Pay Attention To That Man Behind The Curtain



<u>Steven Hentges, Ph.D</u> Thursday, November 15, 2018 <u>SAFETY</u>

If you visit the U.S. Food and Drug Administration (FDA) website and search for the term BPA (bisphenol A), you'll quickly find an important Q&A that tells you exactly what you most want to know about BPA.

"Is BPA safe? - Yes."

It's so short and to the point that you might be inclined to dismiss it as just an idle opinion with nothing to back it up. But unlike the Wizard of Oz who said "pay no attention to that man behind the curtain," you should pay attention to what's behind this curtain.

That seemingly simple opinion is backed up by a longstanding risk-based regulatory system that requires affirmative evidence of safety. To understand the safety of BPA, the first thing we need to know about are hazards. Specifically, does BPA cause harmful health effects and at what dose?

After all, we've known for centuries that "<u>the dose makes the poison.</u>" A couple of aspirin might get rid of your headache, but a whole bottle of aspirin could act as a poison and kill you. That principle applies to just about everything we contact in our daily lives, including BPA.

Fortunately, we have a wealth of high-quality scientific information for BPA from studies on laboratory animals. Most recently, the results of the <u>CLARITY Core Study</u> were released in a final <u>report</u> at the completion of a nearly 5-year study conducted by senior FDA scientists.

The scope and magnitude of the study are unprecedented for BPA and the results indicate that BPA has very little potential to cause health effects even when people are exposed to it

throughout their lives. As <u>stated</u> by the study's Principal Investigator, "*BPA did not elicit clear, biologically plausible, adverse effects*" at any dose even remotely close to typical human exposure levels.

Regarding human exposure levels, we again have an enormous amount of data, in particular in the form of population scale biomonitoring studies conducted by the U.S. Centers for Disease Control and Prevention (CDC) and similar <u>studies around the world</u>. From these studies we know that human exposure to BPA is extremely low.

Put it all together, which is what happens in a risk evaluation, and it is clear that FDA has a very strong scientific basis to support its conclusion that BPA is safe. Regrettably, a risk-based system similar to the one that has served the United States so well is not widely used in Europe. The implications of this difference are highlighted in a recent viewpoint <u>article</u> in Science|Business titled "With European risk management at a crossroads, can reason prevail?"

The article was written by Sir Colin Berry, who is an Emeritus Professor at Queen Mary University of London. In addition to being a distinguished professor, he was knighted in 1993 in honor of his many years of public service.

What he has to say is important for Europe and highlights why FDA's risk-based regulatory system works to our benefit.

"Risk evaluation not hazard identification is the way to protect health and to permit continued scientific development. Decisions based on hazard alone achieve neither."

"Europe is putting informed opinion ahead of scientific evidence and precaution ahead of risk evaluation. Innovation will be the casualty."

Protecting health is not incompatible with scientific development and innovation. With an appropriate focus on risk evaluation, as is done by FDA, both are possible.