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Advanced Medical Technology Association

Research Use Only
Considerations on the Draft Guidance

FDA-Industry IVD Roundtable Meeting

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BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

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Outline

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- Overview/Industry Support
- Background
- General Comments
- Areas of Concern/Clarification
- Specific Comments
- Recommendations

Industry support

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- Intended for research, not clinical use
  - RUO products should not be advertised or promoted for clinical use
  - IUO products should not be advertised or promoted for non-investigational use
- Many key concepts reflect FDA longstanding policy and role of RUO and IUO products

Background

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- 1992 and 1998 Draft Compliance Policy Guides
- FAQs developed with industry
- RUO certification recognized as a useful tool—to help ensure that RUO and IUO products are used properly consistent with their intended use

General comments

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- Current concerns of harm to patients from diagnostic use of unproven laboratory tests not the result of most manufacturer's RUO/IUO marketing practices
- Released in advance of guidance on LDT regulation; issue remains unaddressed
- Care not to hamper legitimate and important uses of RUO/IUO and products used in research to support future discovery and innovation

Areas of General Concern, Further Clarification

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- Imposing responsibility of manufacturers for laboratory's behavior/use
- Policing of customers
- Product withdrawals due to lack of confirmation of user's intent

Specific Comments Include

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- RUO and IUO products not “IVDs”
- Need to differentiate research products (not RUO/IUOs)
  - used in basic research, not being researched themselves
  - used in drug and biological studies; may be indirectly regulated (GLP, IND requirements)

Specific Comments Include

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- Need to explicitly reference RUO/IUO certification
  - a variety of programs in use to help ensure proper use as intended
  - consistent with previous FDA guidance

Specific Comments Include

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– Clarity appropriate use of instructions for use
  - Agree may not promote clinical use of RUO or research products
  - Ambiguous reference to “general instructions”; infers extremely limited
  - Instructions with sufficient information necessary for use in research, esp. highly sophisticated technologies

Policing Role

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- No requirement of <u>any</u> actual knowledge of customer clinical use and suggests apart from <u>any</u> claims made by manufacturer (beyond intended use)
- "Support" could include virtually any activity by a manufacturers that further use of a product (e.g., providing new reagent lots, technical advice) even when no mention of clinical use

Policing Role
(continued)

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- Suggests halt of sales upon “learning” about clinical use as requirement (no other alternatives) absent notice and comment rulemaking
- Absent recognition of shared responsibility of clinical laboratories for proper use of RUO/IUO products
- Must address in guidance-- potential for broad and serious chilling effect and threat to public health

Recommendations

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- Concur with many aspects of the draft guidance and its objectives—consistent with current manufacturer practices
- Carefully consider as not to hamper legitimate and important uses of RUO/IUO and products used in research to support future discovery and innovation
- Encourage open dialogue concerning specific RUO / IOU products of concern

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