BACKGROUND  

- Specialty Pharmacy (SP) products:  
  - Treat specific, complex, and chronic diseases  
  - Are costly, require reimbursement, have handling assistance & training, have unique & limited distribution processes, and are subject to patent infringement.  
  - 43% of specialty products ($384 in 2016, 7.6% higher than $375 in 2015)  
  - 57% from traditional products ($511 in 2016, 0.8% lower than $515 in 2015)  
  - Are predicted to be 44% of the pharmaceutical industry revenue in 2020.

- In the US Market, approvals were granted for the following biosimilars:
  - In 2015, 1 product: Zarzio (filgrastim-sndz) Sandz’s biosimilar of Neupogen
  - In 2016, 3 products: Inflectra (infliximab-dyyb), Pfizer/Celltrion’s biosimilar of Remicade, Eldreliz (etanercept-szsz) Sandoz’s biosimilar of Enbrel, Avatixa (adalimumab-atto) Amgen’s biosimilar of Humira
  - In 2017, 4 products: Cytalo (adalimumab-adbm) Boehringer Ingelheim’s biosimilar of Humira, Mavia (bevacizumab-abwdb) Amgen’s biosimilar of Avastin, Ogrivi (trastuzumab-dkst) Mylan GMBH’s biosimilar of Herceptin, and toft (infliximab-bxts) Pfizer’s biosimilar of Remicade

- Based on recent programs with partnering doctors, Medical Directors and sponsors (pharmaceutical, medical device, and health technology companies), the authors decided to conduct a survey of medical and pharmacy directors involved with P&T Committees on their policies regarding:  
  - Specialty Pharmacy products  
  - Use of Specialty Pharmacies  
  - Expectations for biosimilar use and savings

- Prescribers and members biosimilar education

OBJECTIVES  

- To gain a better understanding of health plan management of SPs, SP products and biosimilars today and compare with prior surveys
- The survey focused on:  
  - Top SP products and co-pays  
  - Biosimilar coverage, copays and expected savings over time  
  - Expectations for prescriber and member biosimilar education

METHODS  

- An interactive survey was developed with 69 questions and included:  
  - Yes / No questions  
  - Lists for users to select single or multiple answers  
  - Invitations to participate were sent to Medical and Pharmacy Directors working with US health plans, PBMs, and insurers from the TPG-NHRT database in November 2017
  - Material or financial incentives were not offered for completion of the survey

RESULTS CONTINUED  

- A total of 77 respondents (31.2% response rate) completed the survey, some questions were not answered by all respondents
- Many respondents reported multiple degrees, and the most common degree was MD (57%)
  - 40.5% worked for health plans, 11.4% PBMs, 8.9% Integrated Delivery Networks (IDNs), 3.8% for Preferred Pharmacy Organizations (PPOs) / Independent Provider Associations (IPAs), 1.3% for the Government, the remainder consultants
  - 39.2% of plans were national, 51% were regional and 23% were local

- The most commonly reported respondent titles were:  
  - Chief / Senior Officer (43%), Payer specific (19%), Regional (8.9%), or therapeutic area specific (3.3%)
- Plans cover multiple types of commercial products (88.8% for commercial)

  - Available at www.TPG-Health.com

CONCLUSION  

- Medical and Pharmacy Directors, who commonly serve as P&T Committee members, have distinct opinions as to how to alter the process to adapt to evolving policies  
  - Health plan policies are expected to grow:  
    - Specialty Pharmacy products  
    - Biosimilar products
  - Formulary management today is changing policies on benefit design, Specialty Pharmacy products and biosimilars to achieve optimal patient coverage at a minimum cost

REFERENCES  

- FDA guidances/briefings. Updated: 12/13/2017. Available at: https://www.fda.gov/Drugs/Briefings/BriefingDocuments/default.htm

Citation: Brook RA, Carlisle JA, Smeeding JE. Management of Specialty Drugs, Specialty Pharmacies and Biosimilars in the United States. J Manag Care Spec Pharm. 2016;24(4-c):S101  
Available at www.TPG-Health.com

Figure 1A: Specialty Pharmacy Restrictions

Figure 1B: Specialty Pharmacy Ownership

Figure 2: Diseases Treated by Specialty Pharmaceuticals

Figure 3: Expected Co-Pay Types For Specialty Pharmacy Products

Figure 4: Biosimilar Education

Figure 5: Predicted Savings from Biosimilars

- Biosimilar use is expected for all reference product indications 53.1% ($; 95.45), while 44.3% will restrict to approved indications ($; 93.1%)
  - 25% of plans expect the biosimilar to be the only product available, copays are expected to be discounted off the innovator 47.9%, and 27.1% to vary based on approval timing
  - Expectations for member and prescriber education about biosimilars are shown in Figure 4
  - Predicted savings from biosimilars are shown in Figure 5