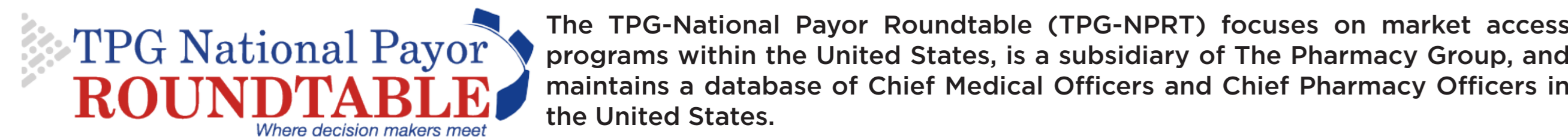


Management of Specialty Drugs, Specialty Pharmacies and Biosimilars in the United States

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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 frequently have patient-adherence programs
- Specialty medicines:
 - Net manufacturer revenue on average for each person in the United States in 2016 resulted in \$895 per year (2.6% higher than 2015's \$872) with:
 - 43% from specialty products (\$384 in 2016, 7.6% higher than \$357 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 revenues in 2020²
- In the US Market, approvals were granted for the following biosimilars³:
 - In 2015, 1 product: Zarxio (*filgrastim-sndz*) Sandoz's biosimilar of Neupogen
 - In 2016, 3 products: Inflectra (*infliximab-dyyb*) Pfizer/Celltrion's biosimilar of Remicade, Erelzi (*etanercept-szzs*) Sandoz's biosimilar of Enbrel, Amjevita (*adalimumab-atta*) Amgen's biosimilar of Humira
 - In 2017, 4 products: Cyltezo (*adalimumab-adbm*) Boehringer Ingelheim's biosimilar of Humira, Mvasi (*bevacizumab-awwb*) Amgen's biosimilar of Avastin, Ogivri (*trastuzumab-dkst*) Mylan GMBH's biosimilar of Herceptin, and Ixifi (*infliximab-qbtx*) Pfizer's biosimilar of Remicade
- Based on recent programs with US payors, Medical Directors and sponsors (pharmaceutical, medical device, and health technology companies), the authors and their organizations 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 member 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 online, 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-NPRT database in November 2017
 - Material or financial incentives were not offered for completion of the survey



METHODS CONTINUED

- Topics included:
 - Plan coverage and benefit design:
 - Geographical coverage
 - Types of lives with multiple member type information
 - Clinical-administered products (office administered products)
 - Restrictions on Specialty Pharmacy providers
 - Coverage of Specialty Pharmaceutical products:
 - Under the Medical or Pharmacy benefit
 - Current co-pays and expected co-pay changes
 - Expectations for biosimilar agent formulary reviews, coverage of multi-indication agents and potential savings
 - Educating prescribers and members about biosimilars
- Survey responses were compared with prior surveys
- Survey invitations were received and reviewed by 247 managed care decision makers

RESULTS

- 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 Prescriber Organizations (PPOs) / Independent Provider Associations (IPAs), 1.3% for the Government, the remainder consultants
 - 39.2% of plans were national, 27.5% were regional and 33.3% were local
 - The most commonly reported respondent titles were: Chief / Senior Officer (43%), Payor specific (19%), Regional (8.9%), or therapeutic area specific (1.3%)
- Plans cover multiple types of members: commercial (68.8%=FFS,76.5%=HMO/PPO), Medicaid (Traditional=36.4%, HMO/PPO=67.9%), Medicare (71.2%,PDP-only=50%), Employer/Self-funded=77.1% and IDN (47.7%, 340B Qualified=43.5%)
- The use of Specialty Pharmacies is restricted by 81% of plans (51% last year) current:
 - Specialty Pharmacy restrictions are shown in Figure 1A
 - Specialty Pharmacy ownership is shown in Figure 1B

Figure 1A: Specialty Pharmacy Restrictions

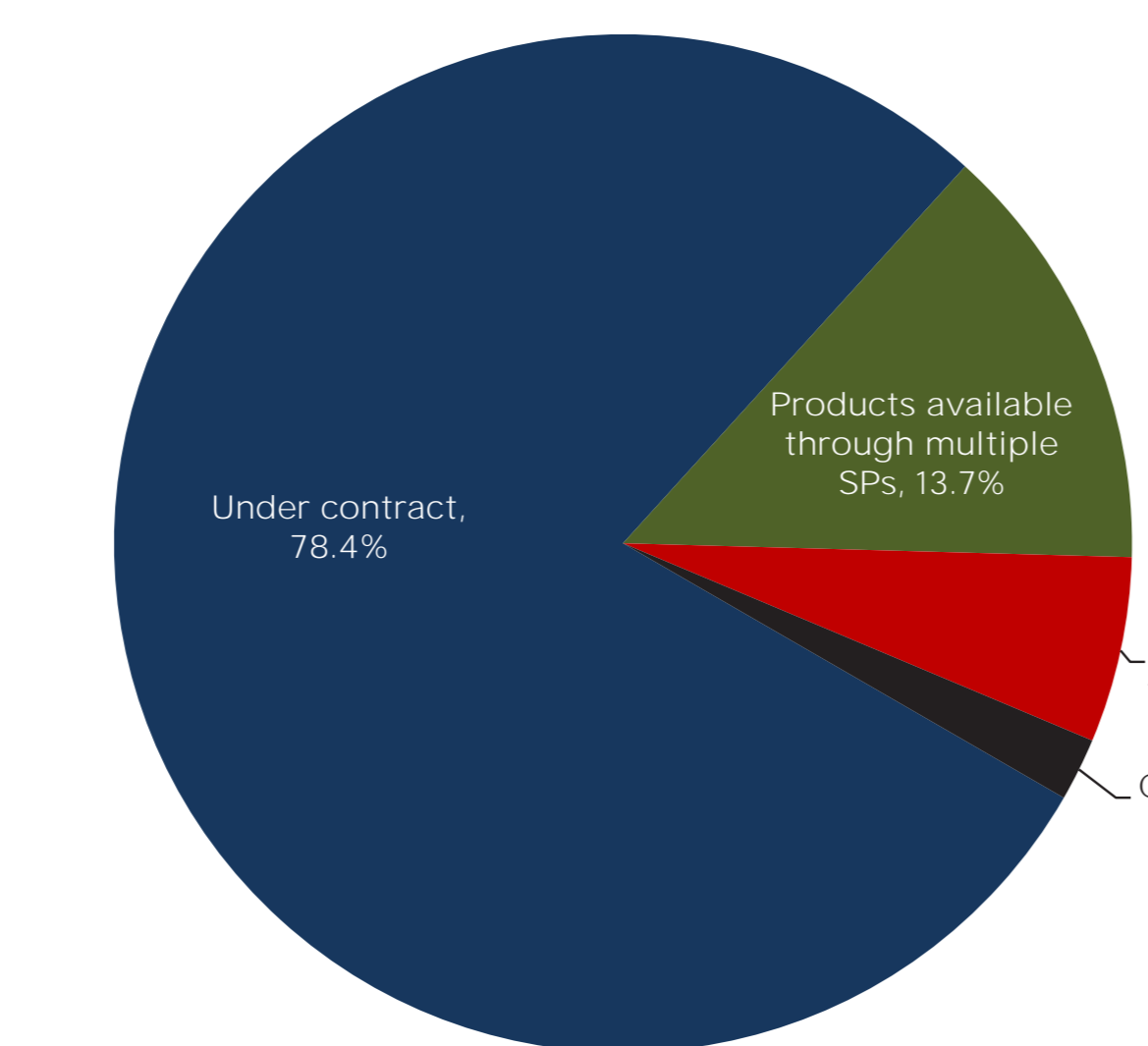
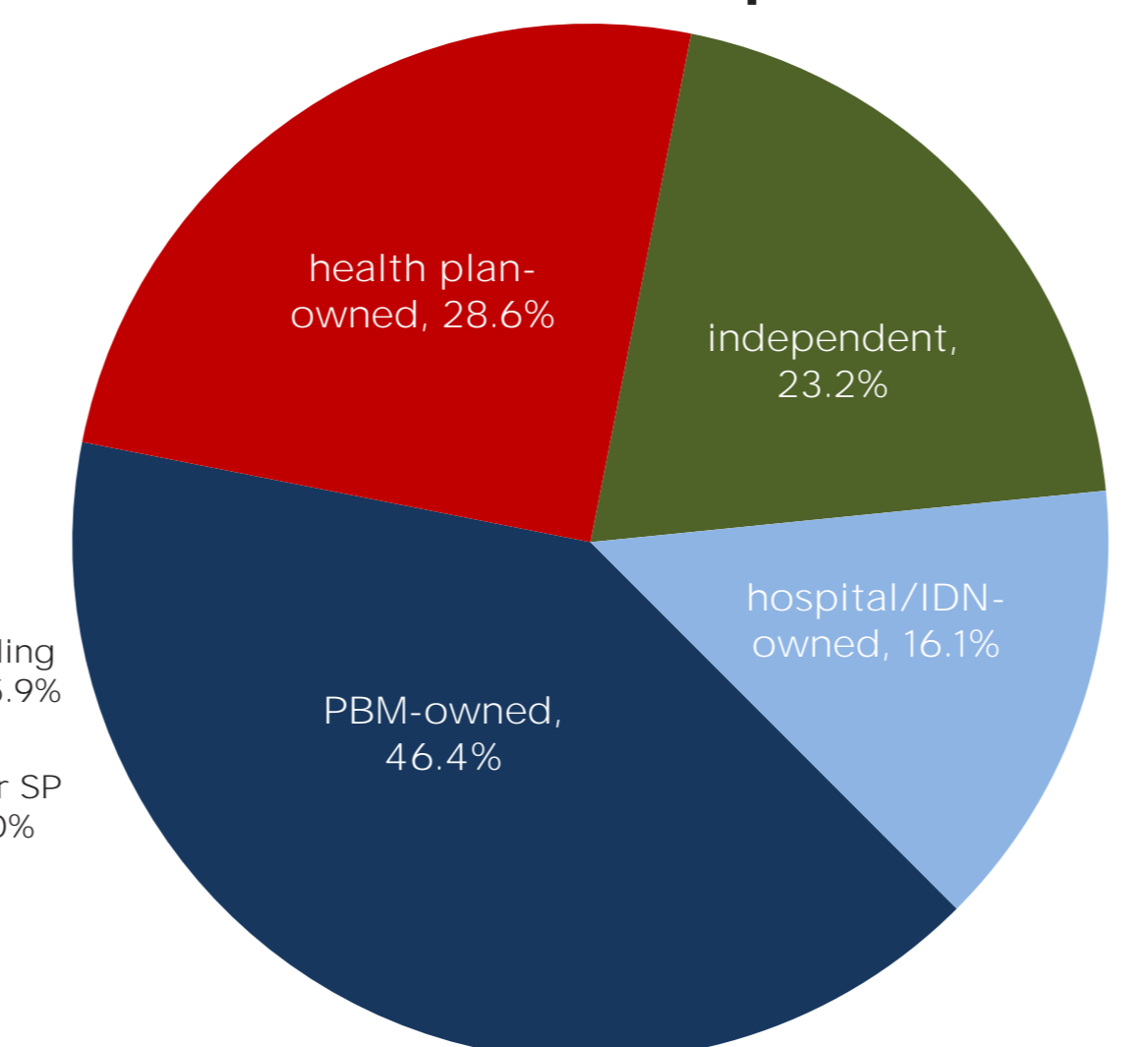


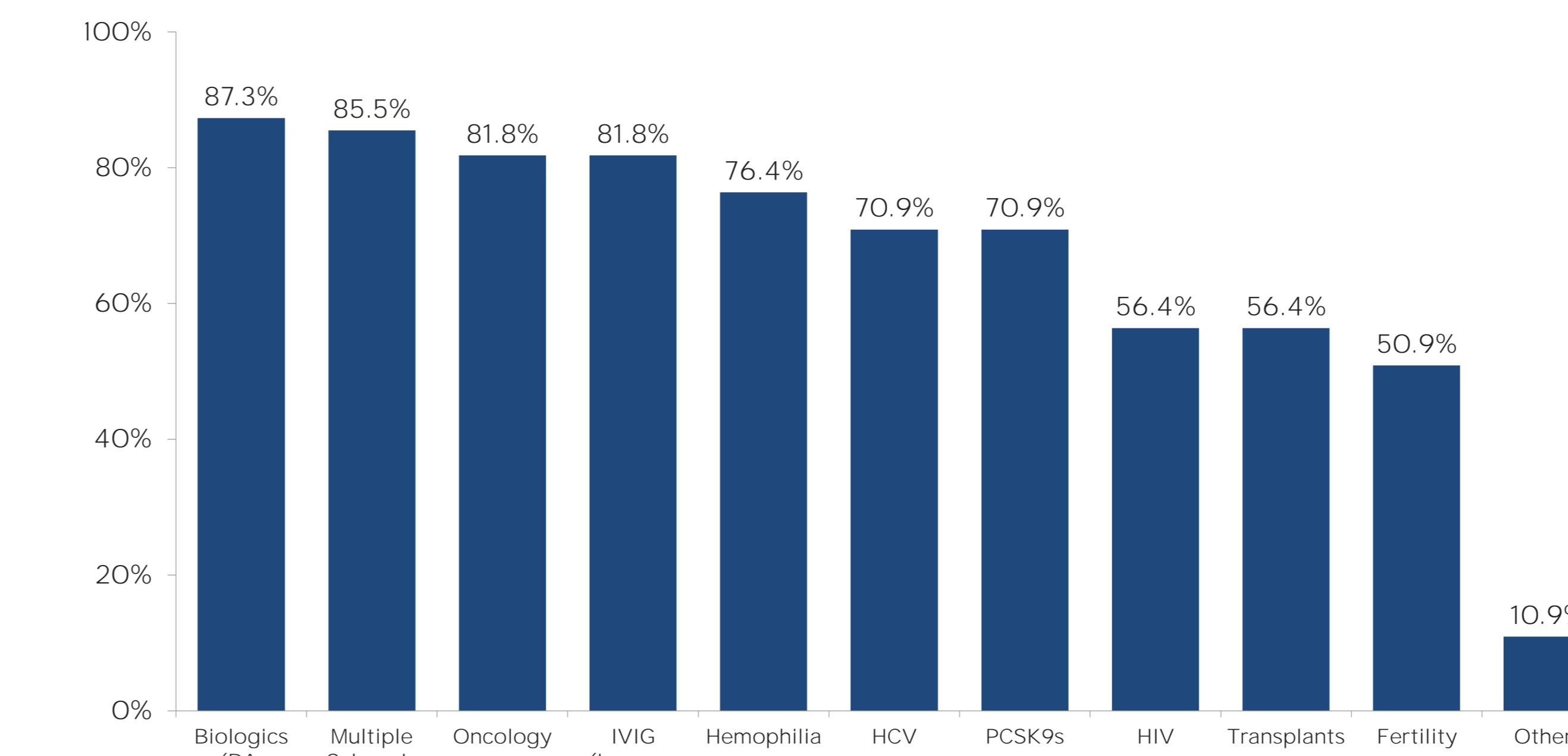
Figure 1B: Specialty Pharmacy Ownership



RESULTS CONTINUED

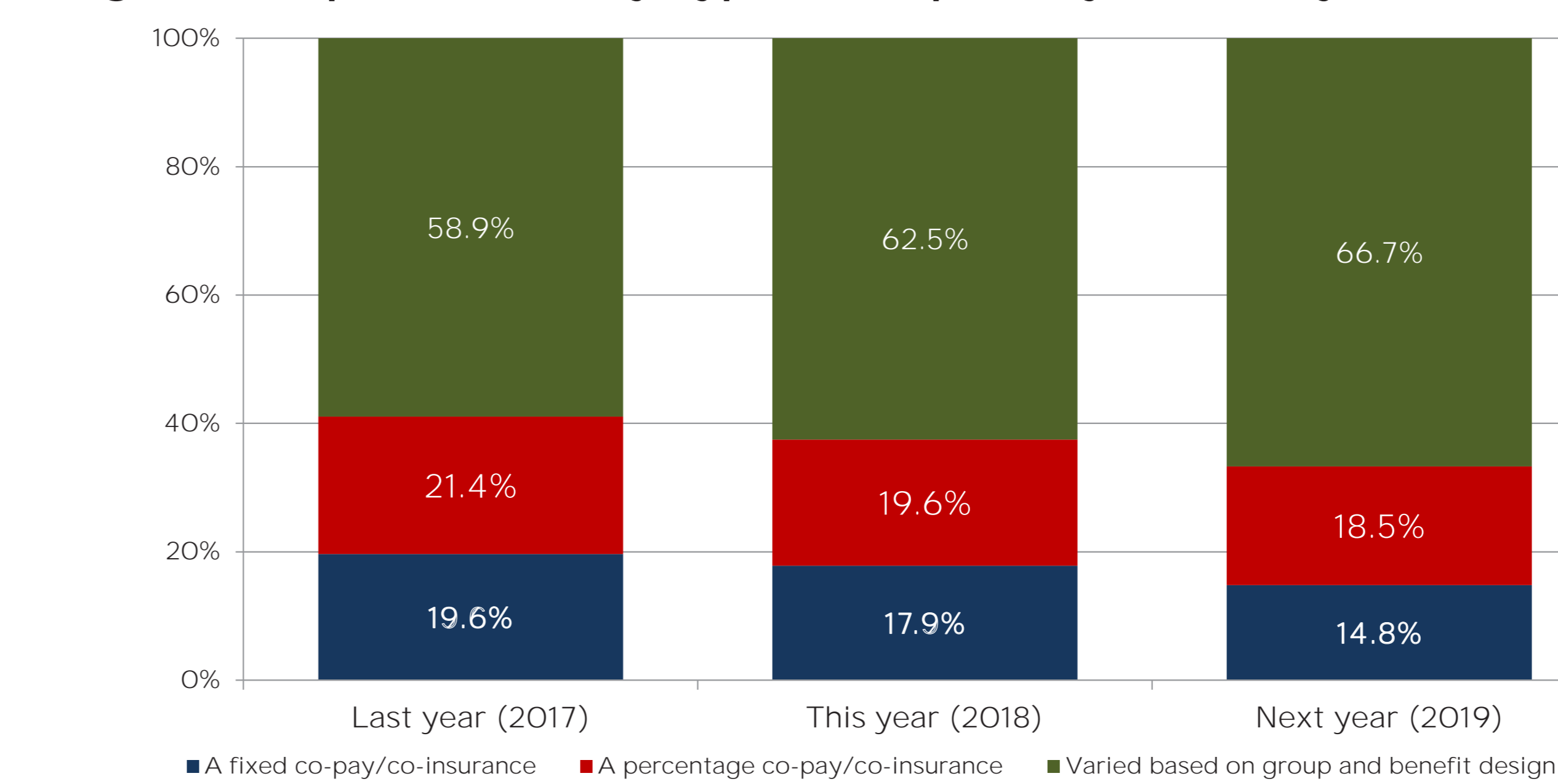
- Specialty Pharmacy ownership shifted about 6% from independents to internally-provided SPs and 48.4% reported the plan's PBM as their SP provider
- Plans covered clinician-administered products under the medical benefit (44.1%↑ from 15.2%), 1.4% under the pharmacy benefit the remainder varied based on price and plan design
- The top diseases treated by Specialty Pharmaceuticals are shown in Figure 2

Figure 2: Diseases Treated by Specialty Pharmaceuticals

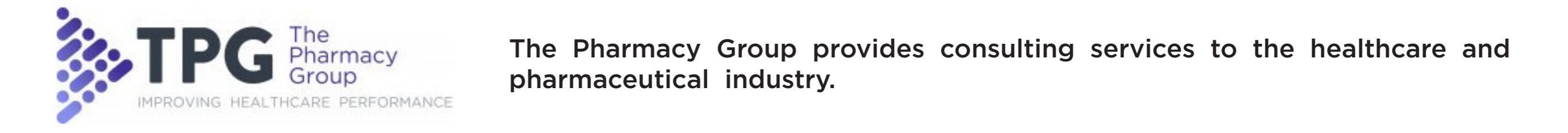


- Specialty product co-pays continue to move from fixed to percentage with more plans using group and benefit design to determine the co-pay as shown in Figure 3

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



- Biosimilar use is expected for all reference product indications 53.1% (↓ from 59.5%), while 44.9% will restrict to approved indications (↑ from 31%) and 2% indication based
- 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



RESULTS CONTINUED

Figure 4: Biosimilar Education

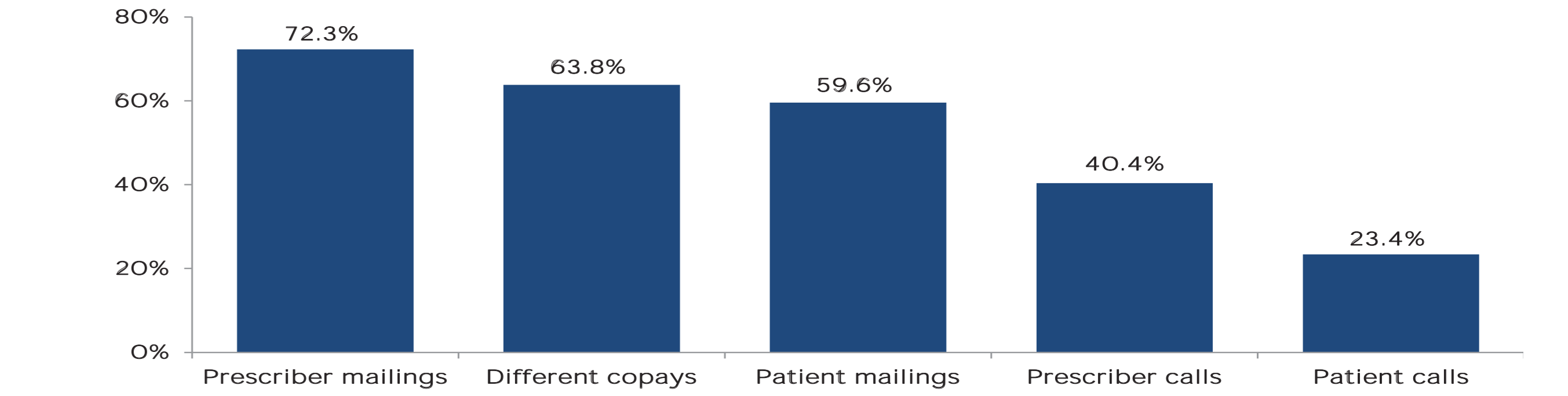
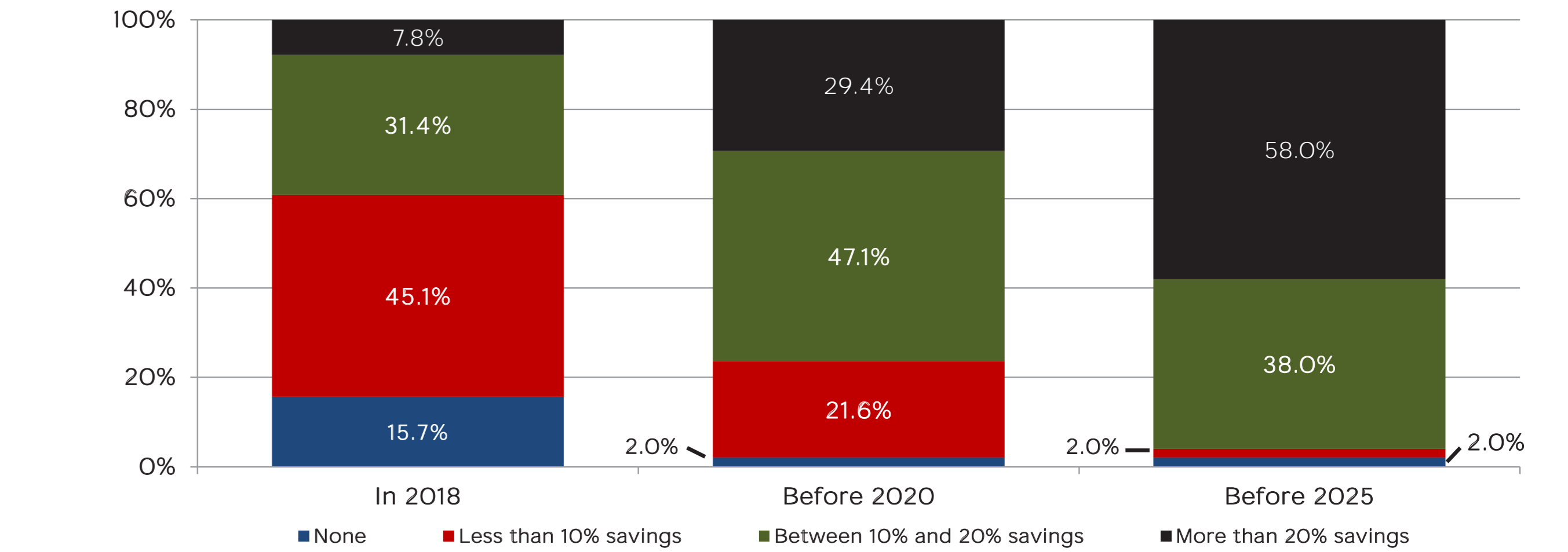


Figure 5: Predicted Savings From Biosimilars



CONCLUSIONS

- 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 plans' expenditures 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

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