Use of Postmarket Data to Support Premarket Approvals

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Summary of Premarket Approval (PMA)

- Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices
- Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury
- PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use
- More specifically, FDA must determine that the PMA provides a “reasonable assurance of safety and effectiveness” using a benefit-risk analysis

Use of Postmarket Data in Determining PMAs

The FD&C Act requires FDA to consider whether the need for premarket data can be reduced by relying on postmarket data (FD&C Act § 513(a)(3)(C)):

In making a determination of a reasonable assurance of the effectiveness of a device for which [a premarket approval application] has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

FDA Guidance – Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

- Issued April 13, 2015
- Outlines: "how FDA considers the role of postmarket information in determining the extent of data that should be collected in the premarket setting to support premarket approval while still meeting the statutory standard of reasonable assurance of safety and effectiveness"
- Clarifies "how FDA considers postmarket data as part of the benefit-risk framework"

FDA Guidance – Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

- Guidance overall emphasizes the potential positive effect of greater reliance postmarket data collection in facilitating innovation and improving health
- States it "can reduce the extent of premarket data collection and directly impact when patients will have access to high-quality, safe and effective medical devices."
- But it also acknowledges a potential to undermine patient safety if the postmarket data collection is not actually done

FDA Guidance – Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

Examples of where FDA may consider increased reliance on postmarket data include:

- Assessing minor or uncommon risks
- Assessing long term benefit-risk issues difficult (or impossible) to determine with premarket data
- Assessing PMAs based on more established technology
- An urgent public health need

Example - Medical Device Label Expansion Opportunities

Current Issues for PMA Applicants

- Innovative medical devices often follow a less predictive pathway relative to clinical use
- Off label promotion guidelines have become more strict and due to compliance issues caution needs to be taken when delving into off label uses of medical devices cleared for specific indications
- Clinical studies, particularly IDE studies, are costly, risky and sometimes are in patient classifications that are difficult for data collections purposes
- While a device may be safe and efficacious for a specific indication without the ability to expand the label reimbursement is often limited or non-existent which hinders its use

Potential Regulatory Solution

- Registry data is becoming more common and is often supported by medical societies as a means to support its members, measure efficacy of types of procedures and track new devices and techniques
- While FDA has often dismissed the potential of registry data as a means to expand specific clinical indications for regulated devices they have shown a greater willingness to consider this option & say so in the recent guidance
- This provides an opportunity for providers and manufacturers but most importantly patients that can benefit from a device that may not have access today due to the medical / legal climate

Real World Case Example

Edwards Sapien Transcatheter Aortic Valve Replacement (TAVR)

- Signifying an increasing confidence in clinical outcomes registries, the U.S. Food and Drug Administration has approved expanded labeling for the Edwards SAPIEN Transcatheter Heart Valve, making the device available to a larger group of patients with aortic stenosis, a heart valve disease that causes narrowing of the aortic valve, restricting blood flow from the heart.
- When TAVR was first approved, it was for device insertion using only the transfemoral approach (via an artery from the leg) in inoperable patients. The labeled indication was subsequently extended to high-risk, operable patients using either a transfemoral or transapical (between the ribs through the tip of the heart) approach; however, that still left a significant number of patients who were unable to be treated—patients who were inoperable and not able to be treated by a transfemoral approach and high-risk or inoperable patients who would be best treated by another “alternative” approach.
- The Society for Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry supplied the FDA with data collected from several thousand alternative access procedures showing no evidence that the device performed differently or had a different benefit-risk profile when alternative access approaches were used.

Takeaways

- FDA appears open to allowing use of postmarket data where appropriate to help drive innovation and make products that can improve health available sooner
- From examples given in the 2015 guidance, postmarket data can be applied in numerous situations = increased flexibility in a PMA and thus increased ability to bring new products to market
- Can apply to original PMAs or supplements
- Label expansion can also apply to de novo 510(k)s
- Optional pathway for applicant – nothing requires the PMA applicant to use postmarket data to support a premarket approval; this is not an additional mandatory reporting requirement

Next Steps

- Medical device planning board (NEST) has highlighted this avenue in its latest white paper published on 9/20 which FDA also supports – pilot opportunities will be looked for
- Manufacturers should continue strong support of registries through the grant process that help proliferate this opportunity

Questions? Comments?