



26th March 2007

RE: Ulmer Report on the Medical Devices Directive (93/42/EEC).

Dear Member of the European Parliament,

When medical devices not only help treat illness but may also contribute to future illness, even when safer alternative devices exist, the contradictions need to be addressed. The revised Medical Devices Directive, 93/42/EEC, on which you will be voting in a few days, makes a start in this direction.

The Parliament, Council and Commission have negotiated a compromise which significantly waters down important parts of the Environment, Public Health and Safety Committee report from last October. More specifically, the proposal to ban all Carcinogenic, Mutagenic and Reproductive Toxic Substances from medical devices was denied. However, it does offer a clear first step, which will assist in eliminating toxic chemicals used in medical devices and which leach into the bodies of patients.

The legislation will require medical device manufacturers to label all devices that contain phthalates, a class of chemicals used to soften plastic. The phthalate DEHP is classified in the European Union as a reproductive toxin (for humans), and significant concerns exist about its leakage from devices into patients, especially babies and dialysis patients. With labelled devices, doctors will be alerted to the exposure risks of their patients, and hospital purchasing officers will be able to easily identify the safe phthalate-free plastic devices which are already available on the market. For sensitive patients, the manufacturers will have to provide explanations on the risks from using device containing toxic substances and suggest precautionary measures.

In the last 3 years, the European Parliament has on multiple occasions challenged both the Commission and the Council to take more action on DEHP. While the requirements in the Medical Devices Directive do not equal the protection offered in cosmetics and childcare articles, we believe it is a requirement that can be built upon in the future.

We therefore urge you to support the compromise package, and thank you for your work in improving the protection of public health.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Hrdinka".

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