

Incorporating Evidence-Based Expert Opinion into the Decision- Making Process

*John J. McCormick, M.D.,
Deputy Director*

**The FDA Office of Orphan Products Development
(OOPD)**





Evidence-Based Expert Opinion

???






Data Always Trumps Opinion

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Why No Data?

✓ **Time**

✓ **Money**






**Is the *Perfect* the
Enemy of the
Good?**

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Risk / Benefit

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**What are the
likely results of a
bad decision?**

Versus . . .





What are the likely results of no decision?





Evaluate the Expert

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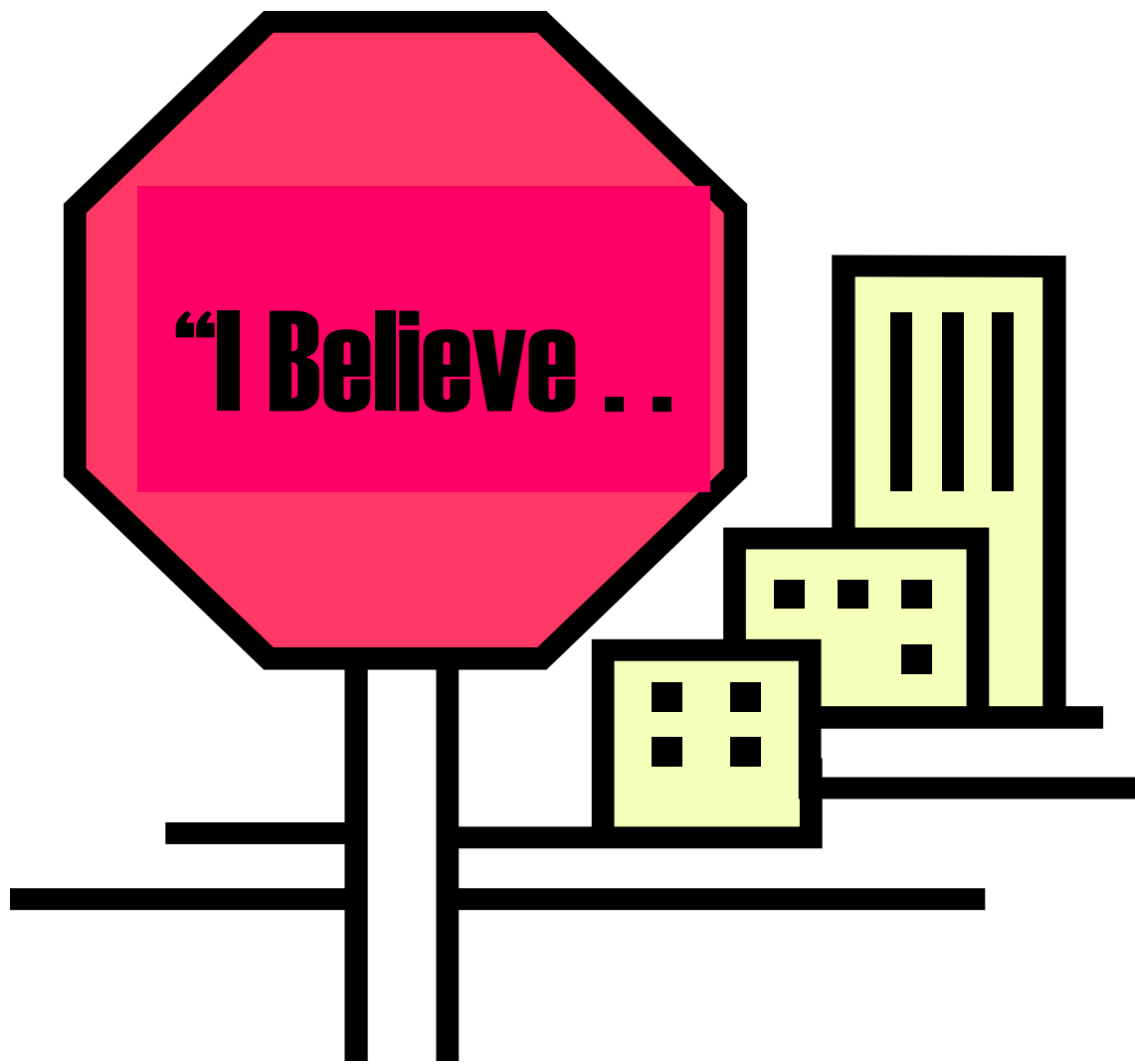
**Expert because of
exposure to
similar data.**





**Expert based on
strong beliefs.**





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How Generalizable is the Expert's Information?

(e.g., Fungi vs Mammalian)





Why This Conclusion?

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Expert Opinion

YOUR DECISION

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**Very Few
Decisions are
Irreversible**

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OPD Web Site



<http://www.fda.gov/orphan>

Your Link to:

Overview of the FDA Office of Orphan Products Development

Guidelines for designation application

List of designated and approved orphan products

Grant application information

List of ongoing orphan grant studies