a performance standard to provide a reasonable assurance of safety and effectiveness for metal/metal hip systems. FDA disagreed with the 1982 Panel's recommendation and classified the devices as class III stating insufficient information existed to support the conclusion that performance standards or general controls will provide reasonable assurance of the safety and effectiveness of these devices.*

So here we are 30 years later? Garbled, fuzzy and squishy terms about "safety and effectiveness" led to inaction and malfeasance on the part of HHS/FDA. Lack of monitoring and insufficient information enabled an unscientific disaster to occur. Gross insufficiency of test data was allowed to become the standard protocol for 510(k) clearances for three decades. Deadly health complications resulting weren't acted upon until January 2013; and only with a "Warning Bulletin", no recalls.

Now today, still asking for more data, HHS/FDA pretends to seek even more evidence of "human safety protocols" to justify its mismanaged negligence for prior unethical decisions. April, 2013 they are seeking "available" populations to create advisory application of all-metal implants for pediatrics-uses. Yet evidence for recall is overwhelming with far safer implant options now available.

Basic findings from scientific and medical data provided in June 2012 Panel Hearings resulted in statements by the FDA Temporary Panel Chairman (Orthopedic Surgeon) William Rohr, M.D. stated that **M-o-M implants "should no longer be used "** as other proven implant materials and devices are available which offer safer results, fewer complications and less risk for disability or death.

Despite last June's 2012 FDA Panel findings, no further M-o-M restrictions have been placed by HHS/FDA. This fact further indicates gross malfeasance, putting all current implant patients at greater risk. To even consider collecting "available"

evidence for use on children/pediatrics populations for ANY PURPOSE appears irresponsible based on scientific evidence.

Scientific presentations and critical Federal Register documents 1985 to 2004, in timeframe HHS/FDA was reviewing M-o-M 510(k) clearance approvals; plus testimony during June, 27-28, 2012 FDA-CDRH Panel Hearings have been largely disregarded or suppressed. Many so-called "Expert Panel" members showed extreme biases, demonstrating lack of technical knowhow with gross inability to comprehend clear medical data, international studies and scientific research.

Examples of Metal Toxicity data - materials of manufacture (see footnotes page 5):

a) 2004 Center for Disease Control (CDC) ATSDR – Cobalt Toxicity reactions i

b) 1996 American Surgical Society Abstract – No further use of M-o-M hip implants should be considered due to safety risks to patients.

c) 1985-2001 Federal regulatory, medical and scientific studies for toxicity and deaths attributed to Chromium ions.

d) Dr. Jeremy Gilbert, PhD – June 28, 2012 FDA Panel Hearings – "Orders of magnitude" (greater than 10 times) ion release in blood, tissues and vital organs.

e) Dr. Katherine Squibb, PhD – June 28, 2012 FDA Panel Hearings re: Rare, difficult to diagnose **Cobalt-induced local sarcomas** in laboratory animal's muscle tissues.

The present situation is clearly a disastrous and unethical regulatory failure, an immoral atrocity on the U.S. Healthcare system causing deadly harms to patients. **Billions of dollar in fraudulent costs to taxpayers**, hospitals and healthcare insurance providers (Medicare, Medicaid, States and private insurers) have already resulted. Most tragically, human costs are beyond current capabilities to measure.

Moreover, manufacturers of such faulty, toxic implants are now claiming, as of March 2013, the fact that HHS/FDA has issued the unethical 510(k) approvals, as fundamental to their legal defense in Federal and State Courts. When patients seek compensation for their medical costs and disabilities, HHS/FDA is now being directly implicated (by a major U.S. manufacturer) in both court cases. This further exacerbates harms to victims. Over ten thousand (10,000) such lawsuits are in Federal Courts at this time (2013).

Gross mismanagement by HHS/FDA-CDRH' failure to properly administer Federal processes for approving clearance of these unsafe, toxic and deadly implants must be considered corrupt, unprofessional and unscientific; and certainly representative of an irresponsible malfeasance, at a minimum. At least fifteen (15) categories of HHS' failure to manage and administer their own processes and procedures were presented to HHS members, both FDA-CDRH and FDA-OSHI, August 2, 2012. Not even a verbal acknowledgement was offered; nor any written response provided.

For over thirty (30) years, HHS/FDA-CDRH has been well aware, culpable and acted irresponsibly in carrying out their Top Priority Mission of protecting patient health and safety for these devices.

HHS/FDA-CDRH' January 17, 2013 Warning Bulletin broadcast to surgeons, hospitals, health providers and patients for these implants recognizes (in writing) that **HHS agencies still <u>DO NOT understand safe levels</u>** for toxic metal ionic materials released into tissues, vital organs, and/or bloodstream of patient victim's of these class III devices. Quote:

"Presently, the FDA does not have enough scientific data to specify the concentration of metal ions in a patient's body or blood necessary to produce adverse systemic effects. In addition, the reaction seems to be specific to individual patients, with different patients having different reactions to the metal wear particles."

Yet only a few (several) components have been pulled from Class III Medical Device markets in U.S. These recall instances were primarily by manufacturers facing lawsuits in tens of thousands from all over the world.

Despite Federal Register postings of Cobalt Toxicity Dangers to humans by CDC (e.g. ATSDR 2004) and over five (5) decades of documented Chromium Toxicity deaths, cancers and major organ failures of humans; and hundreds (if not thousands) of medical journals, research studies and publications by hundreds of medical professionals, surgeons, bio-medical engineers and scientists, HHS/FDA-CDRH is still **<u>incapable of protecting people whose health HHS is assigned to safeguard.</u>**

Such a dismal malpractice by our nations' prime regulatory body is an affront to all citizens, taxpayers and medical patients. The U.S. Congress and Department of Justice must seek transformation of the agencies involved for healthcare safety of all current and future patient populations. Major revamping of Health and Human Services management, its' implementation policies and procedures is required to protect the public. To do any less would be a criminal failure of government.

References/[i]Citations

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[1] Health Bulletin #14 State of Alaska Department of Epidemiology, "Cobalt Toxicity in Hip Implant Patients", May 28, 2010.

[2] Center for Disease Control ATSDR 2004 – CAS #7440-48-4 Federal Register – "Cobalt Toxicity"

[3] "Presence of corrosion products and hypersensitivity-associated reactions in periprosthetic tissue after aseptic loosening of total hip replacements with metal bearing surfaces" - Acta Biomaterialia 5 (2009) 172–180

[4] FDA Executive Summary Memorandum *Metal-on-Metal Hip Implant Systems June 27-28, 2012 -Table Page 42 – Incidence of M-o-M Effect by age of female patients*

[5] IARC MONOGRAPHS, 5A.1 "Degradation of metallic implants in biological systems" 2010, Volume 74, pages 231 to 301

[6] Dayan, A. D.; Paine, AJ (2001). "Mechanisms of chromium toxicity, carcinogenicity and allergenicity: Review of the literature from 1985 to 2000". Human & Experimental Toxicology **20** (9): 439–451.