Potential Administrative Actions:

Fostering an environment that enables industry to advance innovative, safe, effective, and affordable treatments and cures to the patients who need them as quickly as possible.

- Encourage Use of 21st Century Tools for Drug Evaluation, Review and Approval: Examples include:
    - Broader us of biomarkers to speed medical product evaluation and shorten product development timelines.
    - Wider acceptance of new approaches to clinical trial design and statistical methods that could reduce the cost and time to bring a new medicine to market.
    - Greater use of real-world evidence could allow information other than that derived from traditional studies to aid regulatory decision-making.
    - (Reference: PhRMA http://phrma-docs.phrma.org/sites/default/files/pdf/proactive-policy-drug-discovery.pdf)
- Improve Predictability for Payers and Dissemination of Evidence: Provide medical product information to payers either before approval because payers often set premiums and formularies 18 months in advance or be able to provide off label safety and efficacy information not included in the product's labeling. (Reference: PhRMA http://phrma-docs.phrma.org/sites/default/files/pdf/proactive-policy-drug-discover.pdf)
- Explore administrative actions to encourage greater uptake of biosimilar and interchangeable biosimilars.
- Explore ways FDA can better utilize current regulatory pathways including 505(b)(2) and 505(j) to better rationalize awards of exclusivity.
    - https://www.washingtonpost.com/news/wonk/wp/2017/02/10/an-old-drug-gets-a-new-price-to-fight-a-rare-disease-89000-a-year/?utm_term=.30950c545473
- Reconsider FDA's Unapproved Drug Initiative.
    - http://www.latimes.com/business/hiltzik/la-fi-mh-the-little-known-fda-program-20150923-column.html
- Implement the FDA commitments outlined in the PDUFA VI, MDUFA IV, GDUFA II, and BSUFA II commitment letters to Congress. (Source: HHS/FDA)

Rationalizing Reimbursement Policy

- Consider administrative modifications to streamline the Open Payments program in an effort to reduce drug and device manufacturers' burden from reporting and validating data.
    - References:
        - American Medical Association, June 2016 - *Statement on Newly Released Open Payments Data*
        - Bloomberg Bureau of National Affairs (BNA), 2015 - *As Second Open Payments Release Date Nears, Industry Feels Increased Burdens*

- Explore ways to clarify or modify regulations, or pursue future rulemaking as appropriate, to enable manufacturers to voluntarily enter into value-based purchasing arrangements.

Potential Legislative Ideas for Discussion:

Fostering an environment that enables industry to advance innovative, safe, effective and affordable treatments and cures to the patients who need them as quickly as possible.

- REMS and access to brand samples: Removing barriers that delay generic and biosimilar market entry.
    - *Ensure access to brand samples for generic development:* Recent proposals, including bipartisan bills in Congress, are intended to improve generic developer access to brand drugs for product testing.
        - The Fair Access for Safe and Timely (FAST) Generics Act would require brand companies to sell their products, including REMS drugs, to generic developers without restriction.
        - Rep. Marino introduced HR 2212 Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act on April 27, 2017, similar to a Senate version introduced last year by Senators Leahy, Grassley, Klobuchar and Lee would allow generic developers to sue brand companies in federal court to obtain samples of REMS drugs as well as drugs subject to manufacturer-imposed limited distribution networks.

    - *Separate Risk Evaluation and Mitigation Strategies (REMS):* HR 2212 Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act would give FDA the flexibility to allow separate REMS.

- FDA reforms to speed review of complex generics
    - *Expand allowable evidence to support review of complex generics:* Give FDA the flexibility to rely on a broader complement of data for review of complex generic drugs in addition to bioequivalence and bioavailability data when necessary for approval.
    - *Expand threshold for generic approval:* Give FDA the authority to allow generic copies to have minor differences, to account for small variations between brand drug and proposed generic or biosimilar, such as patient retraining.
    - Reference: Dr. Gottlieb (http://www.aei.org/publication/epipen-shows-a-path-to-solve-the-bigger-drug-pricing-challenge/)