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Comment on DOJ CRT Docket No. 110

I am disabled by Parkinson's Disease and by having an implanted medical device (IMD). NIH estimates there are now 25 million Americans with implanted medical devices. The implanted medical device I have is a Deep Brain Stimulator (DBS) for Parkinson's Disease. It completely replaces the medicines, which after 15 years were causing very unpleasant side effects. I worry about EMI/RFI with implanted medical devices and accessibility to public accommodations (including vehicles), commercial, and government facilities which have wireless internet, security, inventory or theft control devices. This makes access through the wired world wide web an absolute necessity and access through wireless (WiFi, broadband, Bluetooth, cellular) a potential hazard (unintended consequence).

The first such worries about interference with IMDs occurred for microwave ovens and cardiac pacemakers, leading to FDA regulation in 1971 [21CFR1030]. In the 1990's, reports started to appear of interference with wheelchairs and implanted medical devices from metal detector security gates commonly used at airports and many other public buildings (including courts, libraries, hospitals, schools and more), limiting access to such facilities by people with disabilities and IMDs. More recently, interference has occurred from retail RFID, anti-theft and inventory control devices (which are often hidden in mall walls so the threat is invisible), from interference between two or more IMD's, and from cell phones (especially the CDMA/GSM/3G/4G/WiFi/Bluetooth "Smart" phones) and other common household devices (such as the light dimmers, heating pads, rechargeable toothbrushes, or Smart Grid devices) or medical investigatory devices (such as MRI's). I have also experienced interference with the operation and programming of my DBS from external sources of EMI, and I have gone through my home with a spectrum analyzer to map and minimize or eliminate interference. (The Medtronic manual for my DBS lists more than 16 pages of EMI concerns and still only partially

lists potential interfering devices such as diathermy, arc welders and MRI's, <http://www.MRIsafety.com>.)

Blomstedt, P., Jabre, M., Bejjani, B-P., and Koskinen, L-O.D., 2006, Electromagnetic environmental influences on implanted deep brain stimulators: *Neuromod.*, v.9, n.4, p.262-269.

Francis, J. and Niehaus, M., 2006, Interference between cellular telephones and implantable rhythm devices: a review on recent papers: *Indian Pacing and Electrophysiology J.*, v.6, n.4, p.226-233.

Hocking, B. and Mild. K.J., 2008, Guidance note: risk management of workers with medical electronic devices and metallic implants in electromagnetic fields: *Int'l J Occupational Safety and Ergonomics*, v.14, p.217-222.(updated PowerPoint available from author)

Hondu, T., Ueda, T., Sakata, Y. and 4 others, 2006, Passive exposure to mobile phones: enhancement of intensity by reflection: *J. Phys. Soc. Japan*, v.75, n.8, p.08401-1 to -5.

Jun, X., Luming, L., Hongwei, H., 2009, Primary experimental study on safety of deep brain stimulation in RF electromagnetic field: 31st Int'l. Conf. Of the IEEE EMBS, Minneapolis, MN, p.3091-3094.

Weick-Brady, M., 2009, Medical devices in the home: new ideas, new risks: FDA CDRH, 7 June 2009 PPT, <http://www.fda.gov/CDRH>

Olhoeft, G.R., 2009, Electromagnetic interference with medical implants: presented to EMR Policy Institute Conf., 8 Nov 2009, CSM, Golden, CO (PPT available from author and video from: http://www.youtube.com/results?search_query=olhoeft&aq=f).

However that concern has broadened with reports in the press and literature that hackers are trying to access medical devices through the web and wireless means:

<http://nwoobserver.wordpress.com/2010/05/26/rfid-chip-implanted-into-man-gets-computer-virus/>
Sutter, J.D., 2010, Scientists work to keep hackers out of implanted medical devices: CNN, 16 April 2010.

Halperin, D., Heydt-Benjamin, T.S., Ransford, B. and 6 others, 2008, Pacemakers and implantable cardiac defibrillators: software radio attacks and zero-power defenses: *Proc. 2008 IEEE Symp. on Security and Privacy*, 14p.

Halperin, D., Heydt-Benjamin, T.S., Fu, K., Kohno, T., and Maisel W.H., 2008, Security and privacy for implantable medical devices: *IEEE Computer Society Pervasive Computing*, v. 7, n.1, p.30-39.

and of reports about “RFID Wars”:

<http://www.engadget.com/2009/12/24/rfiddler-zapper-kills-rfid-tags-dead-the-hard-way/>

or what appear to be completely unregulated “nonlethal weapons” such as TASER's and the Active Denial System (<http://www.jnlwp.com>; <http://www.nap.edu/catalog/10538.html>)

or microwave “car stoppers” (<http://www.eurekaaerospace.com>), which are sought by civilian police as well as military, none of which even mention their impact on people with implanted medical devices.

I gave a talk to the local DBS support group here in June, 2010, and asked how many people had had a problem with Walmart or Best Buy stores retail theft detection systems like myself, and every hand in the group (about 50 people) went up. The FCC's regulatory authority extends from 9 kHz up and doesn't include many lower frequency sources of potential and actual interference such as this, and their interpretation of "harmful interference" seems to stop at interference with communications. The FDA CDRH website says they have the authority to regulate EMI/RFI/EMC for potential radiation emitting devices (as demonstrated by microwave oven regulations), defining "The different forms of EM energy that can cause EMI are conducted, radiated, and electrostatic discharge (ESD)." but they should also include "induced", and they need to regulate over all frequencies, including a broader definition of "harmful interference" to not just communications but also medical devices where people can be harmed by EMI/RFI caused malfunction. Initially, the awareness of the public needs to be broadened about the vulnerability of such devices, but ultimately it needs regulation. Such regulation should include environmental electromagnetic limits for anthropogenic sources as well as medical device EMC hardening to minimize malfunction during common events (nearby powerlines, WiFi), and device protective default or "circuit breaker" safe hardening for extraordinary events (TASERs, defibrillators, lightning or solar storms). Security and privacy regulations need to be in place to prevent interference by intentional hacker attempts at device re-programming or data access. Lastly, the EMI/RFI vulnerability of medical devices needs regulatory limits and independent testing.

In addition, I'm beginning to worry about "secondhand SAR" exposure in the context of secondhand smoke (see Hondu et al., 2006, cited above). Cell phones (and other devices) have SAR measured for the user at levels of up to the FCC limit of 1.6 W/kg, but what about the DBS medical implant patient next to the cell phone user(s) with a SAR exposure limit of 0.1 W/kg for 15 minutes (Medtronic http://www.MRIsafety.com/safety_article.asp?subject=139)? This could be a problem for not only cell phones, but all wireless devices, and especially so in the confined waveguide of an airplane, or with SmartGrid devices inside an aluminum sided house or cell phones and radios inside a

vehicle such as an ambulance, an elevator or a taxi. There is very little literature about secondhand SAR and it urgently needs investigation. The same applies to multiple device interference (ala multiple drug interactions in a similar context to secondhand smoke/SAR).

There is a regulatory gap between the FDA and FCC very clearly for DOJ/ADA to fill. The really big ADA point is people in wheel chairs and with implanted medical devices live in confined spaces or constrained situations and often do not have the choices of being able to avoid things that may be hazardous ...and they often don't even know the hazard exists. Two examples: sitting in a wheel chair in an elevator with one person who has a cell phone on their belt (at head height for the wheelchair bound) within 10 inches of a Deep Brain Stimulator exceeds the Medtronic SAR limit for RFI heating --- multiple people or multi-pathing from multiple reflections in a metal walled elevator, ambulance or taxi is worse (see Vermeeren et al., 2010 below). (Also, most people do NOT know how to really turn off their phone/laptop/iPod, but instead put it in standby where it is still on...) The second example is almost any mall with inventory or theft detection RFID or WiFi devices hidden in the walls ---you don't even know they are there, or taxis, theaters and restaurants with cell phone blockers: (<http://www.thesignaljammer.com/pages/Cell-Phone-Jammer-News.html>). At aS minimum, warnings should be posted that a potential hazard exists for people with IMDs.

Vermeeren, G., Gosselin, M.C., Kuhn, S., Kellerman, V., Hadjem, A., Gati, A., Joseph, W., Wiart, J., Meyer, F., Kuster, N., and Martens, L., 2010, The influence of the reflective environment on the absorption of a human male exposed to representative base station antennas from 300 MHz to 5 GHz: Phys. Medic. Biol., v. 55, p.5541-5555.

/s GRO

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