Andy's Take: Bisphenol A

FDA's Science Board recently addressed a report from its subcommittee evaluating the scientific data on bisphenol A – or BPA. When I spoke with you in August about BPA, I mentioned that as a science-based regulatory agency we need the best science to make good public health decisions. And part of that process is seeking input from experts outside the agency. In this case the experts on the subcommittee presented a perspective that someone described as a "stinging rebuke" of FDA.

My Take is that this report presenting a contrary point of view is exactly what FDA needed to hear. Rather than a rebuke of our position, the report was a strong affirmation of our process – a process to identify information that will better inform our regulatory decision making. FDA asked for this report, asked for this critical analysis, and we will continue to do so. Input such as this as well as information from a variety of sources like analyses conducted by other regulatory agencies will be incorporated into our regulatory decision-making.

Regulatory decisions regarding the safety and effectiveness of a product must always be based on comprehensive knowledge of that product. This knowledge is derived from a rigorous and disciplined analysis of information about that product that is based in turn on accumulation of scientific data. That is why we say that FDA is a science-based regulatory agency.

But science is always evolving, and in fact that evolution has become so rapid that we now describe it as a revolution in science. The Agency seeks the new data coming from that revolution. But these new scientific data must be assembled into information and converted to knowledge upon which our regulatory decisions are based. We cannot short-circuit or avoid this process of rigorous analysis, critical assessment, and stringent validation. Only then will we have the strong scientific foundation upon which to make an enduring regulatory decision to approve a product, change a drug label or issue a call for change in or removal of a product.

At the end of the day, the FDA is not simply engaged in scientific analysis – it is commissioned by law to make regulatory decisions that will protect and promote the health of hundreds of millions of people. We are grateful to the members of the Science Board and the subcommittee for their unselfish efforts in contributing to this process.

Together we will always strive to learn more in order to do more to assure the safety and the effectiveness of the products that affect your health. FDA

Andy

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About Andy's Take

Through this communications column on the FDA Web site, Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., will discuss weekly FDA issues of interest to the American consumer and occasionally preview upcoming FDA issues and events.

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