July 22, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

Please find enclosed, as a direct response to [Docket No. FDA-2014-N-0297], the following two enclosures: the July 22, 2014 open letter addressed to the Honorable Margaret A. Hamburg, M.D., Commissioner of the U.S. Food and Drug Administration (seven pages) and the proposal for The Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process (eleven pages). I am formally requesting that both enclosures, along with this cover letter, are publicly posted to the preceding docket number. As stated at the bottom of page seven of the enclosed letter to Commissioner Hamburg: To suppress public opinion and control the narrative to one-side of this issue is Discriminatory. Thank you.

Sincerely,

[Signature]
David Schmidt
PO Box 43834
Las Vegas, NV 89116

Enclosures
An Open Letter to the FDA Requesting: Appropriate Action

July 22, 2014

The Honorable Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

The FDA, in its proposed reclassification of surgical mesh for the transvaginal repair of pelvic organ prolapse (POP) from a Class II to Class III medical device, appears to also be doing so without attempting to understand the past unreasonable risk of illness and injury, currently being deceptively inflicted experimentally upon not only U.S. women, but women globally.* Irregardless, if the transvaginal POP mesh placement can still continue as “reasonable,” each and every patient voluntarily undergoing an elective surgery in the U.S. with the reasonable anticipated probability to implant, not only a surgical mesh device but on same principle, any other long-term permanently implanted (L-T/PI) risky medical device, also needs the ability to protect themselves from the unreasonable risk for illness and injury resulting from real-world, indiscriminate surgeon abuse. What purpose would informed consent serve otherwise, when a surgeon can and will exploitatively use his/her position of influence to knowingly undermine their patient’s rights – and then following intent, opportunistically cower from accountability behind the standard of care, to habitually again, abusively carryout their own one-sided, best practices?

* Due to the reality that other countries follow the FDA’s regulatory lead, in the aftermath of aggressive and fraudulent surgical mesh marketing tactics, globally women have also been systematically targeted by this particular manmade mesh “treatment” plague. And, as the 510(k) cleared mesh device was never even FDA assessed for safety and effectiveness (because there was no market approval from a clinical trial but “substantial equivalence” to the “predicate” mesh device’s fleeting comparativeness to the pre-amendment mesh device), these currently ensuing, injurious in vivo mesh performance norms create unreasonable risk for illness and injury. A very strong argument can resultantly, now be made that without a reasonable assurance of safety and effectiveness for in vivo device performance, illegally informed patients implanted with 510(k) cleared devices were consequently experimented upon without their awareness – via creep of “the predicate device” along an un-split “same intended use” lineage progression of “same technological characteristics” – from cumulative enough “significant” change to the non-approved pre-amendment device. And, most certainly experimental, when past FDA found “substantial equivalence” was split between the “different technological characteristics” of multiple “predicate” devices.

After decades of the surgical mesh industry's relentless trying, can it now even be left understood as coherently feasible, when stated by William Maisel, M.D., M.P.H., Deputy Director of Science and Chief Scientist at the FDA’s Center for Devices and Radiological Health (CDRH), in the FDA Office of Media Affairs April 29, 2014 press release: FDA issues proposals to address risks associated with surgical mesh for transvaginal repair of pelvic organ prolapse, that there would still remain the possibility “for more safe and effective products,” specifically for, the transvaginal surgical intended use (SIU) of mesh for the repair of POP? More significant, however, as the FDA and NOT industry, “has identified clear risks associated with surgical mesh for the transvaginal repair of pelvic organ prolapse,” will this FDA burden undertaken to now attempt “to address those risks” for the industry’s numerous profiteers, even result in a real-world possibility “for more safe and effective products”? “In the absence of an established positive benefit-risk profile,”* the FDA may still remain unable to even understand what “a reasonable assurance of safety” is, to again prevent a future unreasonable risk for illness or injury. If a “reasonable assurance of the safety and effectiveness of surgical mesh intended for transvaginal POP repair”* could now be magically demonstrated (in defiance to evolving understanding from this current, real-world unregulated human experimentation resulting in an understood unreasonable risk of illness and injury), future possible mesh “approvals” would only have a potential for least risky and not “more safe and effective products.”

* FDA Docket # FDA-2014-N-0298, page 24646
With the scope of this first, possible FDA decidedly taken, Class II-to-III mesh “reclassification” being so narrowly restricted (to illogically isolate a past, FDA found “substantially equivalent” “predicate” mesh’s “same [510(k)] intended use,” to this particular indication for use) it questions what or whose interests continue to play-out here? The transvaginal POP mesh placement may not even continue as a future “acceptable” standard of care.* Is the FDA showcasing the running of a perhaps soon “abandoned train” down a dead-end track…from apparent need…to now take the focus off of other SIU mesh approaches and their currently accompanying indications for use? If the former were true, would this FDA intent only again serve the lesser societal objective of further preserving those past manufacturer-on-surgeon exploited, one-sided mesh benefits, which have followed the wake of this industry’s infliction of its own best practices of self-serving medicine across entire populations of unsuspecting patients? Could the real reason behind this little FDA mesh reclassification, be the resulting intent – to mitigate the recognition of the more significantly encroaching, greater 510(k) hernia “predicate device” family lineage burden? **

* Although, it may preferably be left understood by secondary system interests that one of the primary considerations making transvaginal mesh unfit for its intended use, is placement into “a contaminated field” – reality does not reside in a fairytale world where evil fails to coexist. In hernia literature there is as high as a 63% documented statistic for patients to adversely experience chronic groin pain one year after the modern mesh hernia repair. This patient experience for lack of “treatment” effectiveness is rarely surgically addressed; it is medicated. Could it be problematic for the transvaginal mesh placement that it has a higher rate of revealing product failure than alternative mesh implantation procedures? Whereas, akin to hernia mesh, with promotion of the “public health benefit” from abdominal mesh placement, the predictability of the product failure would also then become more conveniently left obscured, when hidden antidotal in patient experience? The non-transvaginal mesh placement would, therefore, serve to better insulate device manufacturers from liability, while consequently, also sustain the immediacy of the surgeons’ heightened efficacy self-gratification. This subsequent, one-sided surrogate success would then continue as the metric of benefit, not patient effectiveness, void of hierarchal, risk-based treatment stratification.

** Specific to mesh hernia repairs, indicative for the reason behind the myriad of high rates for patient chronic pain documented in medical literature, is it this industry’s continuing negligent complacency to have not surgically verified patient injury? And, following an industry’s habitual gross negligence to have not addressed its high predicted patient chronic pain rates, is this reason why it can still continue to cling to its own belief (when removed from an unwarranted past mesh use) that mesh has had “a long history of safe and very effective use in the repair of inguinal hernias”? Effective for whom? Certainly not for patients abused when denied past, risk-mitigated efficacy successes from tissue repairs, now unable to be performed at acceptable rates of proficiency by surgeons untrained to act in their patient’s best interest. (If there is an argument to the contrary, it will be made from current, best industry practice.) With future transparency, will this industry be able to adapt to a patient driven demand for quality, patient centered, not industry inflicted healthcare? Or, will it seek further refuge by continuing to cling to past successes, where status quo was to undermine patients’ rights for one-sided, self-serving benefit? Consequential, to a future legally informed patient collective, patients may become universally unwilling to sacrifice their lifetime of safety compensatory to the regressively trained surgeon’s own need to act out abusive limitations as best practice.

_Danger comes in many forms for the unsuspecting patient…_It comes through the numerous, loophole riddled pre-market device pathways. Then, pursuing post-market, those grossly unregulated and dangerous devices find their way into the hands of compromised surgeons, industry indoctrinated with their primitive behavioral norms. In a round-about-way, as device industry intent cultivated the conditioning for the compromised physician’s regressive mindset, to later be reinforced with own marketing tactics, its abusive training strings first created the unreasonable: the primacy, of the illegitimacy of surgeon need, placed abusively before willful negligence to recognize patient need.* Self-inflicted beliefs of entitlement run deep through medicine and find rest behind self-serving masks, obscuring one-sided, opportunistic intent.

* In a civilized society, what is a surgeon’s ethical responsibility to his/her patients: “Do no harm?” – yes. But, what are the nuts and bolts of this patient/physician interaction, to thereby, recognize the ethicality of surgeon responsibility? The gateway to either a future positive or adverse patient experience is the pre-surgical office consultation, where every patient should expect an accurate disease/condition diagnosis and upon which the severity of their own disease/condition classified within a hierarchal, risk-based treatment stratification model. If the former is illogical, was it not a personalized medicine verses “a one-size fits all” approach consideration for the patient? But, when a patient seeks an opinion from the industry indoctrinated, regressively trained surgeon reduced to indiscriminately abuse (through preferential surgical approach), the then: unreasonably dangerous L-T/PI device, there was no responsible device use consideration relative to a historical, risk-mitigated efficacy success from a non-device repair. That was a non-treatment choice. Compromised, out of the gate that surgeon is a threat to the safety of his/her patients with infliction of own best practice of medicine. And as a result, what
personalized medicine choice can the compromised surgeon offer his/her patients but only an opportunity which first benefits them? The restriction of once efficaciously viable, risk-mitigated, non-device surgical alternatives – to no current treatment for reckless, indiscriminate surgeon L-T/PI medical device abuse, is NOT the progression of medicine; it is its regression!

In the Institute of Medicine’s (IOM) July 29, 2011 (released) FDA sponsored report: Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years, the first half of IOM Conclusion 7-1 stated: “The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions.” If a regulatory process “is not intended to evaluate the safety and effectiveness of medical devices…” are unsuspecting, illegally informed human test subjects being subjected to an open market experimental abuse of L-T/PI devices? The following (slightly rearranged and accentuated) text excerpts from a March 14, 2014 + MassDevice article, by Arezu Sarvestani: Unveiled emails raise eyebrows about J&J’s ties to consulting docs, would strongly support the former as reality.

“The growing patient injury lawsuits against Johnson & Johnson (NYSE:JNJ) subsidiary Ethicon’s pelvic mesh products have raised some new questions about the relationships between industry and healthcare providers.”

Dr. Vincent Lucente “a physician and Johnson & Johnson consultant is under the spotlight after pending pelvic mesh personal injury lawsuits raise questions about financial relationships and efforts to influence public perception.”

“Emails made public during legal discovery include an exchange between Lucente and J&J executives about concerns that the American College of Obstetricians & Gynecologists referred to transvaginal mesh as an ‘experimental’ procedure. ‘Given the limited data and frequent changes in the marketed products...the procedures should be considered experimental and patients should consent to surgery with that understanding,’ according to the ACOG's original memo” (emphasis added).•

“J&J reached out to Lucente for advice, worried that the word ‘experimental’ would scare away patients and perhaps even threaten reimbursement from insurance companies. The offending word was later removed, a change that Lucente boasted about in subsequent correspondence, the Journal reported” (emphasis added).

“‘No further use of the word experimental!’ Lucente wrote. ‘Well, this is one I’m taking credit for. I led the charge on this and never thought we would get a complete replacement of the earlier bulletin.”

“Bulletin writers balked at the change, saying that challenges to the language were ‘disingenuous at best.’”

“Most of the clinicians who objected to the use of the word ‘experimental’ understood only too well exactly what meaning was intended,’ original bulletin co-author Dr. Anne Weber wrote in a letter to the editor of the International Urogynecology Journal. ‘Such clinicians were concerned that insurance companies would not cover procedures labeled experimental.’”

Is the FDA even listening to a countless number of patients who have been globally harmed by self-serving manufacturer/physician intent? What I understand patients to be overwhelmingly saying, is that the immediacy of the one-sided, risk-disproportionate heighten efficacy benefits afforded to the surgeon perpetrator of a crime against patient orientated medicine (surgeon failure to have responsibly implanted the currently understood least risky L-T/PI device) did not outweigh both the immediate and lifetime of device and reactionary surgical outcome risks deceptively inflicted upon them as either uninformed human test subjects or victims of best manufacturer/physician practice. Any purported “public health benefit” should not remain fixated upon known outcomes of “adverse” harm, but innately conceptualized upon the unreasonable risk, first abusively inflicted* by predatory treatment guidelines propagating indiscriminate, real-world abuse (irregardless, if that abuse was ever experienced by a still unaware patient as “adverse harm”). I implore the FDA to STOP NOW and think about the unwarranted infliction of risk that must be patient mitigated with direct understanding for historical surgeon competency, not reduced to current incompetence, by regressive surgeon need to indiscriminately abuse the risky L-T/PI device. In leveling the playing field, with the below stated primary system control that surgeon competency demand to put their patients’ needs before their own, will and can only come from the legally informed patient collective.

* Patient harm should now be correctly, re-conceptualized pre-surgically at the point of abuse. Pre-surgically, patients are proclaimed to have this legal right to weigh the risks verse benefits from all treatment alternatives, not with regret afterwards. Patient centered healthcare = the mitigation of unwarranted treatment risk. This preceding patient effectiveness endpoint is not reachable through best manufacturer/physician practice. It is a singular endpoint destination. And, as it was never the FDA’s mission to help the device industry identify more “unmet” healthcare needs – to now further justify its opportunity to
“game” more benefit (by expanding or appeasing device indications), the FDA needs to stop being Industry’s patsy. With renewed FDA understanding that its responsibility is to the American people, upon taking **Appropriate Action** to prevent further widespread, systematic human exploitation, FDA will find itself in a role American patients depend upon it to fulfill.

Specific to, the countless number of U.S. women who have been harmed by *“experimental”* transvaginal mesh **“procedures”** indicated for the repair of **both POP** and stress urinary incontinence (SUI), the CDRH should hold an open door public meeting entitled: **How to Prevent Both Defective Surgical Mesh Device Design and Real-World, Indiscriminate Surgeon Abuse, from Creating this Ongoing Unreasonable Risk of Illness and Injury, for the SUI/POP Surgical Mesh Indications?** This meeting will afford the FDA its firsthand opportunity* to learn from the perspective of women who have been currently, adversely harmed (and/or abused with unwillingness to sacrifice their life-time of safety, when rights were undermined by best industry practice), for how fraudulent marketing and an industry’s promotion of its own “treatment” guidelines contributed to this on-going patient burden. Removed from the reality of “the growing patient injury lawsuits” confirming defect of design, the recognition of the life-time of reactionary complications deceptively inflicted upon these women by self-serving manufacturer/physician and FDA’s commingled willful negligence, could be invaluable in establishing a “positive benefit-risk profile.” Due to the fact that there are still “no performance standards applicable to surgical mesh” which “have been established by the FDA” for the **SUI indication** (510(k) clearance # K963226) or **any surgical mesh indication** that I am aware of to date, as a prerequisite for any legally *“marketed”* product being fit for its intended use (irregardless of what showcased indication is being appeased for public benefit), the injurious in vivo unpredictability of non-inert mesh material needs to be **addressed for the entire family of mesh devices.**

* To facilitate a derivable FDA understanding for premeditated patient abuse, in that, if a patient did not post-surgically understand (upon recognition of the reasonably predicted adverse event mesh outcome) the pre-surgical infliction of that abuse = they were not pre-surgically even legally informed of risk, the FDA should suggest to those mesh implanted meeting attendees that they also bring their post-surgical office visit medical records with the implant surgeon to establish proof of premeditation. With a surgeon’s inability to have correctly, post-surgically documented adverse device outcome risk, what credibility would that surgeon still have to claim, pre-surgically they even legally informed their patient of the reality for risk? More so, if a surgeon regessively trained to indiscriminately abuse the risky L-T/PI device did not have a “plan B” for the predictability of adverse device event recognition, did that surgeon subsequently discount their patient’s experience with fraudulent documentation, as a “*positive outcome*”? Is the FDA serious this time about carrying out its mission statement for the benefit of future U.S. patients or does it simply remain complacent, to give still further lip-service to **Appropriate Action**?

Due to the reality that the risky, L-T/PI medical device only has the probability to be regulated to “a reasonable assurance of safety and effectiveness” – real-world, indiscriminate surgeon L-T/PI device abuse creates an “unreasonable risk of illness and injury for patients.” Following coherently – the inherent risk from the practice of medicine cannot then be generalized to encapsulate this heightened adverse device and accompanying immediate and long-term reactionary surgical implantation risk as “reasonable.” With acknowledgment for: the loss of surgical efficacy benefit once found in past, non-device surgical repairs (when preformed with proficiency of practice by ethical surgeons acting competently in their patient’s best interest), current best physician/manufacturer practices of indiscriminate L-T/PI device abuse, one-sidedly increase unwarrantedly abusive risk, for self-serving surgeon efficacy benefit – disproportionate to – the severity of an individual patient’s disease/condition to have first been responsibly addressed within a hierarchal, risk-based treatment stratification model. Indiscriminate L-T/PI device abuse is therefore, the shared physician/manufacturer decision to premeditatedly, adversely harm an unknown percentage of the entire patient population targeted for widespread, systematic exploitation by their standard of care. And, by way of the standard of care, individual patient need is the sacrificial obstacle to best industry practice.

More **“same intended use” (510(k)-to-PMA?)** mesh devices, irregardless of what on-label indication is restricted with what specific contraindication(s), thereby then, the pre-market attempt to have responsibly recognized a disease/condition severity relative to patient population demographic differentiation (the IRU embodiment), will not solve the *crooks* of the problem. The disruption of these current delusional,* one-sidedly self-serving, FDA and manufacturer-to-physician societal indoctrinated thinking patterns is what is most needed now. To break the rigidity of the fixated mindset: there can be no reasonable assurance of
safety and effectiveness for any L-T/PI device, until the reality from the unreasonable risk of illness and injury deceptively inflicted upon patients from this industry indoctrinated-to-narcissistically conditioned, indiscriminate surgeon L-T/PI device abuse, is first effectively addressed. NO WHERE in the U.S. Constitution are physicians and device manufacturers granted the entitlement to systematically undermine and violate the rights of illegally informed patients, so they can exploitatively carryout own best practices. Under jurisdiction of International Law, the U.S. Government is legally obligated by Human Rights Treaty Law ratification, to both recognize and then take the Appropriate Action to prevent the further widespread, deceptive, systematic, predatory exploitation of human beings within its natural borders.

* Delusional, in that there will never be “more safe and effective products,” only the evolving potential to verify the current least risky products. This preceding type of irrational thinking entices the “substantially equivalent” mindset into more “least burdensome” effort. Why leave ongoing, self-serving industry effort further guise as “innovation” when there is no coherent progression to even overcome “substantially equivalent” device limitations? NO future “reasonable assurance of safety and effectiveness” recognition can result in “more safe and effective products.” With paradigm shift into the (to be proposed at a future date) new Effectively Safer (‘ES’) Regulatory Framework, the potential for a pre-market reasonable assurance of safety and effectiveness (to establish the outer public benefit threshold control parameters) will be allowed to form upon FDA verification of the current, least risky Lag Generational Device Model (GDM). To then, build upon FDA approval of the ‘ES’ Lead GDM, CTABBURG hypothesized to have a reasonable anticipated post-market probability to address the limitations of its comparative, FDA verified least risky Lag GDM. (Efficacy will be “cradled” mid-tier in The Effectively Safer GDM Standard.) System equilibrium will codify real-world, responsible device use through The RUPSG Lens, from/for the legally informed patient perspective by way of the primary system control, to thereby establish and/or reestablish best “like patient” demographic practices. Industry’s efforts will then be patient decided, not self-serveingly manufacturer/physician inflicted.

Under Sec. 513(a)(1)(B) of the FD&C Act, the FDA has the statutory authority to establish the “special control” of The Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process (draft enclosed). The FDA should do so at this time, with clear understanding, in the statutory context of “other appropriate actions as the Secretary [FDA] deems necessary to provide such assurance” (for a medical device’s real-world reasonable assurance of safety and effectiveness) that this control is needed NOW upon all “substantially equivalent” surgical mesh devices, currently, legally marketed in the U.S.* Even if any risky L-T/PI device was first effectively regulated pre-market to “a reasonable assurance of safety and effectiveness” – to circumvent the unreasonable post-market risk for illness and injury resulting from indiscriminate surgeon abuse – a patient legally consented to responsible, real-world use would also still be needed to equate any reasonable assurance of safety and effectiveness understanding. Irregardless, if once legitimate or illegitimate past industry effort, its opportunity should never have been left to now abusively plague human health. The success in regressively training a surgeon, to put his/her own need before patient need, is not viable excuse to continue the further predatory targeting of more future patients.

* Under Sec. 513(i)(1)(B) of the FD&C Act, with consideration for: the “substantial equivalence” between any two “same intended use,” comparative “substantially equivalent” “predicate” devices, “with respect to a” (once new) “device being compared to a predicate device,” with insignificant “same technological characteristics” then between, it would have meant “that there” was then and still “is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.” If the former is untrue what is “substantial equivalence” not? And, what sound rationale, would coherently, now result in restricting “the [510(k)] predicate device” lineage progression which evolved the POP mesh indication to lone transvaginal placement? As “substantial equivalence” did and does not consider indications for use – indications are generalized through “the [510(k)] same intended use” thread-through. If the former is illogical, how and why specifically, did the ProteGen bladder sling (510(k) clearance # K963226) need to use five “substantially equivalent” hernia meshes of “the same intended use” to expand an indication for mesh use into the SU1 patient population? And, in following clearances, why is the question if mesh devices are “fit for their intended use” not relative on ALL labeled indications for use?

Why is this improvement to the current, grossly ineffective patient informed consent process needed right now? The FDA, as an entity of the U.S. Federal Government, has current knowledge of widespread, systematic attacks being carried out in clinical practice, under false pretense, against entire populations of U.S. patients being implanted with L-T/PI medical devices acutely unfit and grossly unregulated for human implantation. “With knowledge of the attack,”* the U.S. Government is legally obligated by rule of International Law, under Article 7 of The International Covenant on Civil and Political Rights Treaty
(ICCPR), to take the **Appropriate Action** to prevent further such attacks. **No one** shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, **no one** shall be subjected without his [or her] free consent to medical or scientific experimentation” (emphasis added). **No one** would mean **everyone** has this right to self-preservation against both experimental medical “torture” and FDA predetermined “reasonable” for “public health benefit,” deceptively, inflicted **premeditative attacks** (aka: those industry instigated standards of care deceptively targeting patients for indiscriminate L-T/PI device abuse).

* Article 7(1) “Crimes against humanity” of The Rome Statute of the International Criminal Court (ICC).

Even more significant, however, the U.S. Government as a non-sovereign State Party to the ratification of The ICCPR Treaty, is legally obligated by rule of •International Law to recognize these **attacks** under Article 7(1)&(f) of The Rome Statute of the International Criminal Court, “when committed as part of a widespread or systematic attack directed against any civilian population,” as “acts” of “(f) torture”** premeditatedly inflicted against entire populations of unsuspecting U.S. patients. With recognition of the preceding crime placed under Article 7 of The ICCPR Treaty, the U.S. Government is legally required under •International Law, “with knowledge of the attack,” to take the **Appropriate Action** to prevent such future **criminal “acts” of “torture”** from being deceptively carried out against its citizens as **CRIMES AGAINST HUMANITY**.” If “torture” is still not yet, coherently understood by the FDA, “the growing patient injury lawsuits against Johnson & Johnson” specifically, might better inform the FDA of that understanding correctly from the patient not opportunistically, surrogate industry perspective. **No one** should have to experience the **level of suffering** that some of these women have had”; this was the understanding of Scottish Health Secretary Alex Neil, as stated in the June 17, 2014 BBC News article: Scottish Health Secretary Alex Neil **requests mesh implant suspension** (="emphasis added").

* Article 7(2)(e) of The Rome Statute of the International Criminal Court defines “torture” to “[mean] the intentional infliction of **severe pain or suffering**, whether physical or mental, upon a person in the custody or under the control of the accused; except that torture shall not include pain or suffering arising only from, inherent in or incidental to, lawful sanctions” (emphasis added). Irregardless, if the individual committing the preceding crime is a surgeon following the standard of care, to knowingly or unknowingly inflict own and FDA understood “reasonable” premeditative or experimental patient “torture,” with **cumulative undermining** of Human Rights – ensuing “acts” of “torture” resulting, are not “inherent in or incidental to, lawful sanctions.” Under Article 33(2) of the Rome Statute: “Superior orders and prescription of law” – “For the purposes of this article, orders to commit […] crimes against humanity are manifestly unlawful.” The standard of care is established by societal formed “superior order.” And, although the U.S. Government does not recognize the jurisdiction of the ICC, under Article 25(4) of the Rome Statute: “Individual criminal responsibility” – “No provision in this Statute relating to individual criminal responsibility shall affect the responsibility of States under international law” (emphasis added*).

Should the mass of humanity be left unsusceptibly waiting like cattle grazing in the fields when already opportunistically industry marked to be “**cannibalized**” for some purported greater “public health benefit”? When a future impressionable surgeon is industry indoctrinated with his/her own best practice of self-serving medicine, to subsequently, then go on to dangerously indiscriminately abuse the risky L-T/PI device, each and every patient must be insured his/her ability to give their legal informed consent,* to thereby, proactively then, preventatively take the necessary steps to protect themselves from standards of care propagating the widespread, systematic exploitation of human beings. With the U.S. Government’s failure to both recognize its ratification of The ICCPR Treaty and consequently, to take the **Appropriate Action** to prevent more such future atrocities, it is a **State Actor** in violation of •International Law.

* Behind closed doors: A patient is setup against a surgeon’s ‘remolding of reality’, with physicians’ written narrative left to define patient experience. In the wake of best industry practice, what surgeon competency was there to not carryout intent? Irregardless of surrogate interest entitlement belief, there is legal obligation to not predatory target fellow human beings.

For the universal recognition (under current U.S. Law) of each and every U.S. patient’s Constitutional right to give legal informed consent before undergoing an elective surgery in the U.S. with the reasonable anticipated probability to implant any risky, L-T/PI medical device, the two steps of The Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process will function to effectuate a system of legal checks and balances over the patient/doctor relationship. As the new primary system control, it
will place in check these current industry indoctrinated, predatory surgeon behavioral norms, fixated upon the habitual undermining of patient civil/Human Rights. Independent of honed surgeon marketing tactics (to omit risk and inflict premeditative intent...to again carryout own best practices), the two steps of this improved, informed consent process, will now afford legally informed U.S. patients both the means by which to legally bind their understanding of the current, least risky L-T/PI device – to ability to then – exercise repercussive control over responsible surgeon implantation of that legally designated device(s).

To motivate a misdirected CDRH to: **Appropriate Action**, an FDA leadership collaborative needs to responsibly reflect back upon the reason for its mission statement. At these current crossroads, *where reality shudders*, an FDA decision needs to be made now for whom it will serve: the American people or the globally encroaching medical device industry, evidenced to be preying upon, most notably, by current example: unsuspecting women implanted with surgical mesh for the treatment of both SUI and POP (although metal-on-metal hip implant patients should not be left too far behind). Is the FDA complicit to allow the eroding status quo, to still cling together the device industry’s current, destructive influence denying illegally informed, exploited U.S. patients past benefit opportunities from once responsible, non-industry inflicted, quality non-device healthcare? How long can a civilized society remain idle, to allow the device industry’s past successes in regressively training physicians to undermine patient rights (upon exploiting a patient’s belief that a physician *can act in their* best interest), continue as viable excuse, to further support those man-made justifications, left erected to prey upon the vulnerabilities of more patients?

Thank you, Commissioner Hamburg for understanding that it is **Appropriate FDA Action** which is most direly needed **NOW** in this currently fragmented, fundamentally flawed, pre-paradigm shift regulatory framework environment to protect the American people from the unreasonable risk for illness and injury, resulting specifically, from any surgeon’s indiscriminate abuse of any risky L-T/PI medical device. For the universal recognition of each and every U.S. patient’s civil/Human Rights, the FDA should now use its statutory authority to establish (as a pilot initiative) the primary system control of: The Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process upon the entire family of surgical mesh devices. The strain placed upon the FDA to fulfill its stated mission is understandable; this ongoing FDA failure to take **Appropriate Action** to prevent further, avoidable patient harm from opportunistically inflicted, deceptively carried out industry intent is not. There can be NO reasonable “assurance of safety and effectiveness,” without first recognition of every U.S. patient’s legal right to weigh current knowledge of unreasonable L-T/PI medical device/procedural risk -against- historical, non-device efficacy benefit. This is the “positive benefit-risk profile” that FDA **MUST** comprehend **NOW** to carry its mission forward.

Sincerely,

David Schmidt - A U.S. hernia patient harmed, via the standard of care, by two Bard 3DMax Mesh implants.
PO Box 43834
Las Vegas, NV 89116

Enclosure

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cc: Office of the United Nations High Commissioner for Human Rights  
International Criminal Court  
President of the United States Barack Obama  
Eric H. Holder, Jr., Attorney General of the U.S. Department of Justice  
John F. Kerry, Secretary of the U.S. Department of State  
Sylvia Mathews Burwell, Secretary of the U.S. Department of Health and Human Services  
Attorney Generals of all 50 United States  
Division of Dockets Management [Docket No. FDA-2014-N-0297] - This letter was formally requested to be publicly posted to the preceding docket number. To suppress public opinion and control the narrative to one-side of this issue is Discriminatory.
THE UNIVERSAL, TWO-STEP, IMPLANTABLE MEDICAL DEVICE PATIENT INFORMED CONSENT PROCESS

Please note: Although the preliminary thinking around this proposal began in my November 19, 2012 letter, addressed to the Honorable Harry Reid, U.S. Senate Majority Leader and the Honorable John Boehner, Speaker of the U.S. House of Representatives, entitled: An Open Letter to Leading Members of the 112th United States Congress Asking for: Belated, Responsible, Prompt Congressional Action, this is a first draft proposal. It represents my current thinking (as of 07/22/2014) on how to prevent the medical device industry’s abusive use of its regressively trained surgeons, to maximize its exploited profits, upon undermining the rights and safety of unsuspecting U.S. patients.

by David Schmidt*

* A U.S. patient harmed by the greedy, self-serving efforts of the narcissistic surgical mesh industry’s restriction of hernia repair – to its own, one-sided, self-promoted standard of care: the widespread, deceptive, systematic, predatory targeting of unsuspecting patients, exploited for profitable gain, upon regressively training a surgeon – to carryout in injurious practice: the habitual, indiscriminate abuse of unpredictably behaving = DANGEROUS mesh devices, approved neither for safety nor effectiveness.
This proposed, improved legally informed patient consent process, will mandate under U.S. Law that the following two pre-surgical consent forms are required to be given by every U.S. surgeon, to each and every potential patient voluntarily undergoing an elective surgery in the U.S., which is understood or has a reasonable anticipated probability to implant the risky, long-term or permanently implanted (L-T/PI) medical device. Implemented expeditiously in this current, fundamentally flawed, pre-paradigm shift regulatory framework – with intent to now protect future U.S. patients from the unreasonable risk for illness and injury, resulting specifically, from being deceptively industry targeted for exploitation by the regressively trained physician reduced to follow a standard of care indiscriminately abusing, the then DANGEROUS L-T/PI medical device – this process will evolve as the primary system control. Then, adapt post-paradigm shift into the (to be proposed at a future date) new Effectively Safer (‘ES’) Regulatory Framework,* to begin to effectively regulate all legally marketable, Industry identified and FDA verified least risky, L-T/PI medical devices in the U.S., to both a pre- and post-market reasonable assurance of safety and effectiveness.

* Post paradigm-shift, in the new ‘ES’ Regulatory Framework, The Bur-Metric System for L-T/PI Medical Device Quality’s Four Components of Legally Informed Patient Choice: the Treatment Choice Component, Specific SIU Component, GDM-to-UDI Component, and Specific UDI Component, will harmoniously interlace to create a tangible metric system construct over this new improved patient informed consent process. Every patient voluntarily undergoing an elective surgery in the U.S. with a reasonable anticipated probability to implant a risky L-T/PI device, will then be afforded their subsequent ability to give a legally recognizable informed consent independent of the device industry’s preconditioning of surgeon intent, to fixate upon carrying out own best practice of indiscriminate L-T/PI device abuse. Future, legally informed U.S. patients will then be able to weigh in near real-time, the currently known or reasonably should be known, industry and FDA mandated legally disclosed knowledge of evolving GDM device family and correlating surgical intended use (SIU) risk (via the PAEPR metric – The GDM Procedural Adverse Event Percentage Rate) -against- historical patient benefit and past (medical literature derivable) surgeon efficacy successes from non-device surgical (via the NDESRR metric – The Non-Device Efficacy Success Range) and if individual patient disease/condition severity and/or demographically “like patient” applicable, non-surgical alternatives (via the NSASR metric – The Non-Surgical Alternative Success Rate). Then, via The UDI Risk Assessment Assignment (RAA), patients will have the ability to understand (via The FDA’s GDM-to-UDI RVR Statement) the more risky devices “filtering” through The GDM-to-UDI Risk Variance Range (RVR) control parameters of the different established Generational Device Model Interface Mechanisms (GDMIMs).

Both the first pre-surgical patient consent Form FOCD (Final Office Consultation Day form) and second pre-surgical patient consent Form PSID (Pre-Surgical Implantation Day form), described below, will be mandated to be FDA standardized into a “patient friendly format” on its web site. Then, PDF formatted to be easily downloadable for both surgeons and “user facilities”* to print off and give to each and every U.S. patient, understood pre-surgically, to have a reasonable anticipated probability to be implanted with a risky L-T/PI medical device. As the post-surgical verification control mechanism of this process, every U.S. patient implanted with a L-T/PI device will be legally required to receive either directly from the implant surgeon or user facility, both Card PSDI (Post-Surgical Device Identification card) and within 14 days post-surgical, a free copy of their operative report. Card PSDI will legally require that with every U.S. L-T/PI medical device implantation, the identification of that implanted device by both its UDI “device identifier” and “production identifier.”** Card PSDI, like Form FOCD and Form PSID, will also be legally required to be FDA standardized into “a patient friendly format” on its website and then PDF downloadable and printable for both surgeons and user facilities to give to every U.S. implant patient.

* “User facilities” are the surgical facilities where L-T/PI medical devices are implanted.

** The Final Rule for The Unique Device Identification (UDI) System “…specifies the technical requirements of a UDI. Each UDI will consist of two portions: A device identifier that corresponds to the specific version or model of the device and the labeler of the device (the labeler is the person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label; in most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler), and [a] production identifier that more precisely identifies the specific device by providing variable information, such as the lot or batch, the serial number, expiration date, the date of manufacture, and, for human cells, tissues, or cellular and tissue-based products (HCT/Ps) regulated as devices…”

STEP ONE – Form FOCD (Final Office Consultation Day form)

On or before the day of a patient’s final pre-surgical office consultation, every U.S. surgeon will be universally, legally required under U.S. Law, following the currently mandated informative conversation with a future perspective implant patient (legally informing that patient of their surgeon understanding for the reality of device/procedural risks and potential benefits from all treatment alternatives applicable to that specific patient’s disease/condition severity) to fill out, sign, list his/her state medical license number and then give the potential implant patient Form FOCD. With Form FOCD, U.S. surgeons will universally bind legally designated L-T/PI
medical device use, to their pre-surgical SIU intent, for a future, patient legally consented to responsible real-world use (with the life-time patient SIU implication, now independently derivable from the manufacturer-to-surgeon indoctrination practice bias). Form FOCD will minimally require that every U.S. surgeon with a reasonable anticipated probability to implant a L-T/PI medical device legally bind the following seven disclosers into writing:

1. The main or if applicable all alternate L-T/PI medical devices (identified via the UDI device identifier) intended to be implanted or pre-surgically, surgeon competently understood to have a reasonable anticipated probability to be implanted, with conditions for the responsible implantation of either that main or alternate device(s) legally bound (through discloser # 5) for a future, responsible use in the restrictions for use statement (described below).

2. The quantity of each legally designated main or alternate medical device intended to be implanted.

3. A pre-surgical intent to modify a legally designated medical device.

4. All currently known and/or reasonably should be known anticipated device specific, and/or general device group, and/or greater device family of origin pedigree lineage risks for each legally designated device, with medical literature and patient registry adverse event outcome rates disclosed, if known.

5. The specific surgical procedural approach(s) intended to be performed to implant each legally designated medical device.

6. All currently known and/or reasonably should be known anticipated procedural specific risks accompanying the implantation of each legally designated medical device, with medical literature and patient registry adverse event outcome rates disclosed, if known.

7. A “Plan B” adverse event reactionary and/or end of device life-cycle recognition treatment protocol, with both industry success rate and ability to address the known immediate and/or long-term procedural outcome risks, currently understood in medical literature and/or from patient registries, accompanying the implantation of each legally designated medical device.

Please note: The mandated discloser of evolving, near real-time risk/benefit information required for a U.S. surgeon to complete the preceding disclosures #4 and #6 and for a perspective implant patient (and/or patient representative) to then verify the accuracy of these legally mandated surgeon disclosers, will be obtainable via the proposed FDA UDI Entry Portal (UEP), described further below.

Rationale for Form FOCD:

Form FOCD could be likened similar to a drug prescription. In that, it will also be physician written to now legally bind specific L-T/PI device use. And, akin to a drug prescription, as drug related risk information is independently disclosed to patients in writing through the pharmacy, to then allow patients to make risk-benefit determinations free from bias – upon individual patient risk-tolerance (albeit relative to the accuracy and thoroughness of the evolving manufacturer and FDA, then FDA possibly enforced, risk disclosure), so also will device risk be legally-mandated disclosed in near real-time (via the UEP). Patients will, via Form FOCD, also understand if there is pre-surgical surgeon intent to use a L-T/PI device off-label, to then mitigate the heightening of risk subjected from that abuse.

Form POCD, given to a future potential U.S. implant patient on or before the day of their final, pre-surgical office consultation with prospective implant surgeon, will act as a “check and balance” mechanism. As it will allow each patient and/or patient’s representative to now verify, via the UEP, “the check” – that a surgeon was both competent and honest in informing them of the reality of device/procedural risk. * Then, via the UEP, each patient will have the opportunity to “balance” a greater than individual surgeon derivable device/procedural risk disclosure against potential benefits (via The RUPSG Lens) from both non-device surgical (perhaps now only a hypothetical benefit potential due to the regressively trained surgeon’s “proficiency” to only be incompetent to carry out their own best practice of indiscriminate L-T/PI device abuse) and if disease/condition applicable, non-surgical alternatives.

* The mandated discloser of device quantity (disclosure #2) will act as a “dosage range” to mitigate the heightening of risk subjected to a patient from a pre-surgical (premeditative) surgeon intent to abusively inflict excessive risk onto a patient with multiple L-T/PI device implantations (unknown and/or disproportionate to patient understanding of need but compensatory to surgeon intent). A surgeon fixated upon maximizing his/her own one-sided efficacy success and/or with intent to rack up more profit (to unjustly enrich themselves upon as many device implantations they can one-sidedly rationalize as “needed”…to satisfy intent), may be negligently willing, upon successfully undermining their patients’ rights, to subject patients to a heightening of unreasonable risk (unwarranted to a legitimate, individual patient need). Consequently, the judgment of that surgeon will be habitually impaired with self-serving intent to carry out own, best beneficial practices. As a “countermeasure,” with direct patient understanding for the self-serving benefit gain afforded to the risk-adverse surgeon, Form FOCD will also help address an opportunistic surgeon over-utilization drain of healthcare resources on the U.S. healthcare system.
STEP TWO – Form PSID (Pre-Surgical Implantation Day form)

On the day of a recognized surgery, the second and primary universal patient informed consent form, Form PSID, will be legally mandated to be given to every U.S. patient, during the time of surgical check-in, at the reception counter. Form PSID will restate the information appearing in Form FOCD given to a patient, by the implant surgeon, on the final pre-surgical office consultation day. With Form PSID, patients will legally bind: a legal L-T/PI medical device use designation(s), through SIU, to the conditions (restrictions) mutually agreed upon with the implant surgeon during final pre-surgical office consultation together for a responsible, real-world implantation.

Rationale for Form PSID:

Form PSID, when given to a potential implant patient at the time of surgical check-in, will now no longer allow patient informed consent to be obtained under duress or with coercive, manipulative pressure after a patient has been prepped for surgery. By creating this legal opportunity, to safe-guard every patient’s rights, each patient and/or their support network (present or over the phone) will be afforded the ability to verify that Form PSID correctly restates the same information appearing in Form FOCD from the final pre-surgical office consultation day. If the patient arrived early enough on the day of surgery, they and/or their support network (if not present, via smart phone) would have ample time to thoroughly review the accuracy of Form PSID. This will help prevent an illegal surgeon attempt to undermine his/her patient’s rights. An attorney could also be consulted to review Form PSID.* If the information was not the same as originally stated in Form FOCD, Form PSID could possibly amend the discrepancy in writing, for a patient to then sign, if still believed it was that surgeon’s intent to legally carryout their (the patient’s) wishes.

* Preemptive, pre-surgical attorney involvement could be a very highly profitable future enterprise for entrepreneurial attorneys, as a rationally thinking patient would sooner, pre-surgically mitigate unreasonable risk, than be subjected post-surgical, to the then undoable abusive risk (irregardless, if that deceptive surgeon infliction of risk, resulted in a more apparent future harm). In the private sector, attorneys could advertise smart-phone apps which allow patients to take a picture of Form PSID, and then for a fee (via credit card, debit card or PayPal) legally advise patients, in real-time, if there is an illegal surgeon attempt at hand to undermine their rights. To this same end, attorneys could be on the payroll of private insurance companies. And, in the public health sector, Medicaid and Medicare could also have attorneys on standby to help prevent a current unwarranted or in the future, reactive resulting waste of healthcare resources from being deceptively carried out by abusive surgeon or user facility intent to prey upon patients for their own self-serving, one-sided benefit gain.

The Restrictions for Use Statement

The restrictions for use statement will be a legally binding statement of pre-surgical surgeon intent. During the final pre-surgical office consultation between patient and surgeon, following an informative surgeon conversation with that future perspective implant patient (to legally inform the patient of their surgeon understanding for the reality of device/procedural risks and benefit potential from all treatment alternatives applicable to that individual patient’s specific disease/condition severity) logically, there should be evolving conditions formulated around a future (if individual patient need applicable) understood responsible L-T/PI medical device implantation. These conditions will be surgeon expressed in writing in the restrictions for use statement, as the restrictions which were mutually, legally agreed upon with patient during their final pre-surgical office consultation together for a future, responsible L-T/PI device implantation.* On the day of a recognized surgery, via Form PSID, patients will then legally consent to the previously agreed upon conditions placed upon device use, to make a specific device(s) refit for its SIU.

* A surgeon’s integrity, honesty and competency in informing their patient of device/surgical procedural risks and the benefits from all alternative surgical treatment options (albeit, non-device surgical options the regrettably trained surgeon is not competent to offer patients, as a patient benefit, removed from that surgeon’s own benefit) and if applicable, non-surgical treatment alternatives, and then in filling out the restrictions for use statement (and in general, accurately filling out Form FOCD), will like any other legally binding contract, prevent a future, more burdensome misunderstanding. If there is exploitative surgeon intent to undermine his/her patient’s rights (to habitually again carryout own best practice of efficaciously self-serving medicine, upon negligent failure of ethical responsibility, with abusive inability to risk-mitigate a past surgeon’s unwarranted/unnecessary L-T/PI device risk infliction), on the day of a future recognized surgery, upon a patient receiving Form PSID, that self-inflicted surgeon entitlement belief (to narcissistically, abusively deceive patients into sacrificing their life-time of safety, compensatory to a surgeon’s own need to habitually act out regressive training limitations), may find the burden of reality, with a patient’s unwillingness to be preyed upon and exploited to satisfy those benefit gains exploited by secondary system interests. For example, if a surgeon has a reasonable anticipated probability to implant a risky L-T/PI device, the restrictions for use statement would place restrictions on that device implantation, to thereby mitigate an unnecessary and/or a very foreseeable adverse outcome from being abusively inflicted onto unsuspecting patients, disproportionate to a patient’s understanding of need (in the context of: speculative surgeon gambling with a patient’s life-time of safety
for a future unrealistic and/or then, unsustainable “benefit gain”). If the surgery consented to by a patient was to implant the designated main device, the restrictions for use statement would state the reason(s) mutually agreed upon between patient and surgeon during final pre-surgical office consultation together for a possible alternate device implantation. This will allow each patient to balance the risk-benefit threshold within a legally designated SIU approach (if that approach will even allow for device risk mitigation*), to then restrict the indications for use stated on a device’s labeling, to a patient’s understanding for their legitimate need versus surgeon’s illegitimate need. The restrictions for use statement will be governed by the no greater risk without reason clause (described below).

* The article: Doctors Debate Transvaginal Mesh Risks, Benefits at Urology Meeting, posted May 29, 2014 on Drugwatch.com, by Michelle Llamas, reported on an “annual American Urological Association (AUA) meeting [held] recently to debate the use of controversial mesh slings for the treatment of stress urinary incontinence” (emphasis added). During which, the question of what constitutes a “minimally invasive” surgery was unavoidably raised. Helen O’Connell, M.D., Associate Professor, Department of Surgery at the University of Melbourne and Senior Urologist at Royal Melbourne Hospital, correctly (in my opinion) framed the argument: “The idea that [mesh] slings are minimally invasive just because the incisions are smaller is only part of the story. Synthetics are only minimally invasive in the size of the wound.” (Previously, Eric S. Rovner, M.D., Director of the Section of Voiding Dysfunction, Female Urology and Urodynamics in the Department of Urology at Medical University of South Carolina had stated in this same article: “Polypropylene mesh sutures have been used in hermia repair and sutures for 50 years. Is there any reason to believe that mid-urethral sling mesh will behave any differently than polypropylene mesh used in these other applications?”)** “We’re not debating efficacy.’…’What we are talking about is safety,” stated Jerry Blaivas, M.D., Clinical Professor of Urology at Weill Cornell Medical College and Attending Surgeon at New York Presbyterian Hospital and Lenox Hill Hospital, under section: Mesh Slings Cause Serious Complications. Dr. Blaivas’s following statement, under section: ‘Disasters Are Avoidable’, “So, if these bad complications are up to about 4 percent, which I think we can probably agree on, that’s 1 out of 25 patients,’…’I would personally play the lottery all day if I had a 1 in 25 percent chance of winning the lottery. And it’s not clear to me that we should be making decisions for our patients that allow us to do those same odds,”% not only ended the article, but in my humble opinion, any reason to further debate current “use of controversial mesh slings for the treatment of stress urinary incontinence.”

** Polypropylene mesh use has also had a long history of same type of predictably innocuous in vivo performances and adverse outcome consequences for its hermia patient indication. Material degradation, contraction/shrinkage, migration, erosion, extrusion and hardening to form meshoma (a “mesh tumor”) are all highly predictable in vivo mesh performance norms. Predicted also for patient experience are: fistulas, abscesses (infections harbored in synthetic mesh materials); adhesions; uncontrollable human body inflammatory, autoimmune and excessive scarification responses (or with lack of scarification response – migration for both the fixed and non-fixed mesh devices from possible initial, “minimally invasive” laparoscopic inguinal placement on and/or close proximity to nerves, veins, bladder, and in males, spermatic cords – to then adhere to and/or injure inginal structures, with possible injuries first from the tunneling through flesh to get from the naval area to the groin, with future risk of incisional hernias at port-site holes); ensuing high statistical rates from 0 – 63% for chronic groin pain = “torture,” nerve damage, pain management regiments; adverse impacts on work, relationships and overall health; and then the lack for still more patient treatment ineffectiveness from, if lucky, reactionary surgical strategies needed to address this manufacturer-to-surgeon infliction of own best practice. Was there “any reason to believe” polypropylene mesh would behave different?

The No Greater Risk Without Reason Clause

As it is the reality ensuing that with an industry’s promotion of indiscriminate L-T/PI device abuse into real-world clinical practice, those risky devices (irregardless if first, even able to have been FDA pre-market regulated to a reasonable assurance of safety and effectiveness) then become dangerous devices, to inflict upon an industry’s pre-conditioning of surgeon intent: an unreasonable risk for illness and injury across entire patient populations – pre-surgically, every patient not only needs to understand a life-time of device and accompanying surgical risk, but must also first decide for the regressively trained surgeon: responsible, real-world L-T/PI device use. As the regressively trained surgeon was never competent trained to mitigate the heightening of risk they unavoidably, abusively inflict, indiscriminately onto patients, they can only negligently act out own best practice of L-T/PI indiscriminate device abuse. Therefore, this clause will necessarily require universal legal surgeon adherence for: the recognition of their patient’s civil/Human Rights, before carrying out own, self-serving, risk-adverse intent. The no greater risk without reason clause will effectuate this legal surgeon adherence with its following four prescriptions of law:

1. If the surgical procedure which the patient legally consented to have performed (as conditionally, surgeon-stated in the restrictions for use statement) was to be preformed as a conservative surgical approach (to not implant the risky L-T/PI medical device), and either the main or alternate device was implanted, in the operative report the surgeon would be legally required to explain the reason(s) justifying subjecting their patient to that heightening of a non-legally consented to risk.

2. If the surgical procedure which the patient legally consented to have performed (as conditionally, surgeon-stated in the restrictions for use statement) was to implant the legally designated main device, and the surgeon implanted an alternate device,* in the operative report the surgeon would be legally required to explain the reason(s) to have justified the alternate device implantation and thereby, then subjected their patient to that heightening of a non-legally consented to risk.

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The No Greater Risk Without Reason Clause

As it is the reality ensuing that with an industry’s promotion of indiscriminate L-T/PI device abuse into real-world clinical practice, those risky devices (irregardless if first, even able to have been FDA pre-market regulated to a reasonable assurance of safety and effectiveness) then become dangerous devices, to inflict upon an industry’s pre-conditioning of surgeon intent: an unreasonable risk for illness and injury across entire patient populations – pre-surgically, every patient not only needs to understand a life-time of device and accompanying surgical risk, but must also first decide for the regressively trained surgeon: responsible, real-world L-T/PI device use. As the regressively trained surgeon was never competent trained to mitigate the heightening of risk they unavoidably, abusively inflict, indiscriminately onto patients, they can only negligently act out own best practice of L-T/PI indiscriminate device abuse. Therefore, this clause will necessarily require universal legal surgeon adherence for: the recognition of their patient’s civil/Human Rights, before carrying out own, self-serving, risk-adverse intent. The no greater risk without reason clause will effectuate this legal surgeon adherence with its following four prescriptions of law:

1. If the surgical procedure which the patient legally consented to have performed (as conditionally, surgeon-stated in the restrictions for use statement) was to be preformed as a conservative surgical approach (to not implant the risky L-T/PI medical device), and either the main or alternate device was implanted, in the operative report the surgeon would be legally required to explain the reason(s) justifying subjecting their patient to that heightening of a non-legally consented to risk.

2. If the surgical procedure which the patient legally consented to have performed (as conditionally, surgeon-stated in the restrictions for use statement) was to implant the legally designated main device, and the surgeon implanted an alternate device,* in the operative report the surgeon would be legally required to explain the reason(s) to have justified the alternate device implantation and thereby, then subjected their patient to that heightening of a non-legally consented to risk.
* As the alternate device was NOT the patient’s L-T/PI device choice legally consented to have implanted (as it was an alternate device), it did not form the foundational basis for legal patient informed consent. Thus one would logically assume that an alternate device would be implanted to address a possible greater legitimate patient need during surgery, a need which was not competently able to be pre-surgically surgeon anticipated. The mitigation of risk is therefore, a predominant condition of legally informed patient consent.

3. If the surgical procedure which the patient legally consented to have performed (as conditionally, surgeon-stated in the restrictions for use statement) was to legally implant only one device, and the surgeon implanted multiple devices, in the operative report the surgeon would be legally required to explain the reason(s) to have justified subjecting their patient to that heightening of a non-legally consented to risk.

4. If a surgeon made during surgery, a pre-surgically undisclosed modification to a legally designated L-T/PI medical device (not stated in the restrictions for use statement), in the operative report the surgeon would be legally required to explain the reason(s) to have justified subjecting their patient to that heightening of a non-legally consented to risk.

**The Proposed FDA UDI Entry Portal (UEP)**

The UEP will be an FDA administered* internet portal which will afford patients, their representatives and as previously stated surgeons, upon entering the UDI device identifier, the ability to directly understand (independent of the currently restricted manufacturer-to-surgeon and then surgeon-to-patient marketing avenue) the legally mandated manufacturer and FDA (then FDA also enforced) knowledge discolser of all known or reasonably should be known L-T/PI device and accompany immediate and long-term surgical risks. Post-paradigm shift, the UEP will either incorporate or seamlessly link to *The Responsible Use Patient Safety Guideline Lens (The RUPSG Lens)*. The RUPSG Lens is the risk-stratification mechanism of The Bur-Metric System for Medical Device Quality. This lens will allow patients to weigh (via its NDESIR and NSASR metrics) the historical efficacy benefit potential from a once unnecessary L-T/PI device use against current unwarranted abuse. From which, via this primary system control (The Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process), The RUPGS Lens will create the threshold-around post-market reasonable assurance of safety and effectiveness understanding, to subsequently, “birth form” for the ‘ES’ framework’s *Inner Patient Health (availability for) Benefit Threshold Fold.*

* Also governing the UEP, should be a taskforce formed of public sector entities (patient human rights/public safety groups and non-bias, scientifically like-minded medical journals), mutually dedicated to both the integrity of medicine and insuring the universal recognition of every patient’s safety, with right to choose quality, non-device industry inflicted healthcare. With removal of the “substantially equivalent” obscured safety misconception, the UEP will begin to usher in, under the leadership of a U.S. Government carrying out its international obligations, the era of patient centered medicine. Globally, for the benefit of the world’s peoples, the UEP will also help combat the device industry’s infectious plague of injurious medicine, spreading from nation to nation, to surgeon indoctrinate its own, self-serving practices.

Both Form FOCD and Form PSID will have the web address for the UEP and accompanying statement briefly describing the purpose of the UEP and how a patient can gain access to device specific information upon entry of the UDI device identifier. The UEP could also link to *The Global Unique Device Identification Database* (GUDID). The GUDID, as stated on the FDA’s website, “is a publicly searchable database administered by the FDA that will serve as a reference catalog for every device with an identifier. Under the UDI final rule, the labeler of each medical device labeled with a unique device identifier (UDI) must submit information concerning that device to the GUDID.” This “must [be submitted] information” by the labeler, could also encompass patient informed consent disclosures #4, #6 and #7. It could also include UDI specific pre-market clearance and approval information (to correlate UDI lineage risk back to greater device family SDDDTCTs, defined below) for patient understanding of ongoing flaws, inherent to both those overly injurious lineage strands and/or unaddressed device limitations; and where a device was made (to allow patients to choose devices manufactured in the USA or country of their choice).

**Rationale for a Greater UEP Functioning Practicality:**

Due to the endless technological characteristic changeability potential that can be used to spur L-T/PI device profits along in the post-market arena (currently market incited under “substantially equivalent” device cover), the UEP will act as a “funnel” (following the reinsertion of the fragmentation of that data flow categorization, from the near real-time reintegration of robustly mined post-market UDI performance data*) to allow for the real-world “coagulation” of in vivo device performance understandings to “cascade down” componential UDI device design, upon the significant, defining, dominant (L-T/PI) device technological characteristic traits (SDDDTCT),** composing greater UDI device family of origin pedigrees (post-paradigm shift: GDM lineage strands). Then, as stated above, post-paradigm shift in the new ‘ES’ regulatory framework, The Bur-metric System for Medical Device Quality will equate a tangible metric system construct over the two-steps of this patient informed consent.
process. Inferior device technologies will, consequently, then be patient driven from the marketplace into extinction. While understanding from existing, least risky technologies will begin to adjust within current, industry-controlled treatment protocols, to establish hierarchical, risk-based thresholds for responsible real-world L-T/PI device use.***

* With paradigm shift into the ‘ES’ framework construct, this data projection flow through the public domain into the UEP (following the legally mandated industry and FDA knowledge dissector of all known and anticipated harm from past, current and evolving marketed device use) will become the UDI flow filtering through The Pre/Post-Market L-T/PI Medical Device Interface Matrix (within the control confines of the different, currently established GDMIMs). This UDI data performance dissemination captured in same IRU Axiom Building Block Repositories (ABBR) and then dimensionally extrapolated from the GDM-to-UDI overlay control template filter within the ABBR’s UDI Data Extrapolation-to-Axiom Device Building Block Crystallization Domain, will be crystallized into Axiom Device Building Block (ABBB) norm “constants,” to shadow in vivo SDDDTCT performance (cohort relevant). This dissemination of GDM-to-UDI shared SDDDTCTs (to separate variable from constant) upon contrast drawn from UDI specific, insignificant (L-T/PI) device technological characteristic traits (IDTCT), will first be dimensionally nuanced on same SIU planes and then evolutionally between the different IRU planes. ABBBs will then be categorized back under their SDDDTCTs into Same SIU Data Reservoirs and then, via The ADDB Understanding Reintegration Window, real-world device performance predictability (via the ADBB) will integrate into the two phases of The Clinical Trial and Axiom Building Block Understanding Reintegration Gateway (CTABBURG). The CTABBURG will either for existing GDMIMs, build its next ‘ES’ Lead GDM reiteration or function to first create a new GDMIM, to begin “stitching together” the regulatory fabric along that new SIU/IRU trajectory.

** The rationale for SDDDTCT conceptualization is grounded in drug regulation. Likened to the active ingredients of drugs, which combine to form componential drug design makeup (irregardless if brand name or generic drug), SDDDTCTs combine to form the componential design pattern makeup of devices (irregardless if a past comparative device or next device), while the IDTCTs of UDIs can then be likened to inactive generic drug ingredients. Inherent to both the componential design makeup patterns of active drug ingredients and SDDDTCTs for devices, are within indications, different intended use performance implications. Therefore, the (in vivo) dominance of the active trait is significant, because that dominance is intended to effectuate clinical effects and/or outcomes on the function(s) and/or structure(s) of the human body. If untrue, what is innovation if not first intended to effectuate clinical change, and why effort otherwise, unless following as adverse? (In the game of pool to get a ball in a wrong pocket, does not count as a direct success, to then continue that player’s turn.) More significantly, however, why even have regulation over the medium of device innovation if not to exercise control over the device domain, unless control was intended over public perception, to absurdly masquerade an industry’s profit opportunity to a purported “public benefit”? SDDDTCTs defined are: all tangible attributes of physical device design (with relevance to: shape, size, increase/decrease in volume and/or density, quality and clinical feasibility of componential device materials), and all intangible internal and external means of executing control over device functionality (with consideration of: energy sources, software designs and its security), and/or all other features of componential L-T/PI device design, which intended/non-intended implications, carries within its dominance, risk probability consequence(s), adversely impacting the function(s) and/or structure(s) of the human body and overall human wellbeing.

If every patient purportedly has a pre-surgical, legal right to weigh the risks verses benefits between different viable treatment options – to undermine that patient right is a crime. UEP erection and functioning mobility will sever the physician-to-patient exploitative marketing avenue, which has not only unjustly enriched domestic but transnational device manufacturers also marketing their devices in the U.S.* The severing of this proceeding “industry umbilical cord,” as the “least burdensome” means to its profits, will begin to address its abusive, societal formed control over its surgeons’ infliction of own standards of care. These industry promoted standards of care not only function to unjustly physician indoctrinate highly profitable, patient exploitative, indiscriminate L-T/PI device abuse but also serve to insulate the repeat offender physician from accountability. This industry undermining of the patient.doctor relationship, to thereby insulate the physician perpetrator of his/her crime against patient orientated medicine (with negligent opinion failing in a validity to mitigate a historical, once unwarranted L-T/PI medical device risk, from current, unreasonable abusive infliction), allows for that compromised physician to further, abusively prey upon the vulnerabilities of more future unsuspecting patients, to again carryout own best efficacious practice of medicine.

* Consequently, the UEP will also usher in a new era of U.S. product liability law, as it will render obsolete “the learned intermediary defense” which has allowed for this current, opportunistic marketing of L-T/PI medical devices (through the numerous loophole riddled pre-market U.S. device pathways: 510(k), PMA and the others) to subsequently, search out risk-adverse surgeon benefit tolerances. With the shortening of the manufacturers’ learned intermediary defense liability shield, “substantially equivalent” device cover will rapidly begin to dissolve. In the light of transparency, the more risky devices will be left behind in the wake of ‘ES’ forward movement away from “the {510(k)} predicate device.” Without the necessary patent reform, within an ‘ES’ regulatory framework construct functioning to address those ongoing, unreasonably dangerous lineage strands, with colligation of collective patient understanding around the least risky devices, current “device patent firewalls,” will subsequently, begin to create individual manufacturer quality device monopolies. In The ‘ES’ Regulatory Framework, The GDM Patent System will act to prevent (via GDM formation**) the “non-substantially equivalent” “ES’ device from justly creating this quality market monopoly. Patient risk-tolerance codifying through The RUPSG Lens (via this primary system control of The Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process) will adjust device use, first from and then for, the legally informed patient perspective. Clinical practice will then begin to remodel to “like patient” cohort endpoints to establish hierarchical risk-based treatment stratification thresholds (via the GDM’s IRU part - 2 refinement). The legally informed patient perspective will place in check, these current self-serving, abusive surgeon behavioral norms narcissistically fixated upon the efficacy restricted into an indiscriminate L-T/PI medical device abuse, striving to satisfy this conmilling of manufacturer benefit, from self-serving surgeon intent.
**The generational device model (GDM) is the relationship embodiment contrast between the brand name drug and its “bioequivalent” generic drugs. With inactive generic drug ingredient conformity maintaining the “reasonable assurance of safety and effectiveness,” set within the bounds of a brand name drug’s natural (and/or chemically formed) active ingredient confine parameters; likewise, for IDTCT UDI conformity (comparable to componental same SIU/IRU GDM design formation), SDDDTCTs are necessarily, legally bound together to form componental GDM design (akin to the overarching “active” control parameters inherent to drugs). For drugs, that “reasonable assurance of safety and effectiveness” is maintainable, via the principle of “bioequivalence,” which allows the comparative, “bioequivalent” generic drug(s) to not need to go back through a clinical trial, because its reasonable assurance of safety and effectiveness was transferable on brand name drugs’ market approval. However, for device clearances, with some exception (first avoiding the fact that a pre-market reasonable assurance of safety and effectiveness was never formed within clinical trial confines, and not on assumption from a pre-amendment device’s safety/effectiveness myth-conception), under principle of “substantial equivalence” “a reasonable assurance of safety and effectiveness” is non-transferable due to continuous creep of “the [next 510(k)] predicate device” away from a pre-amendment device. With paradigm shift, a GDM market approval (upon establishing its reasonable assurance of safety and effectiveness within the CTABBURG’s clinical trial control confines – under the governance of The Effectively Safer GDM Standard*** for a same SIU/IRU UDI replication, between the GDM-to-UDI comparison, via the principle of ‘inconsequential difference’ ‘(ID)’.

***The three legislative control attributes of The Effectively Safer GDM Standard’s near-proximate intertwined and synchronized interlacing of the ‘ES’ Regulatory Framework’s tri-tiered statute, between its upper-tier: The U.S. Taxpayer and Secretary (FDA) Efficiency Standard and base-tier: The Inconsequentially Different UDI Standard (to begin to effectively regulate all legally marketable L-T/PI devices (UDIs) in the U.S. to ONLY a pre-market reasonable assurance of safety and effectiveness) are as follows:

- **Lag GDM Verification control attribute**: The FDA’s (CTABBURG preclinical phase) verification, upon Industry identification, of the current legally viable, same SIU/IRU, ‘least risky’ (‘LR’) Lag GDM.

- **Lead GDM Incremental control attribute**: The FDA’s (CTABBURG preclinical phase) confirmation of only one significant incremental change within an existing GDMIM, between next proposed ‘ES’ Lead GDM and the FDA verified, current legally viable, same SIU/IRU, comparative ‘LR’ Lag GDM.

- **Lag-to-Lead GDM Comparative control attribute**: The FDA’s (CTABBURG clinical phase) finding, upon the CTABBURG’s ‘ES’ hypothesis, of the next same SIU/IRU, ‘ES’ Lead GDM reiteration.

The GDM, upon maintaining the overarching, legally formed control parameters of its RVR, will not only just have the ability to then “project” an ‘ID’, same SIU/IRU/UDI replication into the post-market arena (via The Inconsequentially Different UDI Standard) but will also, within its greater GDMIM “vehicle” confines – upon addressing (without creating the quality, least risky device market monopoly) the 510(k) clearance process’s moving phenomenon of “the predicate device” creep – thereby then, start “the engine of innovation.” The evolutionary, progressive GDMIM will “house” only one Lead and one Lag GDM “vessel” at a time for its same SIU/IRU. It will, unlike the innovatively stagnate, “comparative” 510(k) “predicate device,” move within a scientifically progressive construct – The Pre/Post-Market L-T/PI Medical Device Interface Matrix – along a same SIU/IRU trajectory (via the Lag GDM Verification control attribute) with market purge of its innovatively stagnant, ‘left inferior’ (‘LI’) Lag GDM ( likened to a ‘ID’ “predicate device” swath). Then, incrementally (via the Lead GDM Incremental control attribute) build (via the Lag-to-Lead GDM Comparative control attribute) upon that FDA verified current ‘LR’ Lag GDM (the comparison control “grounding” The Outer Public Health (potential for Benefit Threshold Fold of the ‘ES’ Regulatory Framework), a CTABBURG hypothecated and FDA found, progressively ‘ES’ Lead GDM reiteration. Removed from this current, patient abusive, manufacturer enticed surgeon upon misdirected FDA intent, if every rational thinking patient would want the currently understood ‘LR’ device responsibly implanted, an effectively functioning, risk-based regulatory framework paradigm must necessarily purge ‘LI’ device technologies from the marketplace, to then build (from a scientifically grounded, “non-substantially equivalent” foundation – upon a transparent understanding of current device limitations), within the spectrum of individual patient risk-tolerance (the inner threshold surround), hypothecated ‘ES’, innovative technologies.

Card PSDI (Post-Surgical Device Identification card)

Card PSDI will be the verification control mechanism of this proposed improved patient informed consent process. Every U.S. patient implanted with a L-T/PI medical device will be legally required to receive Card PSDI in their surgical discharge paperwork either directly from the implant surgeon or user facility. Then, following within 14 days post-surgical, a free copy of their operative report will be legally required to be mailed out to them (if a patient did not already receive a copy directly from the implant surgeon during a post-surgical follow-up office visit). Card PSDI will now legally mandate, post-surgically, the identification of every L-T/PI medical device implanted in the U.S. by both its UDI device identifier and production identifier.

Rationale for Card PSDI:

Pre-surgically, via Form PSID, as the patient legally bound specific surgeon device use (via UDI device identifier/s) through SIU, to their legal understanding for a conditional, responsible, real-world implantation (via the restrictions for use statement), post-surgically patients will now have the opportunity to verify (via both Card PSDI and their operative report) that their pre-surgical wishes were carried out by the implant surgeon upon the specific conditions they legally consented to in the restrictions for use statement and in Form PSID. If there was an unjust physician deviation from Form PSID, as stated below, the publicly transparent patient complaint mechanism will be “the
doorway”* to a level playing field, by which patients may seek justice accordingly and thereby prevent a surgeon’s cowering from accountability behind his/her peer’s review (with protection by their state’s medical board).

* Akin to the above publicly transparent patient complaint mechanism being “the doorway” for a patient held physician accountability, Card PSDI could also be more effectively utilized to enhance the robust, post-market surveillance of L-T/PI devices. As suggested to the Members of 112th U.S. Congress in my January 23, 2012 mailing entitled: The Reasonably Safe Medical Device Surveillance Act of 2012 (RSMDSA), Card PSDI could as appeared and laid out below, (minus [ ] also have the greater functioning practicality as Form PIMDP.

[Bill RSMDSA….] will mandate that: (1) Form PIMDP (Patient Implantable Medical Device Post-operative) is required to be given to every patient implanted with a LT/PIRMD [long-term and/or permanently implanted risky medical device] by all User Facilities, (2) the formation of an independent, secure PIMD form storage and electronic forwarding hub (SEFH), and (3) the formation of an independent, transparent public database (TPD).

1) Form PIMDP will be available online as a universal, standardized printable form. Form PIMDP will be required to be filled out by all User Facilities, placed into a postage paid envelope addressed to the SEFH (printable online) and given to every implant patient in their post-surgical discharge paperwork. Side “A” of Form PIMDP will contain the patient and User Facility personal identifiable information. Side “B” will contain the unique device identifying information (and barcode from device packaging), significant patient demographic determinants and the adverse event section/text block. User Facilities will be required to submit the filled out PIMDP forms (excluding the future potential adverse event section) online directly to the SEFH.

By the User Facility submitting Form PIMDP directly to the SEFH, and then with the SEFH submitting only side “B” to the TPD (to protect personal information), it will put a denominator on the number of unique device group, family specific LT/PIRMDs being implanted in a demographically diverse patient population being targeted for their use. When this denominator is matched in the TPD by the report of an adverse event (from any source, and/or multiple sources accounting for one expanding reportable event) it would give the necessary numerator to equate the current understanding for the LT/PIRMD/procedural percentage usage safety risk for the patient consumer.

2) The SEFH will be a new entity formed independent from the Food and Drug Administration (FDA). The SEFH will capture all LT/PIRMD adverse events for the U.S. and laid out below is the SEFH could follow: (1) Form PIMD will be sent directly to the SEFH, and then with the SEFH submitting only side “B” to the TPD. Computer software could then be utilized to edit and standardize the handwriting or the computer print pasted into the PIMDP’s adverse event text block. Once in the domain of the TPD, system interests could interpret a ‘cleaner data’ source, built upon real world data coming directly from a patient’s postoperative experience; with that patient’s experience, as the relevant endpoint. The SEFH could follow-up with patients to clean/refine data and do long term follow-up on the submitter’s side; while the TPD could, if necessary, communicate to the SEFH a potential new evolving LT/PIRMD risk. The SEFH could investigate this new risk by sending out questionnaires. By keeping the ‘waters of innovation’ turning it will help sharpen the leading edge of innovation. Current LT/PIRMDs will cut into the future at the point of the understood [from the ‘LR’ Lag GDM] safer and then more effective [via the ‘ES’ Lead GDM] LT/PIRMD. Patient consumer driven market demand for the best available LT/PIRMD will help leave behind their [‘LI’] more unsafe and less effective LT/PIRMDs of the past. The RSMDSA will help link the scientific understanding needed today from a LT/PIRMD’s post-market performance to its future LT/PIRMD’s pre-market pathway.

3) The TPD will be a new entity formed independent from the FDA. The TPD will quantify in an orderly arrangement the number of LT/PIRMDs being surgically implanted in the U.S., while connecting its matching returned PIMDP form(s).

 Enforcement Provisions for Legal U.S. Surgeon Adherence to U.S. Constitutional and International Human Rights Laws

To the end of: the legally informed U.S. patient, this Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process, will also, necessarily require a publicly transparent patient complaint mechanism with subsequent, effective enforcement oversight for legal physician adherence by the Civil Rights Division of the U.S. Department of Justice. This complaint mechanism will preemptively function to help future patients understand the heightened risks subjected to them by the repeat offender physician, as that individual continues to struggle with difficulty, to overcome his/her own abusive need, to deceptively act out their regressive training limitations upon unsuspecting patients as the best physician/manufacturer practice. With the opportunity for a surgeon to abuse his/her position of influence, to undermine their patient’s rights (by obscuring knowledge of device/surgical outcome risk –to then carryout self-serving intent), there also needs to be legal accountably under a just rule of law.

More than just this preceding transparency urgently needed now to warn future U.S. patients of the danger posed to them by the repeat offender physician – removed from the self-entitled physician peer group’s possible only further reinforcement of their own “like” patient exploitative, regressive behavioral norms again as “acceptable” – a greater societal consciousness must decide appropriate physician punishment (to help deter more same, illegally entrenched, abusive surgeon behavioral norms from continuing to be deceptively acted out to harm more, future, unsuspecting U.S. patients). As current, indiscriminate L-T/PI device abuse is the reality that the manufacturer/physician societal collective created to first benefit itself with own best practice – this real-world, indiscriminate surgeon abuse creates an unreasonable risk of illness and injury for patients (irregardless if any risky device was first effectively regulated to a pre-market reasonable assurance of safety and effectiveness). Future premeditated physician “attacks” (Article 7(1) “Crimes against humanity” of The Rome Statute of the International Criminal Court) against unsuspecting U.S. patients, should therefore, be correctly understood and defined under U.S. Law: as a person-to-person assault.
AN OVERVIEW OF THE CONTROL INFRASTRUCTURE FOR THE OUTER PUBLIC HEALTH (potential for) BENEFIT THRESHOLD FOLD

THE TRI-TIERED STATUTE

UPPER-TIER: The U.S. Taxpayer and Secretary (FDA) Efficiency Standard

MID-TIER: The Effectively Safer GDM Standard

BASE-TIER: The Inconsequently Different UDI Standard

LEAD GDM INCREMENTAL CONTROL ATTRIBUTE

LAG TO LEAD GDM COMPARATIVE CONTROL ATTRIBUTE

LAG GDM VERIFICATION CONTROL ATTRIBUTE

FDA Approved: Next ‘ES’ Lead GDM

FDA Verified: Current ‘LR’ Lag GDM

THE GDM INTERFACE MECHANISM (GDMIM)

THE UDI-TO-IRU (Part 2) REFINEMENT PLATEAU

DEMOGRAPHIC SPREAD OF THE DESIGNATED PATIENT POPULATION

THE INTERFACE MATRIX

PRE-MARKET INTERFACE

POST-MARKET INTERFACE

New Lead GDM Petitions Submissions (LPS)

Reintegrating Post-Market UDI Data

THE Reasonable Assurance of Safety and Effectiveness Threshold

The Upper Limit Threshold Control Parameter

The Lower Limit Threshold Control Parameter

RVR

Fig. 10 (1 of 2)
PATIENT LEGALLY CONSENTED TO RESPONSIBLE L-T/PI MEDICAL DEVICE USE VIA THE INNER PATIENT HEALTH (availability for) BENEFIT THRESHOLD FOLD

THE PRIMARY SYSTEM CONTROL: The Universal, Two-Step, Implantable Medical Device Patient Informed Consent Process

The Reasonable Assurance of Safety and Effectiveness Threshold

THE L-T/PI MEDICAL DEVICE USE/ABUSE CONSIDERATION

The Reasonable Assurance of Safety and Effectiveness Threshold

THE FOUR COMPONENTS OF LEGALLY INFORMED PATIENT CHOICE

1st: Treatment Choice Component
- to have a L-T/PI device responsibly implanted
- metrics to equate value
= average cumulative PAEPR for an IRU's SIU designations
- weighed against
= L-T/PI device benefit

2nd: Specific SIU Component
- singular IRU/SIU designation
- metrics to equate value
= PAPER for singular SIU designation
- weighed against
= L-T/PI device risk

3rd: GDM-to-UDI Component
- to implant a UDI "filtered through" the current 'LR' Lag GDM
- metrics to equate value
= 'LR' Lag GDM's cumulative UDI-RAA average
- weighed against
= patient's GDM-to-UDI selection avenue correlates to selected GDM's UDI pool

4th: Specific UDI Component
- surgeon utilized/recommended 'LR' UDI choice(s)
- metrics to equate value
= UDI-RAA rate for one utilized/recommended UDI
- weighed against
= patient's legal designation of UDI(s)

IRU/SIU risks weighed from Industry's collective efforts at GDM level
- to implant a UDI "filtered through" the hypothetical 'ES' Lead GDM
- metrics to equate value
= 'ES' Lead GDM's cumulative UDI-RAA average
- weighed against
= patient's legal designation of SIU

IRU/SIU risks weighed from individual manufacturer effort at UDI level
- surgeon utilized/recommended 'ES' UDI choice(s)
- metrics to equate value
= UDI-RAA rate for other utilized/recommended UDI
- weighed against
= patient's legal designation of UDI(s)

risks/benefits weighed from an IRU's SIU designations
- same IRU's other SIU designations
- PAPERs for that IRU's other SIU designations

The RUPSG LENS

MATCHED “LIKE PATIENT” DEMOGRAPHIC ENDPOINTS

UDI RING

SIGNIFICANT DEFINING “LIKE PATIENT” DEMOGRAPHIC TRAITS

DEMOGRAPHIC SPREAD OF THE DESIGNATED PATIENT POPULATION

THE UDI-TO-IRU (Part 2) REFINEMENT PLATEAU

Fig. 10 (2 of 2)