



FDA Update

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Organizational Change -- Center

- Kate Cook – Deputy Director, CDRH
- Jonathan Sackler-Bernstein – Associate Director, Postmarket Transformation Program



Organizational Change -- Office

- Robert Becker – Chief, Medical Officer
- Maria Chan – Acting Director, Division of Immunology and Hematology Devices



Guidances

- IVDMIA – under review
- ASR Questions and Answers – September 15, 2008; clarifying letter issued June 6, 2008



Notable New Clearances

- LipoProfile – particle number
- Pathworks - characterization of tumors
- Allomap – risk assessment for cardiac transplant rejection
- SPOT-Light – CISH for Her 2
- T-Spot TB - serological test for TB



Postmarket Actions

- Safety tip on glucose meters using glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ)
- Contaminated heparin alerts



Critical Path Programs

- Genomics – interactions with NCI including EDRN, SPORE, PACCT, BRN and with CDC (EGGAP)
- Artificial pancreas
- Nanotechnology



Evolution of Electronics

- Turbo 510(k) – near 20%
- Electronic MDRs – new database
- Patient safety signals – established database



User Fee Mandates

- Review times tight
- Guidances published or under development
- AdvaMed report on pre-IDEs
- AdvaMed proposal for mass exemption of products



SACGHS Report

- FDA mouse not elephant but of more than murine interest
- Ambitious scope of recommendations
- Shift toward interest in evidence based medicine



Lewin Report

- Value of laboratory medicine to health care
- Comprehensive overview
- Echoes of previous Lewin Report commissioned by AdvaMed
- If you keep doing the same thing you've always done, you will keep getting the same thing you got – L. Kessler



EP 22 and EP 23

- EP 22 – risk management – information from manufacturers
- EP 23 – quality control choices based on risk management – advice to laboratorians



Congressional Interest

- Smith round table
- Patrick Kennedy bill
- Obama bill
- Others



Waiver Panel – CBC/Differential Cell Count

- Concrete example to test waiver guidance
- Specific issues raised about technology
 - Simplicity, testing personnel
 - Pre-analytical, analytical and post-analytical issues
 - Acceptable error limits (ATE/LER)
 - Need for quality control testing



Waiver Panel – CBC/Differential Cell Count

- Extremely capable instruments would be needed to make up for lack of formal training of personnel. Economically feasible?
- Issues about what analytes are reportable when some others are not some are not or when specimen is “flagged”.
- Recommendations for stringent ATE
- LER problematic – redefine?
- QC, at suitable intervals, is essential



Epiphany #3 -- Gutman

- Total Product Life Cycle
- Analytical performance
- Clinical performance
- Labeling
- -----
- Clinical validity
- Payment and use



Among School Children -- Yeats

Labour is blossoming or dancing where
The body is not bruised to pleasure soul,
Nor beauty born out of its own despair,
Nor blear-eyed wisdom out of midnight oil.
O chestnut-tree, great-rooted blossomer,
Are you the leaf, the blossom or the bole?
O body swayed to music, O brightening
glance,
How can we know the dancer from the
dance?