Message

From: Michael Dourson [**Personal Matters / Ex. 6**]
Sent: 1/4/2019 4:56:43 PM
To: Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]
CC: Pat McGinnis [mcginnis@tera.org]
Subject: Critical Information on PFOA
Attachments: PastedGraphic-6.pdf; Elcombe et al., 2013.pdf; Lou et al., 2009 Mice PFOA Kinetics-Cmax.pdf; PFOA clinical study.pdf; PFOA clinical study supplemental materials.docx

Dear Mr. Dunlap

TERA has found a US patent that reports giving PFOA to humans for cancer chemotherapy at doses of up to 1200 mg/week. Parts of this application have been subsequently published. Associated with this patent is human kinetic information. Specifically, the attached Elcombe et al. (2013) patent allows the determination of a Cmax in humans from single dose PFOA exposures (see marked pages). Also attached is an older study by Lou et al. (2009) that allows a comparable Cmax estimation in female mice (see Figure 3). TERA is considering this patent information in the determination of a Data Derived Extrapolation Factor (or Chemical Specific Adjustment Factor) for animal to human kinetics using EPA (2014) guidelines based on a comparison of Cmax in humans to Cmax in mice, and is proposing a case study on this issue in the Beyond Science and Decisions workshop series held at the offices of the TCEQ in February. If our proposal is accepted, we will explore whether Cmax or AUC is a better dosimeter when the critical effect is developmental toxicity, as suggested by EPA (1991) developmental toxicity guidelines. We will be using PFOA as the example chemical.

We would value the input of your staff on this patent and its potential application for our proposed case study.

Sincerely,

Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Director of Science

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