

ORIGINAL

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2013 AUG -9 A 11: 26

August 6, 2013

USPS article 9405 5036 9930 0018 7046 47

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



**PETITION TO AMEND EXTERNAL PROSTHETIC ORDER AND
PROCEDURES AND CLASSIFICATION OF ALL EXTERNAL PROSTHETIC
DEVICES IN 21 CFR 890.3420 AND 21 CFR 890.3500 TO READ AS BOTH
"PRESCRIPTION" AND "OVER THE COUNTER USE" IN PARTICULAR
FIRST AND FOREMOST FOR THE C-LEG - K991590.pdf**

Citizen Petition

The undersigned submits this petition under 21 CFR 801.109; 21 CFR 890.3420, 21 CFR 890.3500 and 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 amend an order

**RE: Complaint - C-Leg product under 21 CFR 820.198, unsafe operation &
Violation of: The Consumer Legal Remedies Act, Cal. Civ. Code 1750**

A. Action requested

Amend the approval order K991590.pdf at
http://www.accessdata.fda.gov/cdrh_docs/pdf/k991590.pdf to include "OVER
THE COUNTER USE " in addition to "PRESCRIPTION" at the final page.

B. Statement of grounds

As an over the counter item Otto Bock would be required to provide user support.

The C-Leg presents an extremely dangerous condition when the Li-on battery reaches its end of serviceable life. The C-Leg will change unexpectedly into a free swinging mode and the wearer loses all hydraulic support. Otto Bock's response to a person with such a leg out of warranty is to send it to them and they will check it out for a fee. While the C-leg will work fine when the battery is 100% charged, it will lose charge rapidly – and this is an end of life function of the Li-on battery and again go into free swinging mode unexpectedly at any time.

Warranties do not transfer to successive owners of the C-leg.

The C-Leg begins to behave unpredictably when the battery in it reaches an age and state when it will not put out enough voltage to safely keep the leg in Mode 1. What it does is goes into Mode 2 without warning – also known as bicycle mode – which is a free swinging dangerous state. Despite the Otto Bock literature claiming the C-Leg will go into “safe mode” and lock up into a stick like high resistance mode, this is not what first happens. One could fall and injure themselves. Otto Bock's response is to refuse to assist an owner to replace the battery themselves, and instead claims that because it is a “prescription” device they must handle all service and support themselves – of course for extra costs.

The battery is in the hinge of the knee accessed by unscrewing a cover. Otto Bock will not be clear if to access the battery will cause the leg to lose programming. For instance when the pylon is unplugged the leg goes into native mode and cannot be used again without programming. Otto Bock will not provide the software to program the leg to the owner of the leg, but instead forces a visit to one of their “certified practitioners” who may or may not then perform this service depending on what Otto Bock allows via an internet connection to the particulars of that C-leg of course for an extortive fee.

A voltage measurement at the charging port reveals the battery is too weak to operate the valving in the C-leg and it only charges to about 3.00 volts fully; and is hard to get it to reset and stay in Mode 1. The charging voltage is about 4

volts and the battery at full charge should be around 3.7 volts. The leg resets fine and could be walked in – plugged in to a charger or an external battery.

Otto Bock, as well as the entire EXTERNAL 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 in violation of the Americans with Disabilities Act (ADA) . See 42 USC 12182 et seq.

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.

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 Act (the act) under the authority, of section 515(d)(1)(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), (1) 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) insofar 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.

However Otto Bock, as well as the entire EXTERNAL prosthetics industry in general, have used the word “prescription” to self-add a restriction to refuse to

sell to the amputee wearer directly who may want to build their own prosthetic or has a need to do simple service or parts replacement on their own prosthetic.

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.

Because of the word "prescription", the products are kept at bay directly from the amputee party who needs it for want of a costly visit to obtain services through a "certified" practitioner or prostheticist who is actually nothing more than a party who purchases a certification for a few hundred dollars from one of two on-line providers, and this certification guarantees nothing of the competence of the person who bought same. In fact most parties who pursue and purchase this certification are motivated by financial concerns as the quick way into a "medical like" field for purposes of billing to a healthcare insurance carrier as that kind of payee business, and actually are not amputees who would have any real world experience with the prosthetics they would be fitting.

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.

"Certified" Prostheticists are fancy self appointed "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 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. 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. 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 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.

The greed, controlling nature and secretiveness of Otto Bock is so great they will not even allow a person to replace their own battery when it could be done in five minutes; they seek instead to add costs and inconvenience the ADA person by sending the wearer to an Otto Bock certified practitioner who disassembles the leg, ships it to Otto Bock who 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

¹ The Li-on battery alleged to fit the C-leg is the 18650 size and it comes in three 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

insurance – they do not even want to talk to you. You have no source of revenue for them. Often Otto Bock takes the opportunity to “discover” something else is wrong with the leg and this starts a quest to sell a new one and bill for same.

If a person has no insurance Otto Bock bills for all of this, and it simply is not needed, as a business necessity but they base this all on the power of the word “prescription” as though it gives them a “lessor’s” right to be the only party who can service the item at all. Otto Bock has found a way using the FDA to extort money from amputee ADA persons who then have nowhere else to turn

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.

Often the co-pay alone is the cost of the prosthetic parts to build it one’s self

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. Then there is always the small MAJOR part 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.

Attached are the email volleys to Otto Bock describing the dangerous scenario of the C-leg I own and the lackadaisical attitude to assisting me 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. (Exhibit A)

The State of California enacted legislation creating the Bureau of Automotive Repairs (BAR)² so unscrupulous selling and repair methods of vehicles could be gotten at by law, but here the Doctors do not, let alone the insurance carriers themselves barely understand the ICD9 coding and billing for prosthetics, and the resultant ignorance is costing millions per year because of marketing and distribution schemes like this one Otto Bock uses with the help of the FDA. Still nowhere in any law Automotive or Medical, is there any law to prevent one from building and working on their own property – be it a vehicle or a prosthetic.

The crux here is that 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” they are too stupid to know how to walk in their own leg – is patently unlawful and currently supported by the FDA because of the single word “prescription” without the “over the counter” box area also checked. 21 CFR 890.3420 and 3500 items are largely crutches, canes 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, forces one to buy a used one which may well be malfunctioning or inoperative and raises an issue like the reason BAR was needed to keep unscrupulous sellers and auto mechanics from preying on desperate people needing what they think is help - is worse.

² "California Business and Professions Code" Scroll to Division 3, Chapter 20.3

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."

and there is a section ii through iv

But this is exactly what Otto Bock does using their belief the word "prescription" without the "over the counter" box also checked runs afoul of.

In fact a "prescription" is not a prescription at all, it is a build list, and format of one is found at http://pwop.net/word/PROSTHETIC_PRESCRIPTION.doc (Exhibit B) This is only a 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.

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.

Currently as the person is 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 - and it is thus 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.

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)

(B) Integrated settings

Goods, services, facilities, privileges, advantages, and accommodations shall be afforded to an individual with a disability in the most integrated setting appropriate to the needs of the individual.

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 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 and feed them BS 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.

Olmstead has become the mantra case for striking down ADA discrimination where ever and in what ever format it is found and here are two more website pages illustrating that => <http://www.ada.gov/olmstead/> and http://www.ada.gov/olmstead/olmstead_about.htm Most recently president Obama re-affirmed the Olmstead issue in a presidential proclamation at http://www.whitehouse.gov/the_press_office/President-Obama-Commemorates-Anniversary-of-Olmstead-and-Announces-New-Initiatives-to-Assist-Americans-with-Disabilities/

It is that section the supreme court keyed in on - 42 USC 12182(b)(1)((B) - which means I cannot be forced to go to an Otto Bock "certified practitioner" and send my property back to them because that is how they want to do it - with no legitimate business reason - and keep the service information from me on something like changing a battery and re-programming my own leg affecting the quality of my life. I cannot be kept in a symbiotic relationship to Otto Bock.

Olmstead has been expanded to mean so much more - as to mean ADA persons cannot be told what is "best for them" - and here we now have the "certified practitioner" argument of Otto Bock. The ADA person themselves must be too stupid to know how to do this so we will do it for them at great inconvenience to them that we think we are doing to help them "get it right". Change a battery.

There are some things that pose no legal or medical liability which translate into no legitimate business reason, and are then thus unlawful and unfair business

practices in this case violating the ADA. If a "certified practitioner" can be taught to program a C-leg with a computer (with an on-line class at that) - so too can the owner of the C-leg - if Otto Bock can replace a battery by unscrewing a cover and sliding it in - so too can the wearer and owner of the C-leg.

All this extortive withholding of information is just that - extortive unlawful business practices that could not exist if were an "over the counter" item.

And here we circle back the "certified practitioner" source being a self appointed online "certification" organization - the two firms of <http://www.bocusa.org/> or <http://www.abcop.org> - designed in a conspiratorial violating 42 USC 12182(b)(1)(A) by a way to keep the ADA person themselves from being able to buy the item they need in the setting most appropriate to them and having another person now deciding and telling them what is best for them.

That is why this is unlawful - and it all is supported by the failure of the FDA to mark the OVER THE COUNTER section of the approval orders.

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:

Thus the order of approval should be modified to allow **"over the counter"** sales and Otto Bock should be 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

C. Environmental impact

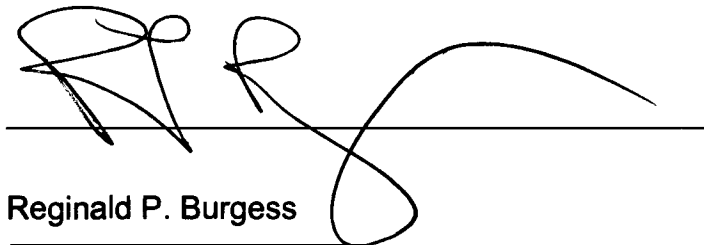
None

D. Economic impact

There is no economic impact. In fact Otto Bock may well sell MORE product selling direct.

E. Certification

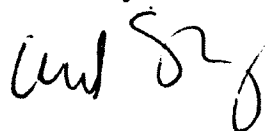
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Reginald P. Burgess

[REDACTED]
[REDACTED]
[REDACTED]

Sincerely



Garrett Skelly, Attorney for Reginald Burgess

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