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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room. 1061
Rockville, MD 20852

Re: C-leg wearer
Reginald Burgess
[redacted]

PETITION TO AMEND 21 CFR 820.198 TO ADD A PROVISION AS (a)(4)

Citizen Petition – Amend 21 CFR 820.198 to add an "(a)(4)" section

Petition to Amend 21 CFR 820.198 (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to add a section (a)(4) as shown

RE: This is a separate petition Related to Petition FDA-2013-P-0949

A. Action requested

Amend 21 CFR 820.198 to add a section "(a)(4)" as thus:

(4) Complaints or requests which involve requests direct or indirect from end user consumers for information for, or parts for, any item the manufacturer has manufactured under any FDA regulation, 510K exempt or not, under sections 21 CFR 890.3420 or 21 CFR 890.3500 for external prosthetic items or parts not available anywhere but from the manufacturer shall be addressed directly to the complainant and shall not be delayed or deferred. The manufacturer may not rely on in house distribution models or programs as any restriction to deny

access to the parts or information requested to keep the subject item operating in a safe manner, unless there is complete and accurate evidence the item is completely malfunctioning where 21 CFR 820.200 would reasonably apply. The manufacturer shall provide all materials and instructions to the owner to operate or repair the device themselves or program or re-program the item as need be unless it is a restricted item under 21 CFR 801.109, and this provision shall apply whether the item is under warranty or not. If the owner seeks to do repair work themselves, unless the manufacturer can show a legally sufficient business reason – of a "fundamental alteration" or "undue burden" or "direct threat" reason the owner cannot do said work, the manufacturer is to provide by sale of the parts needed at proper and reasonable costs the parts and/or instructions to the owner/ wearer and document same under the provisions of 21 CFR 820.200 as a "service" to the item in question and said records shall be kept as such. This requirement does not apply to resellers, distributors or end use manufacturers.

B. Statement of grounds

See also as related **Petition FDA-2013-P-0949**

There is a general belief that there exists some Federal Law for EXTERNAL prosthetics that a "prescription" is required to "use" a prosthetic, when there is indeed no "prescription" per se, but rather a build order of medical necessity for an insurance carrier to be required to pay for the prosthetics under a Medical Insurance Policy. However the Prosthetics industry of DMEPOS manufacturers, distributors and builder manufacturers (the prostheticists) use a convenient construction of this belief to deny service, support and duties under the law to incorrectly and untruthfully disclose service and support issues of products required under 21 CFR 820.198

These "build orders of medical necessity" are called properly "Detailed Written Orders" and are NOT prescriptions in the true sense of the word. See Exhibit D, the "Ossur Rheo Knee Reimbursement Guide – Coding" at page 6 of 12. The document speaks to a "prescription" as a build order – the DWO, and in fact it cites at page 6 of 12 Medicare policy that the document claims "Under established Medicare policy, "[s]omeone other than the physician [i.e., the prosthetist] may complete the DWO. However, the treating physician must review the DWO and personally sign and date the order to indicate agreement." The DWO is only a reimbursement tool.

While 21 CFR 801.109 applies as to largely INTERNAL prosthetics that a prescription and controlled installation, surgery or setup is required for those devices which are NOT 510K exempt, no such limitation applies to EXTERNAL prosthetics under 21 CFR 890.3420 and 3500 class items.

The language below was submitted also as a proposed order to Petition FDA-2013-P-0949 and is a statement of grounds here. The Federal courts have already defined how an act would not be discriminatory under the ADA IF and ONLY IF, the party discriminating can defend their actions as a "fundamental alteration" or "undue burden" or "direct threat" to the way they do business or as harm to others as set forth in a "failure to sell" case setting forth the legal issues of ADA discrimination in Dudley v. Hannaford Bros. Co. 333 F.3d 299 (1st cir June 24, 2003). None of those defenses can apply here disallowing an ADA person to buy or build their own prosthetic.

In reply to a request to be given proper and safe instructive assistance to be allowed to replace his own battery on a C-Leg (K991950.pdf); Otto Bock counsel replied with a counter-offer to send the C-leg to Otto Bock at great cost and inconvenience to the petitioner. Exhibit A and FDA-2013-P-0949.

Otto Bock counsel believes it some kind of assistance to make a hardship counter-offer to a simple request of how the safest manner is to change the battery – an off the shelf item petitioner already has. See attached letter of Exhibit A of this petition. See photo of how proof is obtained the C-Leg works fine and is not malfunctioning otherwise as Exhibit B this petition.

The charging port PINS of the C-Leg from inner-most to outer-most of the charging port is (no more than) 4 volts positive, charge feedback, negative ground and negative ground. A fully charged 3.7 volt Li-on 18650 battery will set the C-Leg to mode 1 and power the C-Leg with the leads set across the inner most positive pin and outer most negative (ground) pin. It will walk fine and behave fine – "like new" - in all other respects.

STILL Otto Bock would rather allow a person to either not have use of the item or use the item in an unsafe condition even when notified, rather than reveal the safe manner to change the battery. See email sent to Otto Bock August 19, 2013 which was opened 6 minutes and 18 seconds after sending by Otto Bock counsel Stephen Carr and then forwarded to CEO Scott Schneider who read it at least 9 times. See Exhibit C 9th to final page

21 CFR 820.198 has no enforcement or directive language of what is prohibited, and instead the company – Otto Bock - would rather force a legal issue to their violation of the law and extortive marketing model.

This is likely because the FDA has very little power to discipline, punish or otherwise to hurt Otto Bock for this lapse in social consciousness but under 21 USC 331(a) it appears only the Secretary of HHS can do this.

However, a Federal Court can take notice of the standard of adjudication as to 21 USC 331(a) as interpreted by the Secretary of HHS as to what constitutes misbranding and adulteration of a medical device. These manufacturers will not disclose the dangers of the design features in plain English and will not truthfully speak to what laws actually apply to DMEPOS - prosthetics – because mostly there are none. The prosthetics industry instead is two-legged people trying to protect their meal ticket – the amputee, by extorting actions of the amputee by discriminately refusing service to any amputee who wants to service their own equipment.

Otto Bock and the DMEPOS industry in general do not want the knowledge of how to service one's own prosthetic to be let loose and they violate 21 CFR 820.198 and 21 CFR 820.200 to do so. There is no direct mention of a prostheticist "required" in any law. The medical policies of the various insurance carriers do not speak to any such requirement and in fact the insurance providers will deal direct on a claim from an insured person and pay them directly if they so seek and have a verifiable claim that meets the issues set forth in Exhibit D; BUT of course the DMEPOS industry prevents this by unlawfully refusing to sell or service the ADA person directly in violation of 42 USC 12182 and the Olmstead ruling mentioned herein.

In fact it is not unlawful to own a prosthetic absent a "prescription"; but what we have is an industry that is preying upon ADA amputees causing them to cower and take this abuse – as they have nowhere else to turn.

The most obvious demonstrative reason for instance Otto Bock keeps battery replacement so secret is because the billing for a $10 18650 Lithium Ion battery that takes ten minutes to change is under L-Code 7367, which bills at a maximum of $420 and minimum of $315 – (on the 2010 DMEPOS schedule) for a TEN DOLLAR battery which means the Otto Bock DMEPOS healthcare machine is actually printing money by secrets and extortion.

Places such as eBay and others on the Internet are sources of reasonably priced free-market pre-owned and NEW parts, the DMEPOS industry fights

B. SECTION TWO - TEXT OF A PROPOSED ORDER

A citizen petition was submitted requesting modification that external prosthetic parts and supplies be clarified and /or changed to be an over the counter item in

addition to being able to be prescribed by a licensed practitioners such as a physician. The petition points to issues and sections of the Americans with Disabilities Act (ADA) providing freedom in the law from a requirement that ADA persons be required to do things against their will, or being forced to allow others to do things for them that they would rather do themselves if they can.

The petition makes note of a landmark ruling of the US Supreme Court that ***Fifteen years ago*** in OLMSTEAD V. L. C. (98-536) 527 U.S. 581 (1999) the argument at the US Supreme Court keyed in on 42 USC 12182(b)(1)((B) which was what the petition argues is the case today because industry practices have now rely on the word "prescription" as a manner to deny access to the amputee community direct sales of parts and supplies they need and want to buy.

The FDA cannot speak to a function of the courts, but the petition is correct in that external prosthetic devices have NEVER met the definition for restriction to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food. Drug, and Cosmetic Art (the act) under the authority, of section 515(d)(I)(B)(ii) of the act.

Also NEVER has the FDA ever determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) Under the authority of section 515(d)(1)(B)(ii), (I) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2).1insofar as the sale, distribution, and use must not violate sections 502(q) and (r):of the act."

This language is found ONLY in the orders of INTERNAL, surgically implanted prosthetic knee, hip etc, or other medical devices as pace makers and the like.

The Petition keys in on the Otto Bock C-Leg granted a 510K exemption in 1999 as K991950 (http://www.accessdata.fda.gov/cdrh_docs/pdf/k991590.pdf) where

at the final page an "X" is placed at "prescription" and none at "over the counter use"

"Prescription" as defined in the law is found at 21 USC § 829 – Prescriptions, which refers to Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], has always been a term which refers to a "drug", but lately has been used to describe medical orders for use of a medical device. "Medical order" might be a more appropriate term of use when referring to a medical device.

21 USC § 360c – is where the classification of devices intended for human use is defined. The C-leg is classified as a class I and class II device; however it does not meet any standard for one that is used for sustaining human life. Thus while it has a design which must be monitored and reporting records keep as 21 CFR 820.198 demands, the C-leg 21 USC § 360k requirements have to do with safe performance of the item, not dangers associated with sustaining human life.

On the contrary, the C-leg, and most "microprocessor controlled" prosthetic knees bring a new level of safety to the above knee amputation community by use of microprocessor controls to make the use of an above knee prosthetic safer. This is indeed their claim to an advantage over their higher costs.

The argument of Otto Bock Healthcare was that the entire prosthetic knee system consisting of a foot, a specially designed pylon which has a sensor in it, and the knee unit itself must be used in a complete combination in order for the C-leg to operate properly. This is not in question in the citizen petition, but what is in question is a dangerous condition that arises because Otto Bock refuses to provide simple user support as providing instruction on how to change an end-of-life battery or provide software to the owner of the leg to re-program it if a part needs to be changed. Indeed it appears no skill level is required to re-program the leg and the software Otto bock provides has default settings that will result in a walkable C-leg by accepting the default settings.

The C-leg is powered by a lithium ion battery, which by its very nature decreases in effectiveness by a combination of charge cycles, age and discharge rate between charges. The citizen petition cited laboratory grade industry data in the attachment of emails the movant sent to the manufacturer, Otto Bock.

In an email returned to the petitioner, Otto Bock seemed to admit an old battery might behave this way; however, but failed to address what the petitioner was stating as to how the C-leg was performing versus what the company literature claimed it would behave as. Instead of locking up stiff like a stick for safety, it did the opposite and lost all powering force and effect to the hydraulic valves thus causing no support at all. The petitioner alleged that the proof of this came through plugging in the leg to wall power – which reset it to "mode 1" or attaching an external battery to power it externally which caused the C-leg to behave properly and stay in "mode 1" able to be safely walked in.

This would not be such a serious matter, if Otto Bock provided the user instructions and easy access to change the battery and the software to re-program the leg, but Otto Bock does not. The citizen who uses this product contacted Otto Bock in July 1, 2013, and asked simply if it was safe to change the battery without losing programming and never got a straight answer.

Apparently the C-leg was designed with a feature that causes the leg to reset itself to what is called "native mode" in which it will never work again without re-programming but remain locked up stiff like a stick. When the petition was filed on August 8, 2013 Otto Bock had stopped communication with the petitioner and had not relayed the requested information. Otto Bock essentially left the ADA consumer with an unsafe prosthetics product they knew was unsafe and refused to assist as requested with a simple battery change as all that was needed.

The citizen petitioner claims Otto Bock has adopted this marketing model and strategy to force the ADA person who is an amputee depending on this product, to then go to an "Otto Bock Certified Practitioner" where the solution is to

disassemble the leg and send it to Otto Bock for service. The petitioner claims this is not only inconvenient to him and costly in terms of dollars, but to force him into an operation which has no legitimate business reason is a violation of the ADA. It appears this is couched under the guise of the item being "prescription"

This service is "free" to persons with C-legs under warranty, but not to those whose legs are not under warranty. Warranties do not transfer to successive owners of the C-leg. There was no mention of whether the "certified practitioner" charges or bills other parties for the time associated with the send in service.

Otto Bock then will replace the battery and the owner has no idea what was put in it.[1] This disassemble and reassembly service is not free, and it is usually billed for to an insurance carrier; however for a person with no insurance it will cost hundreds or thousands for ten dollar battery replacement.

External prosthetics have been built and used since man first started surviving amputations, and they were often fitted by artisans, now called "prostheticists" who originally were amputees themselves having devised a helpful device for an amputated person, but today this is a huge business where the players in the business seek to gain unfair competitive advantages over both the customer amputees and each other to vie for an ever more competitive piece of the pie.

The petitioner argues this flies afoul of the ADA at section 12182 in that it has created classes of ADA Amputee individuals who are discriminated against in the sale and ability to obtain the products and services; and, who are otherwise extorted upon further service BECAUSE they are the disabled person with nowhere else to turn, and that Otto Bock, as well as the entire EXTERNAL

[1] The Li-on battery alleged to fit the C-leg is the 18650 size and it comes in five Mah ratings of 1800, 2250, 3000, 3400 and 4000 Mah hour capacities, all of which will work, but all of which will power the leg for different lengths of time, also the Li-on battery begins to die the moment it is manufactured, so the age of the manufacture date will affect how much charge the battery will hold as to a voltage level. See a thorough dissertation on the issues and factors affecting at http://batteryuniversity.com/learn/article/how_to_prolong_lithium_based_batteries

prosthetics industry in general, has misconstrued the true meaning of the word "prescription" to be used to build and maintain a discriminatory sales and distribution model and system in violation of the Americans with Disabilities Act (ADA) . See 42 USC 12182 et seq.

A prosthetic device is typically held on by a socket built for the wearer of FDA approved skin contact materials and the prosthetic device then attaches to the socket device by an adjustment screw or set-screw system. Petitioner argues the artisan skills to build a socket are not those of "licensed practitioners" as a physician or the like, but are "purchased" certifications from self appointed companies who sell the certification for what amounts to an annual fee or parts.

This "certification" is today used as a way to exclude and isolate the ADA amputees from any ability to procure the parts, items and service they need, and the above battery example is but one tip of very deep iceberg. The ADA person is prevented from buying any parts to do work themselves on their prosthetic.

Petitioner likens "Certified" Prostheticists to "auto mechanics" who need the business of the amputee to survive and thrive in a business. They need repeat business also in their geographic area. There are not that many amputees to go around to make the business lucrative thus costs are inflated to keep the lights on and business afloat. The industry has built this with specific ICD9 coding with prices built in for the labor which often amounts to parts and materials of just a few dollars upon which billing is done for upwards of $70,000 for a C-Leg.

A prosthetic for a leg wearer is only as dangerous the build and setup of the prosthetic given that the modular components of it are manufactured to be safe – as reported the FDA - and simply bolt together in an alignment using typically four set screws. The same instructions provided the "prostheticists" is the same instructions that could be provided the wearer amputee, and but for the word "prescription" – any amputee could save thousands of dollars and build their own prosthetics from the same components the prostheticists' buy and order.

Petitioner argues this is what the industry does not want to happen, and how and why Otto Bock especially has discriminatorily shut access to their products off from other distributors or the amputee and will not provide even the software to the buyer of their own C-leg to program it with. Petitioner further argues this flies in the face of OLMSTEAD V. L. C. (98-536) 527 U.S. 581 (1999) and Presidential Executive Order 13217 ordering all Federal arms of the government to implement the Olmstead decision force and effect wherever it is found and in whatever format it is found.

The FDA agrees it has a duty to make these items classification approvals "over the counter" because they have in effect always been so even before the Food Drug and Cosmetics Act was enacted as in use prior to 1976 as market items.

A C-leg is not a prescription medical device defined at 21 CFR 801.109 and no EXTERNAL prosthetic component or system ever has been classified as such

An EXTERNAL prosthetic device is NOT:

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

Additionally a "certified" prostheticist is NOT a medical "practitioner licensed by law" and never will be – but the two firms of http://www.bocusa.org/ or http://www.abcop.org simply sell the initial certification needed to then become one to be "licensed" in the few states which have consumer protection laws as to prostheticists. Often amputees come away from a prostheticist with a poorly adjusted or built leg and have to either return for another visit – which is billed again and a co-pay collected again; or they must re-adjust it themselves.

To create these desperate classes among amputee ADA members for an exclusionary marketing and distribution plan is unlawful as found at 42 USC

12182, and that is what the word "prescription" without the "over the counter" box also checked has led to in the approval orders for 21 CFR 890.3420 and 21 CFR 890.3500 items causes. There is always small MAJOR parts needed which can be replaced often with only two screws, and does not affect the geometry of the leg at all – like a replacement hydraulic cylinder which is out of their reach also.

Certainly a "battery" is a bit far fetched to disallow the owner to replace. The email volleys to Otto Bock describing the dangerous scenario of the C-leg owner by the petitioner illustrate the lackadaisical attitude to assisting him in fixing it. After 60 days progress appeared to have been made to a solution, their attorney got involved and it all went right back to square one of stonewalling.

This kind of discriminatory distribution model to keep the item they need actually from the amputee – because they are the disabled party – presumably because not being "certified" appears is patently unlawful and currently supported by the FDA because of the single word "prescription" without the "over the counter" box area also checked. It also appears to violate the ADA at 42 USC 12182..

21 CFR 890.3420 and 3500 items are largely crutches, cranes and wheelchairs which are all just as dangerous as would be a prosthetic as a crutch one wears, but to not be able to even GET one, may force one to buy a used one which may well be malfunctioning or inoperative and that raises an issue of preying on desperate people needing what they think is help – is then worse.

Regardless, it still is not illegal to possess external prosthetic parts no matter what, or to build them yourself - and that is the crux of the ADA argument at 42 USC 12182(a) and (b) states as below:

"(a) General rule No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations . . ."

"(b) Construction (1) General prohibition (A) Activities

(i) Denial of participation It shall be discriminatory to subject an individual or class of individuals on the basis of a disability or disabilities of such individual or class, directly, or through contractual, licensing, or other arrangements, to a denial of the opportunity of the individual or class to participate in or benefit from the goods, services, facilities, privileges, advantages, or accommodations of an entity."

It is not the function of the FDA to adjudicate matters of law outside the Food Drug and Cosmetics Act, but in fact a prosthetic "prescription" is not a prescription at all, and rather it is a build list of parts, and a format of one is found at http://pwop.net/word/PROSTHETIC_PRESCRIPTION.doc This is only a Medical Order document a Healthcare Payor needs to pay a claim and or IF the patient wants a Doctor to sign on to a specific build an amputee knows they want. An amputee could buy direct and build the prosthetic cheaper and pay less of a co-pay even if the insurer was paying, or could afford the item with the absent labor costs of the prostheticist that are built into the ICD-9 coding.

It appears by Olmstead, the only argument to not allowing purchase of EXTERNAL prosthetic items and parts **"over the counter"** by the wearer is one of extortion, and the only medical argument would be an Against Medical Advice determination that because the subject person has vertigo or other musculoskeletal disorder - which if the person is so wise and coordinated enough as to build themselves a prosthetic, and this case would be so rare as to be negligible, then maybe the motivation to walk again might be one which overcomes the Olmstead type decision of another that the ADA person cannot do this.

Of course nowhere at no time could any person in states which do require licensure of prosthetic businesses be able to build a prosthetic for another, and in states which do not require licensure to build a prosthetic for another, that

party still takes on liability for such acts directly, but that still would not prevent anyone from buying parts to do so for their own use or for a gift.

Currently as the person as the amputee, they cannot participate in building their own prosthetic as they want and how to purchase it; and instead the "contractual, licensing, or other arrangements" of the two firms of http://www.bocusa.org/ or http://www.abcop.org are designed to exclude them from building and servicing their own prosthetic by denying them availability to parts as the industry has constructed its distribution model - appears patently unlawful by the ADA.

In fact the Supreme Court has visited this very issue of others thinking they know what is best for an ADA person and creating scenarios to control their lives, AND in that vernacular declared freedom of choice for ADA persons and that other parties deciding things for them and creating systems of "care" without legitimate business reason was "discrimination".

Here there is no reason the actual wearer cannot be instructed as to the same service issues a "certified practitioner" can - and in this case probably better because they actually wear the prosthetic item. In short the court said stop trying to keep them in the dark so you can make money on their disability.

Then there is also Presidential Executive Order 13217 commanding all branches of the Federal Government to implement the principles of the Olmstead ruling.

A court order may well be necessary to halt the practice industry wide, but right now it is 100% true a C-leg – nor any other EXTERNAL prosthetic component is not a prescription medical device defined at 21 CFR 801.109 and no EXTERNAL prosthetic component or system ever has been classified as such

An EXTERNAL prosthetic device is NOT:

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate

directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

The order of approval K991950.pdf is hereby modified to allow "**over the counter**" sales and Otto Bock is further commanded as part of its 510K exemption to provide ***all*** the accessory items both direct to persons holding a "prescription" who want to buy direct or not for cash and carry or not at any time upon request

Further, any EXTERNAL prosthetic device not bearing a 21 CFR 801.109 restriction is one that may be sold by prescription OR over the counter.

IT IS SO ORDERED. Commissioner of the FDA

C. Environmental impact

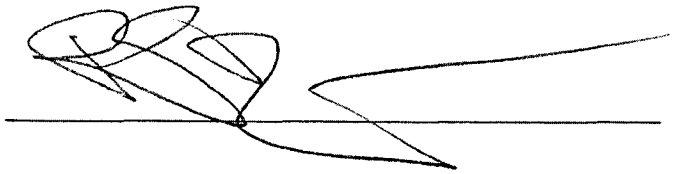
None

D. Economic impact

The economic impact will be to free more amputees to be able to afford prosthetics by enabling the pre-owned market to lower income persons who could afford to repair or build a prosthetic from a pre-owned device rather than buy a new one only. The most applicable and comparable kind of impact is the auto industry of new car buyers who can afford same and the financing, versus used auto buyers of whatever market they exist in. In fact the industry may well sell MORE product selling direct, and allowing parties to repair their own prosthetics the healthcare insurance industry may well save billions in un-needed new prosthetics builds and purchases. But yes, it will not fare well for prosthetics businesses everywhere who the market never should have supported in the first place but for artificially inflated pricing. The Veterans Administration saved millions by doing centralized in house wholesale DMEPOS.

E. Certification

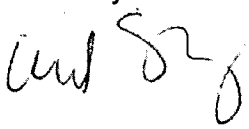
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Reginald P. Burgess

[redacted]

Sincerely



Garrett Skelly, Attorney for Reginald Burgess