



Recommendations for the FDA

1. Appoint FDA Commissioner who has public health at the center of his or her vision and values
2. Reverse the current FDA position on pre-emption (previous FDA counsels saw FDA activities and tort litigation as complementary--can get reference if you need it).
3. Withdraw the current plan for permitting sponsors to promote drugs for off-label use (see 11550.pdf)
4. Implement IOM recommendation 4.3 to develop a mechanism to identify, organize, and fund large long-term trials of public health importance
5. For approvals based on surrogate end points, conduct trials to demonstrate actual health benefits (see first half of 11827.pdf on judicious use of randomized trials and 11549.pdf for illustration with lipid lowering drugs)
6. Use peer-review in the design and evaluation of phase 4 safety studies (see 2nd part of 11827.pdf)
7. Implement directed review at time of approval to identify, design and plan phase 4 clinical trials or safety studies that may be necessary to address key questions (historically, approval has often been the end of evaluation and the beginning of marketing; not all drugs will require major phase 4 studies, but all drugs should have this question posed)
8. When post market safety problems arise, the original reviewing division and the original reviewers should no longer make "safety" decisions about the drugs for which they had originally recommended approval; let OSE with other OND reviewers make the decisions.
9. If disagreements about post-market safety issues persist, use independent scientists without any conflicts to resolve scientific disagreements. Some scientific disagreements are likely to need new data to be resolved.
10. Frame direct-to-consumer advertising as a public health issue (rather than a first-amendment issue), evaluate risks and benefits, and as indicated, seek to limit DTCA, especially on TV
11. Seek authority to enforce key FDA provisions as perjury (rather than civil) violations by sponsor's senior management