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**RE: CITIZEN PETITION FOR A FOOD AND DRUG ADMINISTRATION
REGULATION OR GUIDELINE TO LABEL MEDICAL DEVICES THAT LEACH
PHTHALATE PLASTICIZERS**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

To Whom It May Concern:

As an organization involved in the health care supply chain, MedAssets supports the Food and Drug Administration (FDA)'s development of a regulation or guideline to require manufacturers to label medical devices that can leach di-ethylhexyl phthalate, or DEHP. Today the FDA supports voluntary DEHP labeling, but does not require it. Mandatory labeling will complement the FDA's existing DEHP Public Health Notification and allow health care providers to avoid known risks to vulnerable populations.

MedAssets partners with healthcare providers to improve operating margins and cash flow while supporting quality of care goals. MedAssets implements integrated solutions to address the greatest opportunities for financial and process improvement and drives performance in revenue cycle, supply chain and clinical service line management. MedAssets is a business partner to more than 2,400 hospitals and 28,000 non-acute care healthcare providers.

MedAssets' Environmentally Preferable Purchasing Program (EPP) was created in 2004 to help our members identify opportunities for pollution prevention, including mercury elimination, waste minimization and toxicity reduction, and to provide products that support and encourage practice changes that protect the health of the community and the environment. A key initiative in our EPP program is to identify non-DEHP products in MedAssets' contracts.

Twice in the past six years expert panels convened by the Center for Evaluation of Risks to Human Reproduction (CERHR) of the National Toxicology Program (NTP) have affirmed that there are reasons to be concerned about overexposure to DEHP in specific vulnerable populations undergoing medical procedures. Animal studies indicate that high levels of DEHP exposure are associated with liver, kidney and lung damage, and that

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they can adversely affect the development of the male reproductive system. Testicular damage, reduced fertility, abnormal sperm counts, miscarriage and birth defects have all been linked to DEHP exposure in such studies, and the NTP panels have affirmed that the evidence is suggestive of potential harm to male fetuses and neonates who are exposed to high levels of DEHP. The NTP panels noted the populations that might be particularly at risk, as follows:

"There is serious concern that certain intensive medical treatments of male infants may result in DEHP exposures levels that affect development of the male reproductive tract."

"There is concern for adverse effects on development of the reproductive tract in male offspring of pregnant and breastfeeding women undergoing certain medical procedures that may result in exposure to high levels of DEHP."

"There is concern for effects of DEHP exposure on development of the male reproductive tract for infants less than one year old."

"There is some concern for effects of DEHP exposure on development of the reproductive tract of male children older than one year."

"There is some concern for adverse effects of DEHP exposure on development of the male reproductive tract in male offspring of pregnant women not medically exposed to DEHP."

Many of MedAssets member organizations are attempting to implement the recommendation of FDA's Center for Devices and Radiological Health that DEHP-free medical devices be used in cases where there is concern over health effects related to excess DEHP exposure (<http://www.fda.gov/cdrh/safety/dehp.html>). However, because there is no requirement that such devices be identified through labeling, it is very difficult for clinicians to ascertain at the point of use whether they are using DEHP-containing or DEHP-free devices. We at MedAssets have encountered difficulty in assisting our members to identify such devices in an initiative to identify DEHP-free alternatives on contract for use in the Neonatal Intensive Care Unit (NICU). Responding to this request involved making contact with individual manufacturers to request specific information on a line-by-line basis for all products covered by the respective contracts. To this end, we have instituted DEHP disclosure requirements for medical devices. Yet even where such information is obtained, it is not readily at hand in the clinical setting where treatment decisions must be made, so unless a facility has completely eliminated use of DEHP-containing devices, it is possible to expose vulnerable patients unknowingly to potentially harmful levels of plasticizer.

We support the petitioner's request that the FDA issue guidance or regulations requiring that

"Medical devices that leach DEHP or other plasticizers shall include in a box a prominent, clearly-worded warning label stating:

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- i. A statement that the device contains and may leach DEHP;
- ii. A statement that exposures, including prenatal and postnatal exposures, may interfere with the normal development of the male reproductive tract; and
- iii. Identification of the populations for whom alternative devices may be appropriate including pregnant or breast feeding women, male infants and boys through puberty.

Thank you for your consideration of this petition as a step toward reducing patient exposures to a potentially toxic substance.

Sincerely –

A handwritten signature in black ink that reads "Janelle Johnson". The signature is written in a cursive, flowing style.

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