# BGM Test Systems Guidances—Perspectives and Key Issues Looking Ahead

FDA-Industry IVD Roundtable

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# Background

- Guidance for Industry and FDA Staff: Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use ("POC Guidance")
- Guidance for Industry and FDA Staff: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use ("SMBG OTC Guidance")

# Guidances Raise Key Policy and Regulatory Science Issues

- Industry met with FDA and discussed its views, including industry's comprehensive comments, scientific white papers, and larger meetings
- Helpful dialogue, but key aspects remain unchanged
  - Some examples, but not comprehensive list here
- Guidances raise key policy and scientific issues from a BGM and larger IVD perspective

# Departure from International Consensus Standards

- Guidances depart from international consensus standards without scientific or clinical justification
  - For example, interference concentrations recommended in the Guidances that depart from existing CLSI EP7-A2 (FDA recognition number 7-127)
  - Interference concentrations several times greater than the toxic levels in scientific literature
  - Troubling precedent

# Performance Standards

- FDA has clarified that the criteria in these Guidances are not mandatory performance standards
- FDA can only establish mandatory performance standards after providing the full protections of notice-and-comment rulemaking, including requirement that Agency respond to each comment. 21 U.S.C. § 360(d)

# Scientific Issues with Hematocrit Provisions

- Expecting all individual results to fall within specified bias threshold raises serious statistical concerns and is precedent-setting
- Method of bias calculation for hematocrit evaluation should be control
  - Consistent with approach to interference in Guidances

# CLIA POC Issues

- Broad labeling in provision—"not intended for use in point of care settings"
- Distinguishes artificially between setting/user rather than use via two separate guidances
- OTC Guidance Labeling imparted off-label status for HCPs for all uses--impact on broad range of users
- Disregards statute, attempts to use guidance to circumvent OTC statute--42 U.S.C. § 263a(d)(3)
- Overly broad approach to regulation
- Lack of nuance with respect to use (all deemed into one bucket, based on user)
- Overly mechanistic approach to scope and application of POC testing
- BGM guidance-not a model or intended for this discussion
  - Not a model for IVD or POC regulatory approach or future guidance
  - Future meaningful discussions needed from scientific, legal, and regulatory perspective and concerns from broader IVD perspective

# OTC Labeling Accuracy Key Hard to Read, Confusing?

- Strip performance statistics on each OTC strip carton can be confusing for patients
- Space and type will make it hard for patients to read

# Inconsistency with Labeling Regulations -- Symbols & English Only

- SMBG OTC guidance says labeling of these devices should not use symbols, conflicting with the final symbols rule
- SMBG OTC Instructions for Use in method comparison/user evaluation study in English only:
  - 1) Counter to FDA efforts for broader population representation in clinical studies
  - 2) Counter to 21 C.F.R. § 801.15, which permits other languages in labeling

# Use of 510(k) Guidance to Impose Ongoing Post-Market Expectations

- FDA has used premarket 510(k) guidance to impose ongoing post-market expectations.
  - Lot Release Testing
  - Control Solution

# Control Solution Provision

- Scientific rationale?
- Customers have sufficient access to control solution
- Generates medical waste
- Proposed alternative: Customer can get timely control solution (within 48 hours of request)

# Implementation/Pipeline

- Transition period needed
- BGM POC guidance states it does not apply to "devices used to screen for and/or to diagnose diabetes (such as clinical chemistry analyzers)."
  - Reviewers need to be cognizant of this provision and its application to hand-held analyzers

# Conclusion

- Continued dialogue with FDA is critical to resolve these important issues
  - Provide an appropriate transition period
  - Departure from international consensus standards only where impractical or contrary to law, or FDA provides appropriate clinical/scientific rationale
  - Align interferences with international standard CLSI EP7-A2
  - Guidance cannot override statute
  - 95% of all individual Hematocrit results within ±10% (POC ) or ±15% (OTC ); control as bias calculation method
  - Customer can get control solution within 48 hours of request
  - Permissible use of symbols and other languages in labeling
  - Consumer must be able to read and understand OTC accuracy labeling
  - Work together to ensure best science for regulatory decision-making
  - Such policy necessitates notice-and-comment rulemaking; illustrates concerns with use of guidance