Patient Groups' Meeting Agenda with FDA on Oct. 31st

1. Opening Statement (thanking FDA for meeting, briefly why patient groups are concerned and have come together, future patient involvement in current process and biosimilar drug development, developing next steps after meeting)
2. Introductions by each organization explaining their disease community, treatments and what biologics they may use. *(Everyone)*
3. Explanation from each organization's perspective why they thought the need to come together. We don't all agree on every detail but we have come together on consensus Principles. *(Everyone)*
4. Outline each Principle.
5. Access to safe and effective biologics and biosimilars
    - *i.* Classes of similarity (meaning and use of "similar", "highly similar", "highly similar with fingerprint-like similarity" and "interchangeability")
    - ii. Indication Extrapolation
6. Need for unique non-proprietary names for biosimilars
    - i. Why it is important
    - *ii.* Post-market surveillance and adverse event reporting
7. Automatic substitution and switching
8. Questions of FDA regarding guidances
9. Ask for explanation of the process in developing the pathway as well as what is contemplated during the biosimilars drug development process itself.
10. Next Steps
11. Thank You