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April 22, 2008

Ms. Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street SW
Washington DC 20554

Re: ET Docket Nos. 06-135 et al., *Spectrum Requirements for Advanced Medical Technologies Ex Parte Communication*

Dear Ms. Dortch:

On behalf of Transoma Medical Inc., pursuant to Section 1.1206(b)(1) of the Commission's Rules, I am electronically filing this written *ex parte* communication in the above-referenced docket.

Transoma seeks rules permitting the limited use of telemetry in the 401-406 MHz bands for laboratory animals, under the same technical rules as for humans.

This letter responds to questions raised during a meeting with Commission staff on April 9, 2008.

1. LIMITATIONS ON LABORATORY ANIMAL USAGE

Transoma proposes the following regulatory language for these bands:

Operation in laboratory animals is limited to research specifically directed to the betterment of human health, *provided that* operation is prohibited within 20 meters of any diagnostic or treatment area in a hospital, clinic, or other health care facility.

This language, in combination with high cost (\$6-8K per animal for an entry level system), will limit proliferation of animal devices.

2. "LOGICAL OUTGROWTH"

The Administrative Procedure Act (APA), as construed by the courts, permits an agency to adopt a rule not specifically proposed in the NPRM if it is a "logical outgrowth" of the NPRM.¹ The test is whether a party reasonably should have anticipated a need to file comments on the issue.² In the D.C. Circuit's unforgettable phrase, an agency may not pull a "surprise switcheroo."³

The use of implants in animal laboratories is a logical outgrowth of this proceeding's NPRM.

At the outset, we note that the NPRM does not include proposed rule language.⁴ (If it did, and that language specified human implants, the case might be very different.) We must therefore look to the overall text of the NPRM for the intended scope.

Nothing in that text restricts the NPRM to human implants. The term "human" and its synonyms appear only four times: referring to signal propagation in the human body as a basis for the *present* (not proposed) rules;⁵ in a party's proposed definition of a body-worn transmitter;⁶ in a reference to human RF exposure⁷ (there are no comparable rules for animals); and in a note that harmonization would allow persons with implanted or body-worn devices to travel internationally.⁸ None of these instances can reasonably be read to limit the scope to devices for humans.

¹ *Covad Communications Co. v. FCC*, 450 F.3d 528, 548 (D.C. Cir. 2006).

² *Northeast Maryland Waste Disposal Authority v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004).

³ *Environmental Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005).

⁴ *See Spectrum Requirements for Advanced Medical Technologies*, 21 FCC Rcd 8164 (2006) (NPRM).

⁵ NPRM at para. 12.

⁶ NPRM at para. 27.

⁷ NPRM at para. 28.

⁸ NPRM at para. 40.

The Notice does, however, repeatedly signal an intent to expand the present rules: *e.g.*, "to accommodate . . . a variety of new medical devices";⁹ and the "development of newer, more capable, and more sophisticated devices."¹⁰

More important, however, the inclusion of laboratory animals would not raise any new or different issues for the parties. We propose the same technical and interference-mitigating rules for animals as for humans, including listen-before-talk and automatic frequency assignment. An animal-implanted device thus has the same interference potential (*i.e.*, almost none) as a human-implanted device.

The only effect of allowing use in animals is a modest increase in the number of devices at limited locations. That same increase in human devices would not raise APA issues; neither, then, should the same usage in animals. In an excess of caution, moreover, to resolve any possible concern about impact on human devices, we propose to keep the animal devices away from human patients in a diagnostic or treatment area by at least 20 meters -- approximately ten times the device's useful range.

CONCLUSION

Under our proposed language, the use of 401-406 MHz devices in laboratory animals will have no effect on human users. Nothing in the NPRM rules out this application. Nor does animal use, under the same technical rules as human use, fairly raise new issues under the NPRM.

We urge the Commission to adopt our proposed language.

Respectfully submitted,

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⁹ NPRM at para. 1.

¹⁰ NPRM at para. 2.