

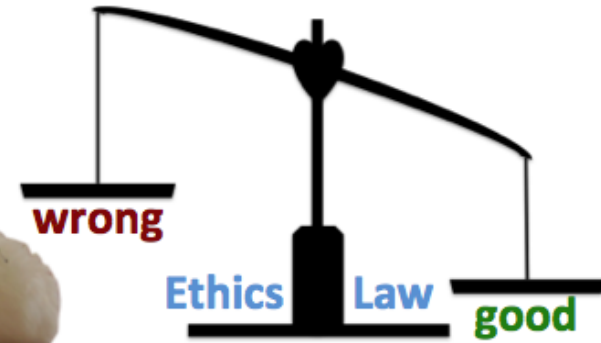


## New Friends

The 1st international conference on social robots in therapy and education

# 2015

October 22-23  
Almere  
The Netherlands



# Toy Robot vs Medical Device

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# Dilemma

All robotic designers face this question when they are prototyping a new robot:

Toy robot or a medical device ? or monitoring device ?

When I design a robot I think about:

- Certifications ?
- Time to market ?
- Intellectual property ?
- Applications ?
- International regulations ?

# What we can find out there

This controversial about which kind of product should be assigned to a robot is already there

## It's Not a Stuffed Animal, It's a \$6,000 Medical Device THE WALL STREET JOURNAL.




*Medical Device* → whether a given article is intended either "for use in the diagnosis,... treatment, or prevention of disease," 4 or "to affect the structure or any function of the body." 5

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>

Is this a medical device? -

Romibo is not a medical device or a replacement for existing therapy. It is a tool that caregivers can use to reduce anxiety and increase vocalization in some children. It is meant to augment and enhance traditional accepted autism therapies.

Meet  
**ROMIBO**  
(pronounced roh-MEE-boh)



(Press play)

An engaging smart toy for  
autism education and language learning.

Gameran, Gary E. "Intended Use and Medical Devices: Distinguishing Nonmedical Devices from Medical Devices under 21 USC 321 (h)." *Geo. Wash. L. Rev.* 61 (1992): 806.

# Reflections

How the community is acting about that?

Almost all robots that claim to be social that are used in therapy and education are certified as toy robots.

Designers and Researchers split the device itself from the application.



This strategy accelerates the time to market of the robot. Some applications are known before launching a toy robot to the market → Unethical behavior