

**Statement of the Pharmaceutical Printed Literature
Before the FDA Public Hearing on
Communication of Drug Safety Information
December 7-8, 2005
Washington, DC**

Good afternoon. My name is Peter Mayberry and I serve as Executive Director for the Pharmaceutical Printed Literature Association. The PPLA is a not-for-profit trade association comprised of companies that print inserts, outserts, labels, and other material used to minimize risk by helping ensure that medications are dispensed and consumed properly. For more information about the PPLA, I invite you to visit our website www.pplaonline.org.

I am here today to respond to FDA's request for comment on nine specific "risk communication tools" that take the form of electronic sources of information – Internet websites in other words – and to provide the PPLA's perspective on the six questions that FDA has raised about these Websites.

Generally speaking, the PPLA notes that the greatest drawback to *any* electronic source of information is availability. Simply stated, the PPLA cannot condone any risk management system that relies on a network of computers as the exclusive source of information to the general public. While such networks definitely offer benefits when they operate properly and users have access to them, there are numerous ways that networks can fail. And when such failures are catastrophic in terms of scope or duration, it can literally be a matter of life and death.

We note, for instance, that earlier this year, in the wake of multiple hurricanes that devastated the gulf coast of the United States, hundreds of thousands of people – if not millions – had no access whatsoever to any of the communication tools listed in the Federal Register for weeks on end.

The PPLA notes, therefore, that each of the nine communication tools for which FDA seeks comment can be quite valuable to people who seek information under normal conditions; but none of them is sufficient as an exclusive, or even as a primary public resource. Indeed, while I can very comfortably refer FDA to the Internet to learn more about the PPLA, and while I am quite comfortable suggesting to my parents that they look to FDA Web pages for information about their medications, I cannot say that FDA has gone far enough in ensuring risk communication simply because the Agency has invested tremendous resources in a series of Websites.

Moreover, as Internet-based resources proliferate, it is the PPLA's great concern that pressure will be placed on FDA to eliminate risk communication tools that are not based on electronics. This would be a tremendous mistake that, as I have already noted, could potentially leave the entire population without critical information in time of a national emergency.

Noting that FDA has said that comments about labeling, Consumer Medication Information, Medication Guides and patient package inserts are "outside the scope of [today's] hearing," I will not dwell on any of those risk communication tools.

But I will say that any one of these printed sources of information, by itself, is a far greater risk communication resource than all of the Websites for which FDA is seeking comment today combined. This is simply due to the fact that reliable, useful printed information that accompanies a drug product can be counted on far more dependably than information that can only be obtained through the use of electronic networks.

Thank you.

Bio: Peter Mayberry is President of Mayberry & Associates, LLC, a management consulting firm that does work on behalf of three not-for-profit trade associations and is located in Falls Church, Virginia. In this role, Mr. Mayberry serves as Executive for the Pharmaceutical Printed Literature Association and the Healthcare Compliance Packaging Council. He also serves as Director of Government Affairs for INDA, Association of the Nonwoven Fabrics Industry that is headquartered in Cary, North Carolina. Peter has been the primary staff representative for the HCPC since its inception in 1990 and the PPLA since its inception in 2001. His work with INDA began in 1989.