Panel Questions

FDA asks the General Hospital and Personal Use Advisory Panel to discuss the following questions:

1. Various indications for use statements describing the performance of antimicrobial agents might be sought for PPE incorporating antimicrobial agents. Please discuss what types of indications for use statements may be appropriate for such devices. In your discussion please describe the meaning of such indications statements and what sort of data should be presented to support such indications. In particular, what would a "reduces contamination" or a "protects from microbial contamination" indication mean for PPE? How might performance for such a claim be evaluated? What might "reduces colonization" mean for PPE, which can become contaminated during use but are promptly discarded afterwards? How should such an indication be supported?

   As the Panel discusses its response to the above question, please consider the points listed below:

   - Would only in-vitro performance data be enough to support indications for use for antimicrobial agents on PPE ?
   - Could in-vivo testing be of use in evaluating either safety or performance? If so, what type of data or study might be feasible?
   - Should clinical studies be requested? If so, under what circumstances and what types of studies might be appropriate?

2. For each of the following types of PPE with antimicrobial agents added, please discuss what time frame would be appropriate for demonstrating antimicrobial efficacy in order to kill/inhibit microbes and to reduce the risk of transferring organisms from one site to another.
   - *Medical gloves (examination gloves and surgical gloves)*
   - *Surgical masks*
   - *Surgical N95 respirators*
   - *Medical gowns (isolation gowns and surgical gowns)*

3. For antimicrobial agents added to surgical N95 respirators or surgical masks, please comment on whether performance testing for antimicrobial efficacy should be expected to
   - significantly reduce an aerosol of infectious inoculum (compared to an untreated device) or
   - simply demonstrate an ability to kill pathogens on the surface of a device

   As masks and respirators conventionally have at least 3 layers, the middle layer serving as the "filter" for the device, please also discuss whether the location of the

antimicrobial agent in the device should determine, in part at least, the type of performance testing needed?

4. For antimicrobial agents added to surgical masks and N95 respirators please discuss the safety issues or risks to which the device wearer might be exposed and how these might be evaluated including but not limited to:
   - Effects on the oral, nasal or ocular mucosa
   - Effects on the lower respiratory tract

5. For antimicrobial agents added to PPE, especially medical gloves, please discuss the safety issues or risks for patients exposed to such devices and how these should be evaluated. Should the potential for an antimicrobial agent on the surface of medical gloves or other PPE to leach off into body sites or onto surfaces being touched be evaluated? In your discussion, please comment on whether your concerns about such exposure are increased in pediatric and neonatal patients.

6. Please discuss whether there is a reasonable possibility that the presence of an "antimicrobial agent" on PPE might lead the wearer of the PPE to be less likely to follow correct infection control procedures or proper techniques. If such risk seems to be a possibility, what steps could be taken, including product labeling, to help reduce such a risk?