The Second Annual
FDA Regulatory and Compliance Symposium

Managing Risks – From Pipeline to Patient

Policy Implications of Greater FDA/CMS Collaboration

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August 24, 2006

The Mission of the FDA

Determines Safety and Effectiveness

- To promote and protect the public health by helping safe and effective products reach the market
- To monitor products for continued safety after they are in use
- To provide the public science-based information needed to improve health

Fundamentally, FDA's focus is on risk assessment-based policymaking

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The Mission of CMS

The Most Influential Public Health Agency?

- No statutory or regulatory definition of “reasonable and necessary”
- However, CMS has generally interpreted “reasonable and necessary” to mean that the item should improve health outcomes overall for Medicare beneficiaries
- Using CMS influence and financial leverage, in partnership with other healthcare stakeholders, to reform healthcare
- Focusing on not just Medicare & Medicaid, but also commercial payers
- Quality, Value, Efficiency, Cost-effectiveness
- Assisting patients and providers in receiving evidence-based, technologically-advanced care while reducing avoidable complications & unnecessary costs

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A Vision of Evidence-based Medicine

"We will have to have more comprehensive and timely evidence on the value of new medical treatments. With this evidence, we could do a better job of helping patients find the right treatments for their needs and help health care providers make better use of quality measures and payment incentives. It would encourage the more rapid diffusion of new treatments that really are worthwhile. Together these steps will improve medical innovation, since it would be clearer to product developers that they will be rewarded when and only when their new treatments truly add value to patient care. We cannot get this valuable evidence unless more routine and extensive data collection and analysis tools are systematically built into our delivery of care."

Mark McClellan, Sept 2004

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Areas for Collaboration

- Pre-approval & pre-coverage
- Postmarket surveillance

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The Take of the Agencies

Interest in modest interagency collaboration with four objectives:

1. To improve the quality of information available on new technologies and emerging trends;
2. Shortening review timeframes;
3. Avoiding unnecessary duplication of effort; and
4. Leveraging the best scientific and other expertise between the two agencies to specific types of product reviews

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Inter-Agency Collaboration Flourishing

- FDA Sentinel System
- New Medicare drug benefit
- FDA postmarket surveillance and CMS registries => CED
- Off-label (colorectal cancer)
- AHRQ Comparative Effectiveness Reviews

CED in Action

Absent data on effectiveness for Medicare population per se, CED provides a means to earlier coverage:

Coverage with Evidence Development:

- **Coverage with Appropriateness Determination**
- **Coverage with Study Participation**

Examples:

- ICDs
- PET scans for Alzheimer
- Colorectal Cancer drugs
- Cochlear implants
- PET scans for oncology indications
- Home Oxygen

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What are the Problems that Advocates for Greater FDA/CMS Collaboration are Trying to Address?

What can we all agree on today?

Improving access to care is a universal and paramount concern!

- The lag-time between the approval of breakthrough medical devices by the FDA and the issuance of coverage determinations that make those devices available for the treatment of Medicare beneficiaries (and follow-on commercial payer coverage) is excessive.
- The tendency of CMS to reevaluate issues of safety and effectiveness during its coverage review that are clearly within the scope of FDA's evaluation (CMS has neither the scientific expertise or staff resources and funding). Other such duplicative efforts of the agencies must be reduced in order to speed innovative medical technologies to patients.

There is growing industry support for initiatives already underway or which could be undertaken absent legislation, such as:

- Provisions of the MIRA / MMA bill that reduce the coverage and coding decisional time lines, and make other reforms (CTI) intended to speed patient access to new technologies;
- CMS should work with the FDA to identify the criteria that are resolved during the FDA review and ensure that CMS reviewers do not impose requirements that revisit those criteria;
- CMS should end its practice of refusing to begin the coverage review process until a product has received approval from the FDA (DES is a solid precedent from which to build).

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AdvaMed Consensus Principles

1. AdvaMed supports reduced time frames for the Food and Drug Administration (FDA) regulatory decisions and clearances as well as the Centers for Medicare and Medicaid Services (CMS) Medicare coverage, coding, and payment determinations to assure patients have access to the best technologies and devices in a timely manner.

2. AdvaMed supports the preservation of the currently separate and distinct regulatory missions and review processes of FDA and CMS. FDA is a regulator with an appropriate emphasis on public health and safety, whereas CMS is generally a purchaser of health care services for Medicare beneficiaries.

3. AdvaMed believes that FDA and CMS must each strictly preserve the confidentiality of all company trade secrets and other proprietary data that are provided by manufacturers. The transfer of confidential company data from the FDA to CMS should occur only at the request of the submitting manufacturer.

4. At this time, AdvaMed opposes legislation concerning the relationship or communications between FDA and CMS.

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Does the Law of Unintended Consequences Take Hold?

FDA and CMS have very distinct missions

- FDA and CMS reviews of new technologies are based upon analyses and criteria that are fundamentally different.
- On the other hand, as a prudent purchaser of health care services for a defined population, CMS is clearly concerned with the clinical outcomes that will result from the use of a new technology on that population.
- Further hampering FDA new product reviews by projecting CMS criteria onto that process, distracting reviewers from pre and post-submission consultations, or worse still inviting some FDA/CMS understanding of cost-effectiveness criteria to be employed by both agencies.
- While it is clear that the decisions made by the FDA are relevant for the purposes of CMS review, the reverse is not true.
- First to market could alter playing field for all to follow.
- Mitigates against Administration move to choice and private plans as we move closer to a single-payer system with one agency in a dominant role.

Thoughtful Policy Offerings:

- Some have advocated conferring “interim” or “resultant coverage” on all FDA-approved products for a period of one or more years during which time clinical outcomes data would be collected for the Medicare population.
- Parallel review of clinical trial designs
- Others have suggested additional models including:
  - Parallel Play
  - Limited Information Transfer
  - Coordination
  - Harmonization
  - Consultative
  - Collaborative
  - Mutual Recognition Agreement

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So, where does this leave us?

Conclusions:

- Today, device manufacturers face an "innovator's conundrum" – that is many new technologies cannot be used until coverage is granted, and coverage is conditioned on the development of more clinical evidence, and evidence cannot be produced until a new technology is used!
- Consensus may be unattainable and ill-conceived solutions to a problem that has yet to be adequately defined could create adverse unintended consequences
- Countless AdvaMed working groups, the HHS Regulatory Reform Commission, and the Congress in the Medicare Contracting Reforms bills and elsewhere, have all considered more aggressive collaboration proposals and found them lacking.
- FDA and CMS continue to work on an MOU to guide future information sharing and collaboration, though the process has bogged down over sharing of proprietary data concerns.
- Greater information sharing is desirable, particularly given current resource constraints at both agencies and waning scientific expertise. Upon completion of a clinical trial and panel review, and yet before FDA final action, it is entirely appropriate in some cases that CMS commence discrete elements of its own coverage determination process.
- Should always be at the discretion of the manufacturer, but if an NCD is sought, greater collaboration may actually be desirable.

Questions or Comments

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