

Comments on:

**Guidance for Industry - Development and Use of Risk
Minimization Action Plans**

Dear Christine and Mark:

The three drafts do a great deal toward improving patient safety. My comment is regarding only this guidance and specifically Section IV, Part B – Categories of RiskMAP Tools. I agree with the three suggested tools and would like to offer one additional tool for consideration. The suggestion is to ask life-science companies to give greater attention to the incoming contact/call center as a tool for improving patient safety.

I believe this addition to the guidance would be helpful. My experience in this matter comes from 3 years as the call center director of a large mid-west pharmaceutical company. The call center received 300,000 calls each year with about 15% of the calls involving adverse events and/or product complaints. The call center accounted for nearly 80% of all the adverse events and product complaints collected by the entire company.

While I was at this organization, we paid very close attention to adherence to quality system guidelines provided by the agency. I believe additional and specific guidance on the importance of the life-science contact/call center will further improve patient safety and reduce patient risk.

I would be pleased to provide further information on contact/call centers and their role in improving patient safety and reducing patient risk. Please e-mail or call me with questions

Respectfully submitted,

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