Researchers identify phthalates in numeruous medicines and supplements

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Researchers from Boston University's Slone Epidemiology Center (SEC), in collaboration with Harvard School of Public Health, have found numerous prescription and over-the-counter drugs and supplements use certain chemicals called phthalates as inactive ingredients in their products. The findings appear on-line in *Environmental Health Perspectives*.

Phthalates such as dibutyl phthalate (DBP) and diethyl phthalate (DEP) are used as inactive ingredients in FDA-approved medications where they may serve a variety of functions. Most commonly, they are used in the coating of a drug product to target the delivery of the active ingredients to a specific area of the gastrointestinal tract, or manage their release over time. Some phthalates, including DBP have been identified as causing adverse developmental and reproductive effects in laboratory animals. Limited human studies have suggested a possible association of DBP and DEP with male reproductive health outcomes.

Using a combination of resources, the researchers were able to identify over 100 drug and dietary supplement products that indicated they contained phthalates, including 50 prescription, 40 over-the-counter (OTC) and 26 dietary supplement products with labels that listed DEP or DBP, of which nine contained DBP. In addition, a large number of product labels listed phthalate polymers that are considered to be of little or no known toxicity but which are often used in combination with other phthalates.

"Given the thousands of orally-ingested products on the market (prescription, OTC and dietary supplements), it is difficult to know exactly how many contain phthalates. However, it is informative and important to identify the specific drug products that have included phthalates in their formulations," said lead author Kathy Kelley, MPH, RPh, a research pharmacist at BU's SEC.

According to the researchers, the potential health effects of human exposure to these phthalates through medications are unknown and warrant further investigation. "The present findings should assist researchers in conducting the necessary studies of potential risk of phthalates in human populations, but such efforts are limited by the lack of centralized, comprehensive, and publically-available information on the presence of phthalates in the full range of prescription, OTC and dietary supplement products," added Kelley.

The researchers recommend that future studies should pay particular attention to the amount of phthalate, specifically DBP, used in each dosage form so that estimates of exposure from medications and supplements can be quantified.

Provided by Boston University Medical Center