Payor Strategies to Drive Biosimilars Access and Savings

GRx+Biosims Conference 2019

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Discussion Today

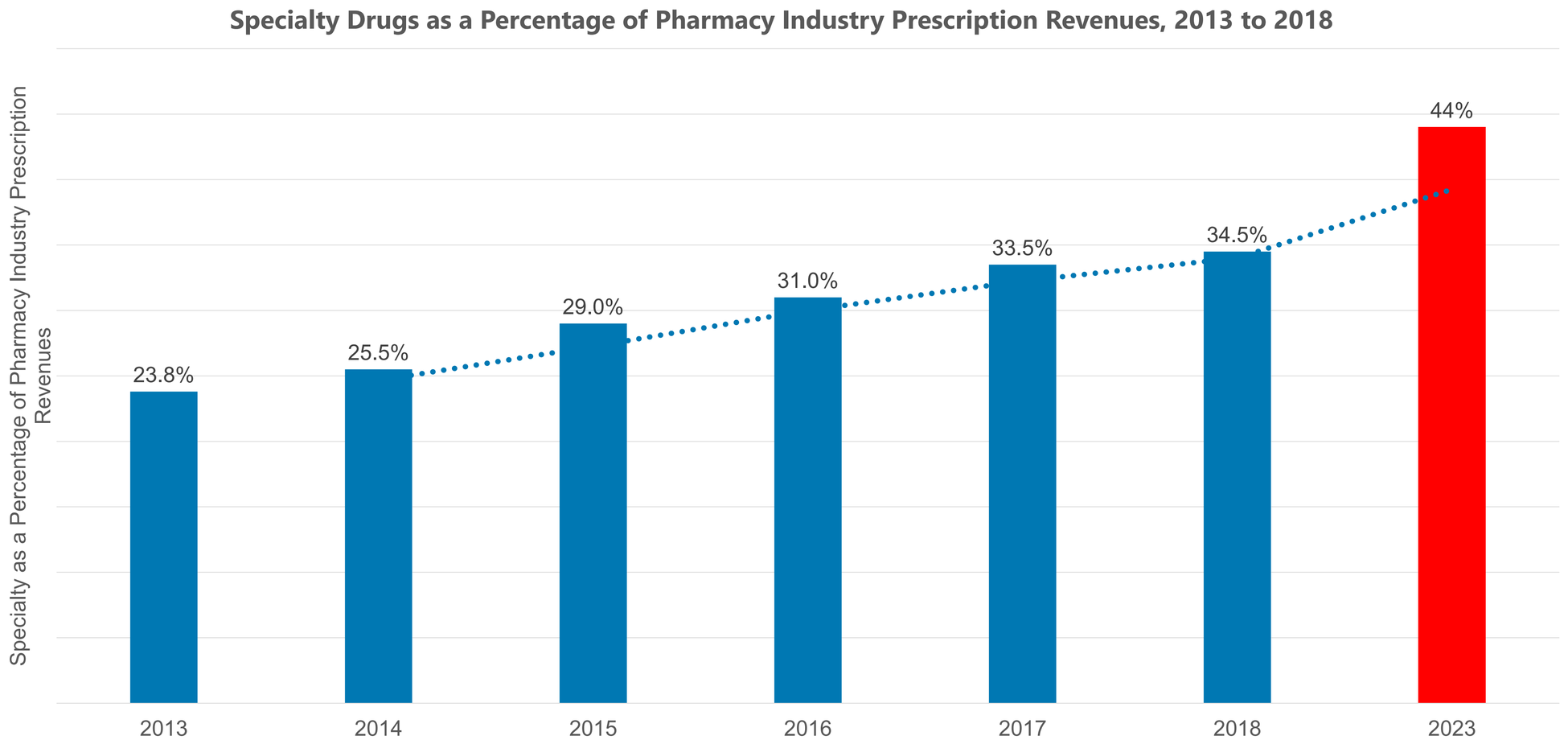
- Biosimilars Overview
- Kaiser Permanente Experience with Biosimilar Therapy
- Addressing Challenges for Biosimilars in the U.S. Market

Unsustainable Rising Drug Costs – US Marketplace

- 1 in 4 people have a difficult time affording their medications[1]
- Newer, innovative therapies cost ~$500K-$2M per patient
  - CAR-T therapy
  - Gene therapy
- Specialty drugs now account for more than half of drug budgets in many organizations
- How can we afford to provide these therapies?

Source: Kaiser Family Foundation Health Tracking Poll (conducted Aug 6-11, 2015)

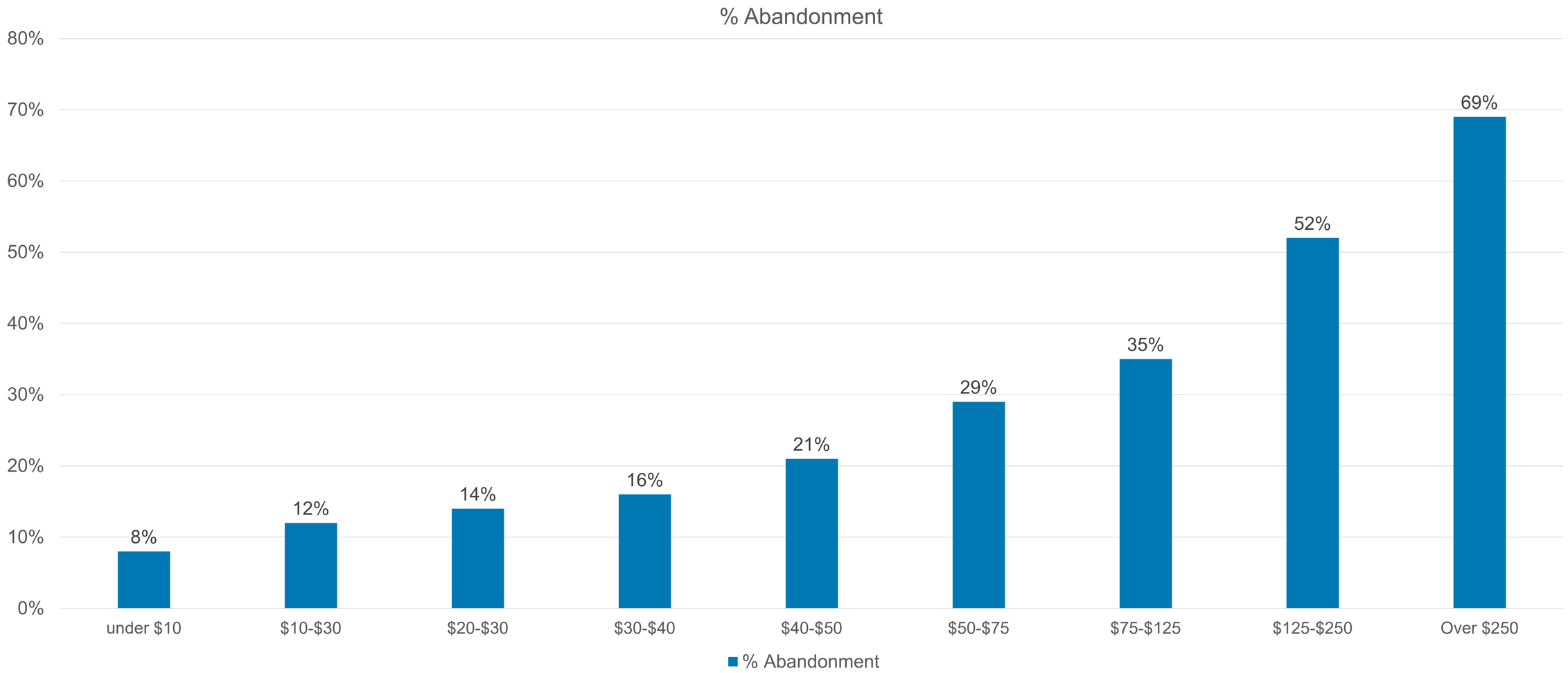
Specialty Drug Trends 2013-2023



* Includes retail, mail, long-term care, and specialty pharmacies

Source: 2019 Economic Report on US Pharmacies and Pharmacy Benefits Managers - Drug Channels Institute

New Prescription Abandonment Rate by Patient Co-Pay Amount



2019 Economic Report on US Pharmacies and Pharmacy Benefits Managers - Drug Channels Institute

KAISER PERMANENTE® Who We Are

12.3M Members

39 Hospitals

701 Medical Offices and Care Facilities

219K Employees

23K Physicians

59K Nurses

Kaiser Permanente Pharmacy

556 KP Pharmacy Patient Sites

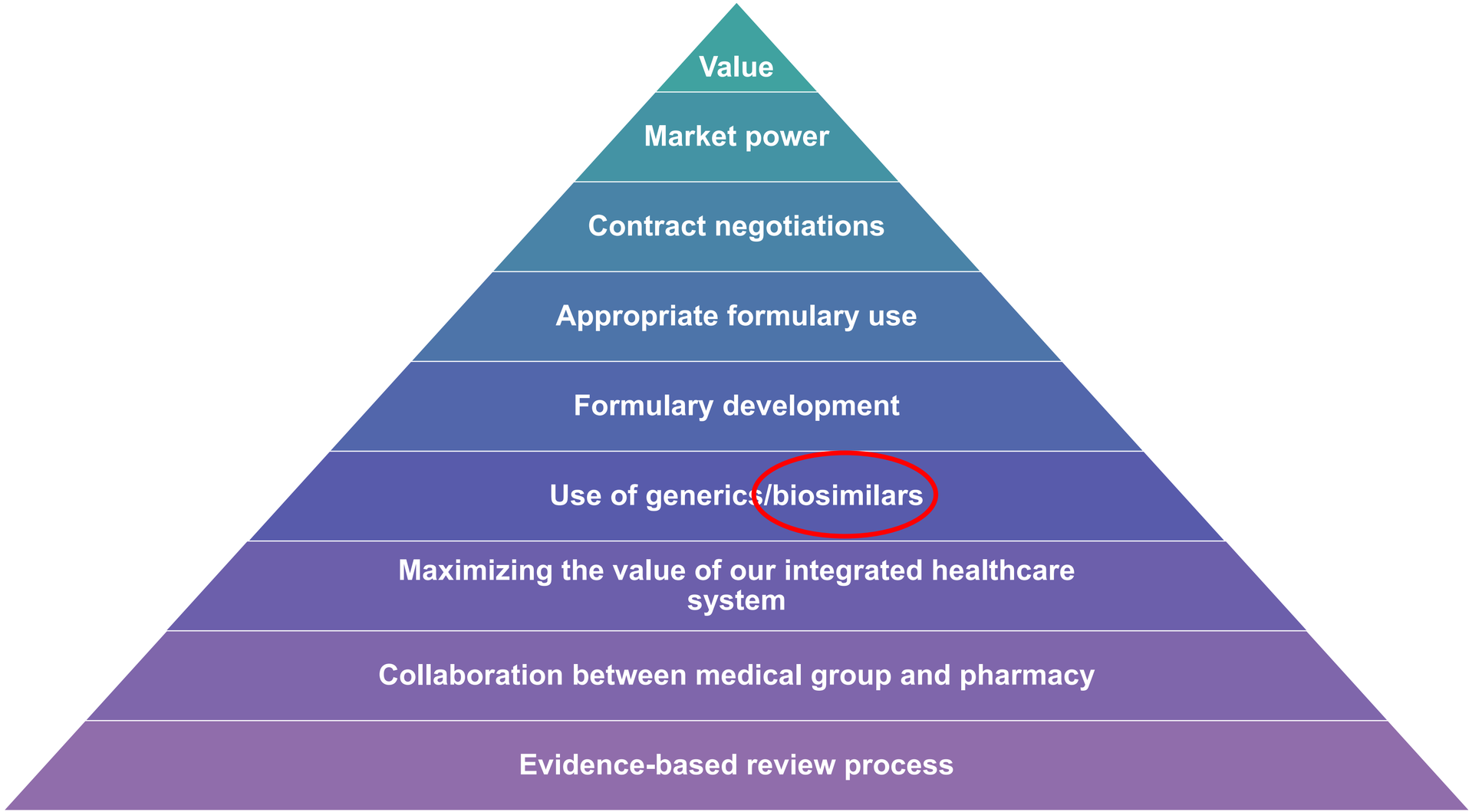
- **395** Outpatient and **42** Inpatient Pharmacies
- **94** Clinic Administered Sites
  Oncology, Outpatient Infusion, & Specialty
- **25** Call Center and Central Fill Operations

Employing **14,000** KP Pharmacy Staff Members

~150,000 + Daily Member Interactions

One of the highest volume and most frequent member touch points across our Kaiser Permanente network

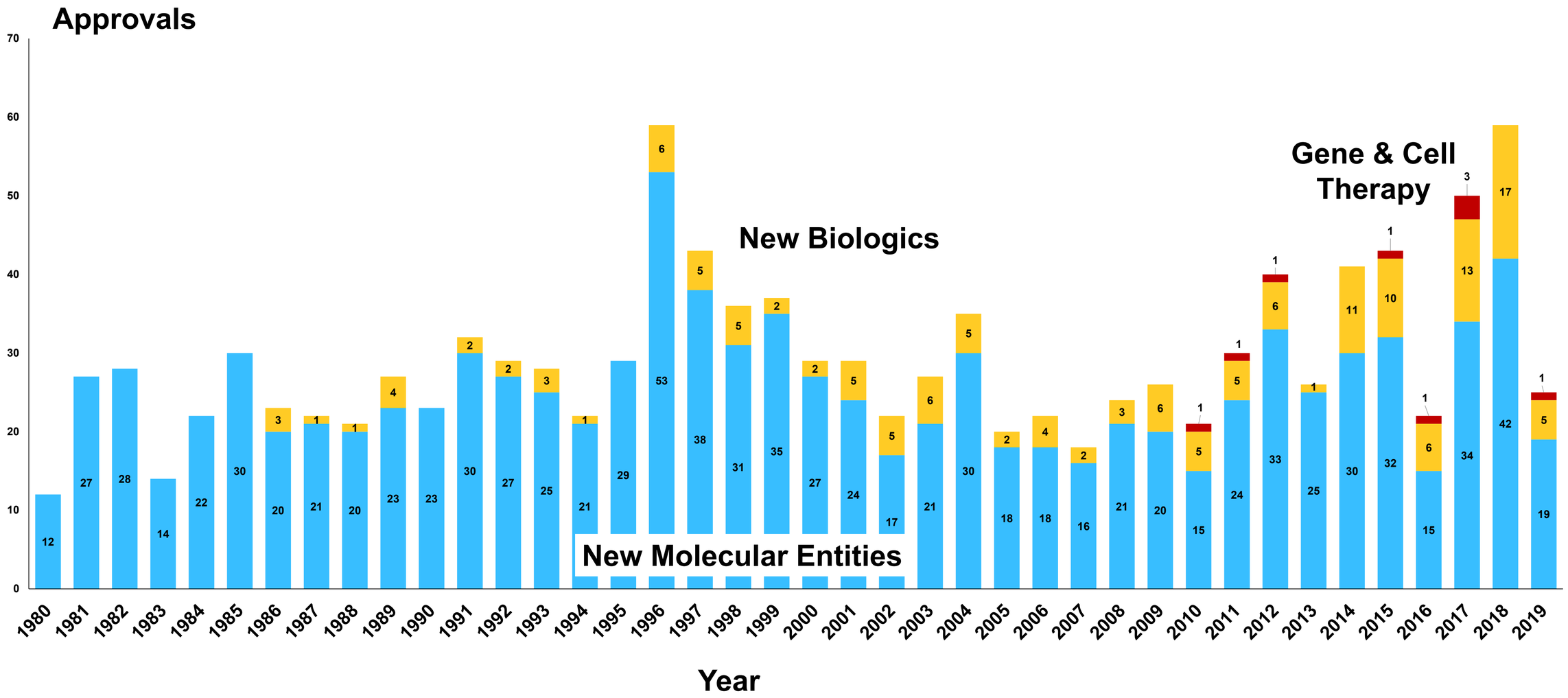
Kaiser Permanente's Drug Cost Containment Strategy



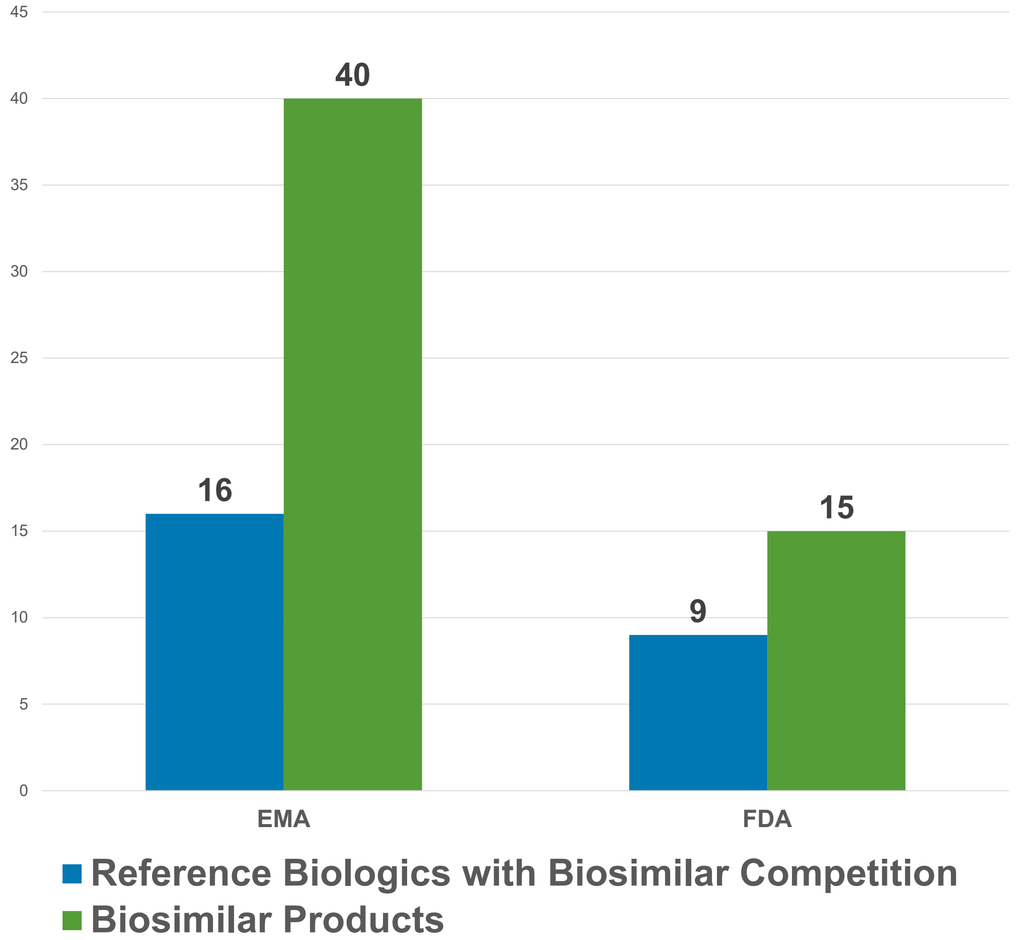
2018 National Kaiser Permanente Pharmacy Market Statement

- Provides a national market and value proposition statement for KP pharmacy
- Used by Kaiser Permanente health plan sales and pharmacy leadership in engagement with customers, prospects, consultants, and brokers to describe how KP is maximizing clinical outcomes and controlling pharmacy costs.

FDA New Drug Approvals (1980-Oct 2019)



Biosimilar Products Authorized by EMA and FDA 2007-2018



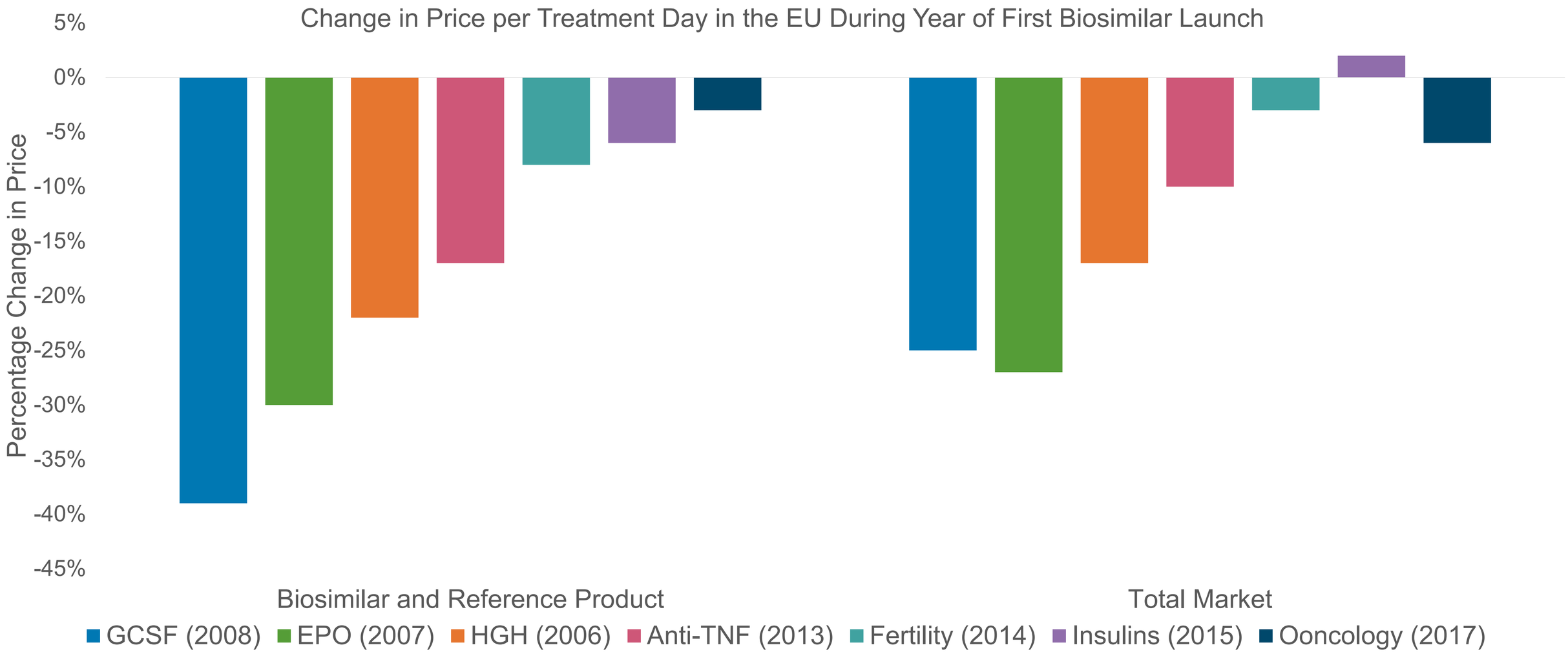
- The FDA authorized **15** biosimilar products as of Nov 30, 2018. Biosimilars were available for 9 biologics- representing 6.8% of all FDA authorized biologics. Biologics with biosimilar competition included: adalimumab, bevacizumab, epoetin alfa, etanercept, filgrastim, pegfilgrastim, infliximab, rituximab, and trastuzumab.
- The EMA authorized **40** biosimilars for 16 biologics as of Nov 30, 2018. The EMA authorized biosimilars for 2 biologics not available in the US (interferon alfa-2a and epoetin zeta). EMA also authorized 3 insulin and 4 products approved by the FDA using the New Drug Application approval process.

Regulatory Time Lag for Biosimilar Drugs Authorized by EMA and FDA, 2008-2018

Biosimilar	FDA Authorization Date	EMA Authorization Date	FDA-EMA Difference (years)	First Authorization
filgrastim	3/6/2015	9/15/2008	6.5	EU
infliximab	4/5/2016	9/10/2013	2.6	EU
etanercept	8/30/2016	1/14/2016	0.6	EU
adalimumab	9/23/2016	3/22/2017	- 0.5	US
bevacizumab	9/14/2017	1/15/2018	- 0.3	US
trastuzumab	12/1/2017	11/15/2017	- 0.0	US
epoetin alfa	5/15/2018	8/28/2007	10.7	EU
pegfilgrastim	6/4/2018	11/20/2018	- 0.5	US
rituximab	11/28/2018	2/17/2017	1.8	EU

Game Changer: 2010 Biologics Price Competition and Innovation Act (BCPI)

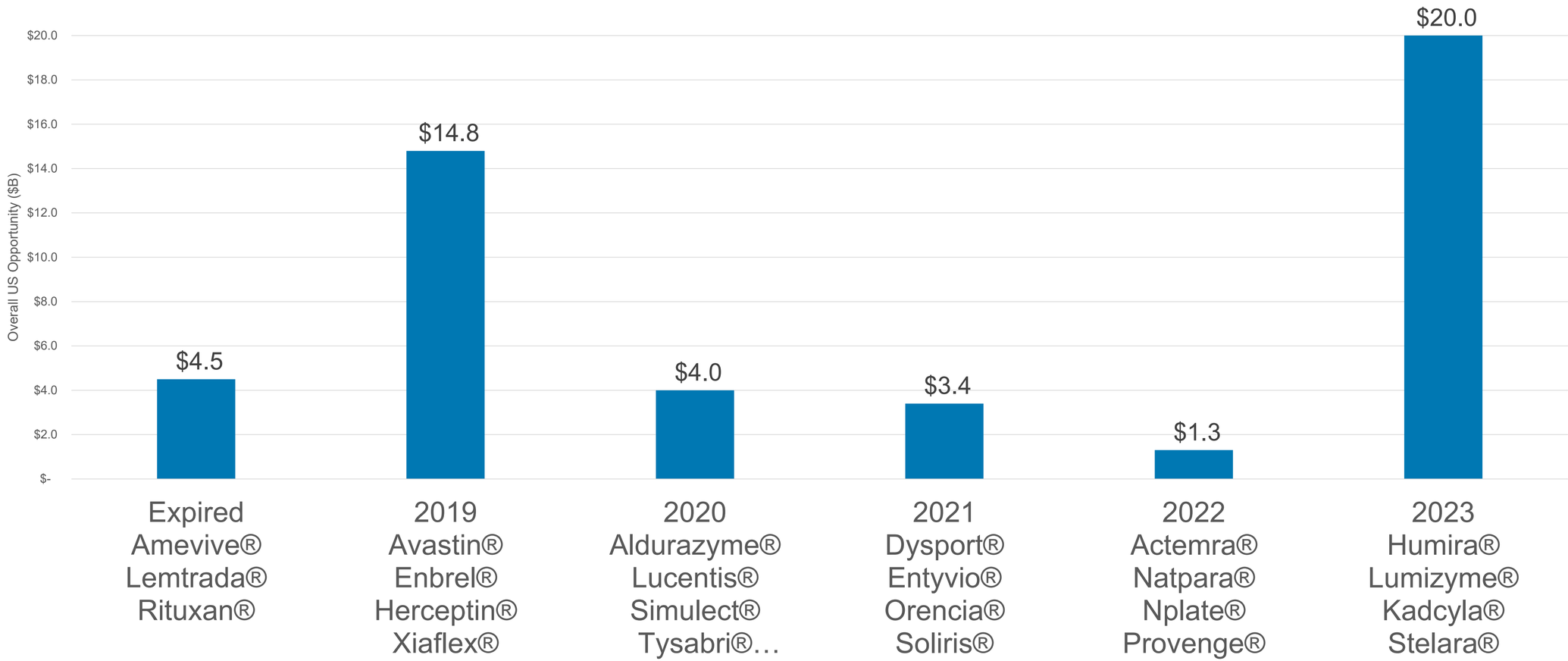
Biosimilar Competition Drives Down Prices in the Europe[1]



1. Adapted from IQVIA The Impact of Biosimilar Competition in Europe. September 2018. https://ec.europa.eu/docsroom/documents/31642/attachments/1/translations/en/renditions/native

US Biosimilar Opportunity

- **$55B opportunity with 71 patent expirations through 2023[1]**



1. Adapted from AMCP 2019 Presentation on Specialty Pharmaceuticals in Development

Unique Advantages and Challenges With Recent Biosimilars

Biosimilar	Advantages	Challenges
Filgrastim	• Supportive care • 1 FDA approved product until recently • EU with experience	• 1st biosimilar to US • Formulation differences • Patient copay
Bevacizumab	• Only used in palliative setting • Same FDA indications as reference product except for orphan indication	• 1st biosimilar in oncology treatment setting • No switching study • Product selection: 2 FDA approved products • Delays in launch due to litigation
Trastuzumab	• EU with experience • Switching study • 4 of 5 products have same FDA indications as reference product	• 1st biosimilar in oncology treatment setting • Product selection: 5 FDA approved products —3 studied in curative, 1 in metastatic, 1 in both —2 with issues with non-superiority —1 without all FDA indications • Delays in launch due to litigation • Evergreening: SQ vs IV
Rituximab	• EU with experience • Switching study	• Product selection: 2 FDA approved products • Studied in oncology palliative setting only • Narrow label • Delays in launch due to litigation • Evergreening: SQ vs IV

Why Move to Biosimilars?

- Advantages:
  - Equivalent efficacy and safety to originator products
  - Reduced cost
- Similar scenario as to when **generics** were first introduced to the market
  - Concerns initially about efficacy/safety of generics vs brand
  - Acceptance of generics over time has improved resource utilization while maintaining quality of care

Generics and biosimilars are a key component of maintaining high quality, affordable, and accessible care

Supporting the Fight Against Higher Drug Costs

"Without truly innovative treatments emerging from a successful pharmaceutical industry, our hopes for a 21st century healthcare system will be dashed. Yet, those innovations will be lost to history if they are not affordable to the patients who need them and if the pressure they put on the system is too great to withstand."

-Bernard Tyson, Chairman and Chief Executive of Kaiser Foundation Health Plan, Inc. and Hospitals

Forbes Op-Ed, July 30, 2015. http://www.forbes.com/sites/matthewherper/2015/07/30/why-pharma-must-change-its-model/#40db43b77c27

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Kaiser Permanente Journey with Biosimilars

Filgrastim-sndz (Zarxio)

- 1st biosimilar at KP
- 1st biosimilar in supportive care setting

DEC 2015

Pegfilgrastim-jmdb (Fulphila)

DEC 2018

Trastuzumab-anns (Kanjinti)

- 1st biosimilar in oncology curative treatment setting

JUL 2019

MAR 2017

Infliximab-dyyb (Inflectra)

- 1st biosimilar in treatment setting

JUL 2019

Bevacizumab-awwb (Mvasi)

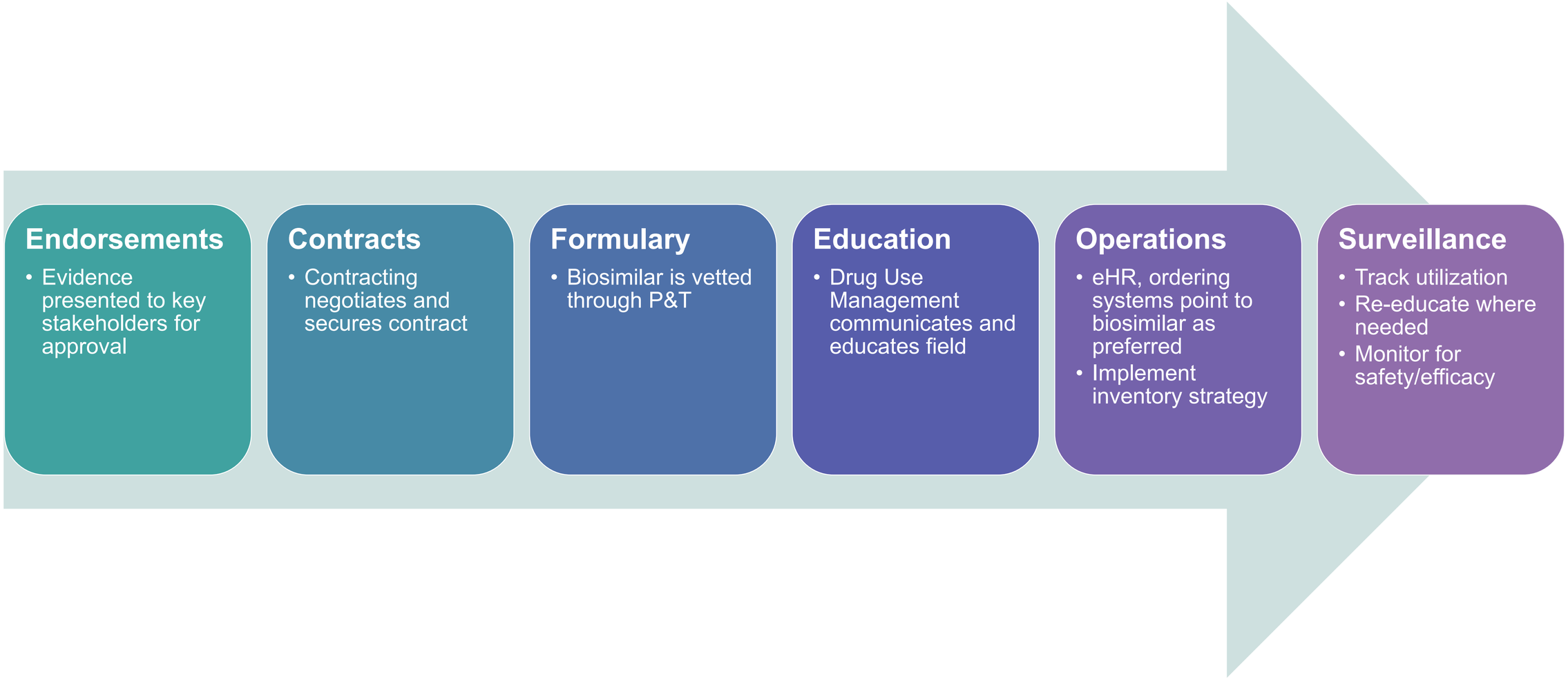
- 1st biosimilar in oncology treatment setting

OCT 2019

Rituximab-abbs (Truxima)

- 1st biosimilar using extrapolated evidence in oncology curative setting
- 1st biosimilar using off-label indications

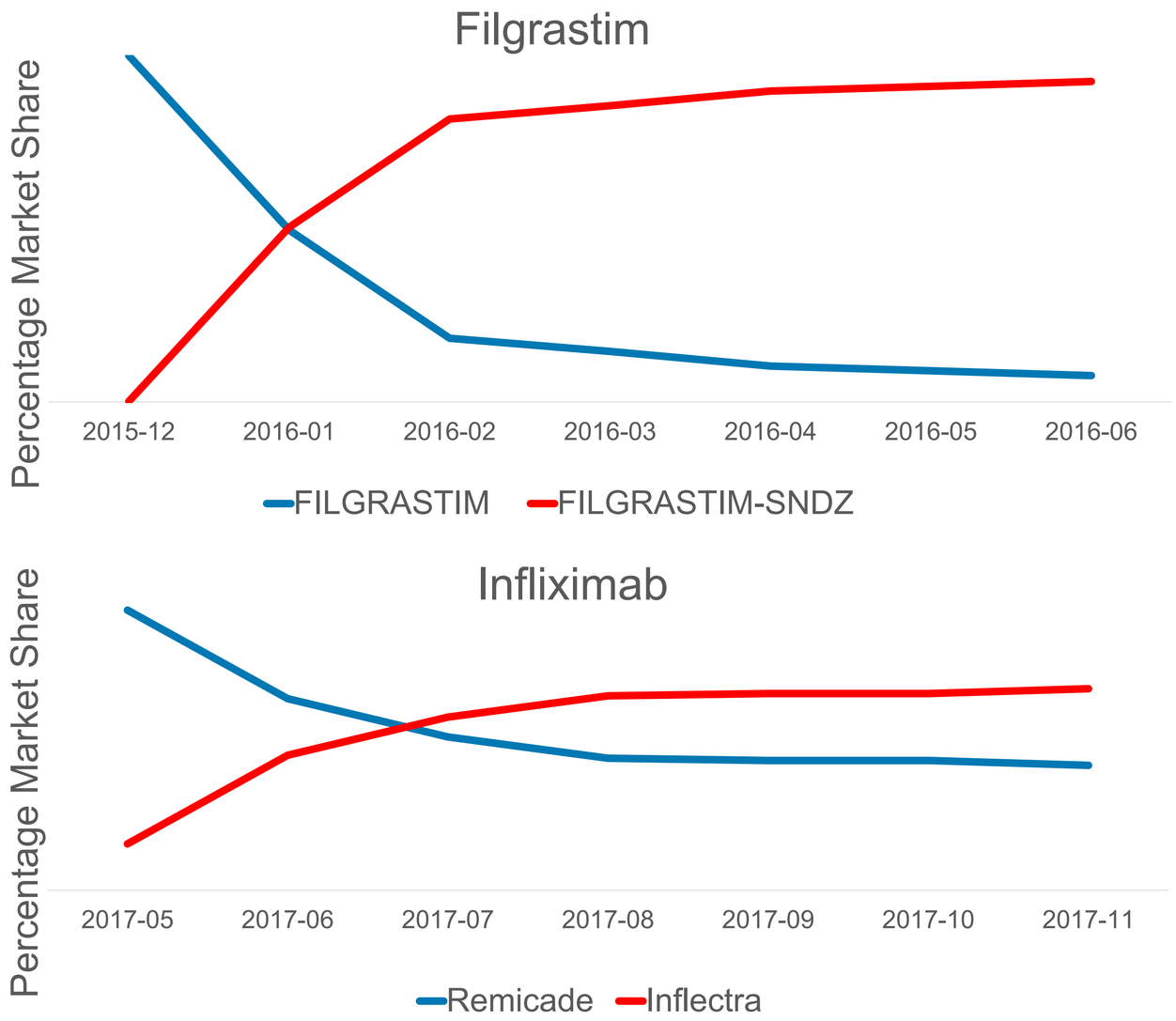
Kaiser Permanente Process for Biosimilars



- Note: Kaiser Permanente is an integrated health system, so some processes may be unique

Kaiser Permanente Success With Biosimilars

- Currently using **5** biosimilars
  - 1 additional biosimilar soon-to-be adopted
- 80-95% Biosimilar market share
- Estimated savings: ~$200M since inception
- Higher/faster success rates with:
  - Supportive care vs treatment
  - Palliative vs curative
  - Increasing familiarity with biosimilar concept
  - Full label vs narrow label?



Considerations When Implementing Biosimilars

- Supply & stocking
- Efficacy
- Safety
- Immunogenicity
- Indications
- Treatment category
- Treatment intent
- New vs existing patients
- Infusion time
- Patient copay
- Reimbursement rates
- Staff education
- Patient education
- Patent litigation
- Clinical trial use
- Formulation presentation
- Evergreening
- Administrative Issues

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Supply & Stocking Concerns

- Supply issues may occur due to various reasons, including litigation and manufacturing issues
- Examples of litigation delaying biosimilar launches:

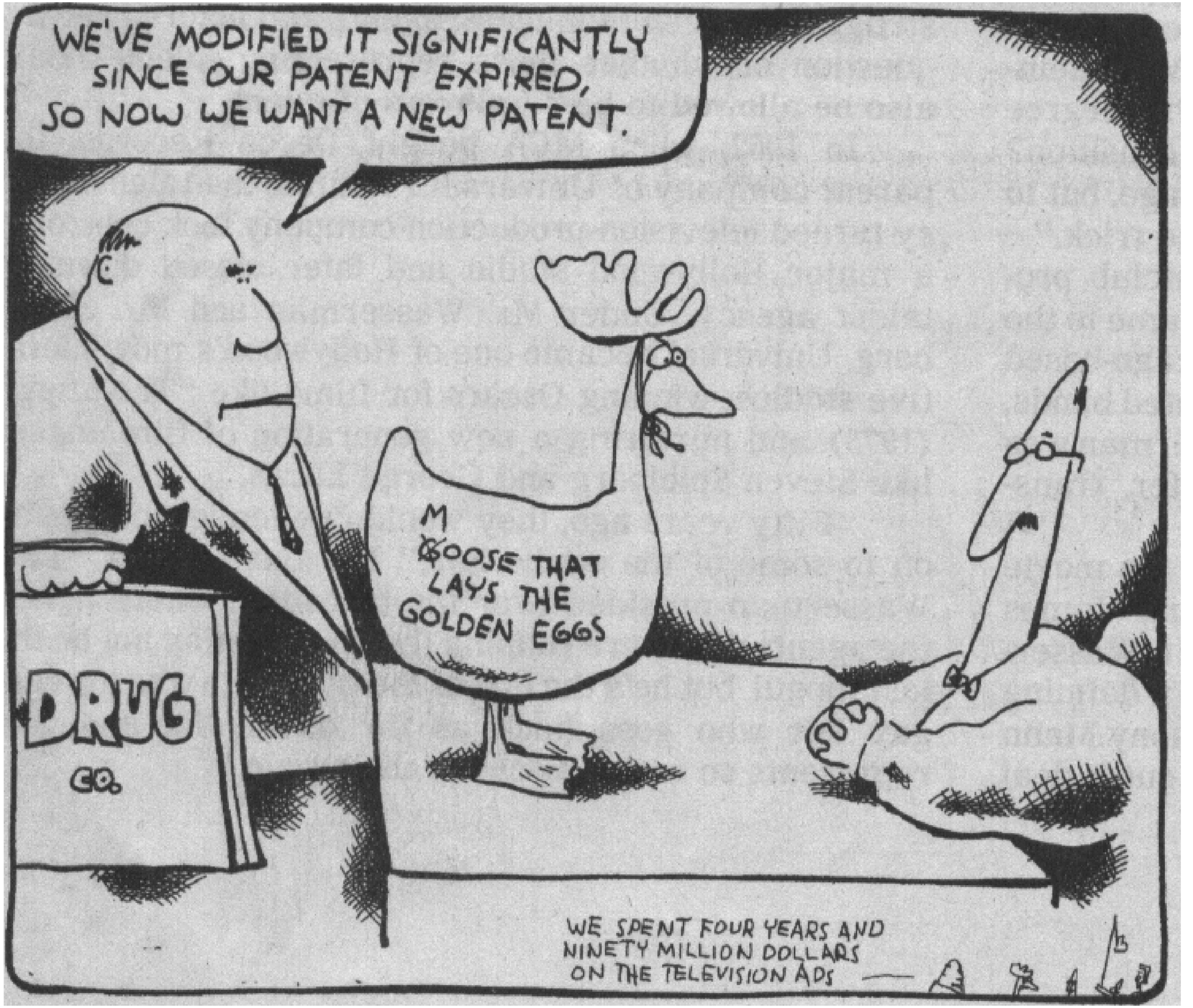
Non-proprietary name	FDA approval of biosimilar	FDA approval of brand	Patent Expiration	Expected launch in US
Bevacizumab	09/14/2017	02/26/2004	07/04/2019	07/22/2019
Trastuzumab	12/01/2017	09/25/1998	06/18/2019	07/22/2019
Rituximab	11/28/2018	11/26/1997	09/22/2016	11/2019

- Potential for biosimilar drug shortages if manufacturer cannot keep up with demand
  - Concern for increased immunogenicity with multiple switches between various products
  - If more than 1 biosimilar product available, may influence provider/payor decision on which product to adopt
- Potential for errors if pharmacy stocks multiple biosimilars when there are differences in payor coverage

Indication Concerns

- Clinical trial likely only in 1-2 indications and extrapolated to other indications
  - Comfort level for use in extrapolated indications?
  - What if studied in palliative setting but not in curative?

- Some indications not on FDA label due to litigation and/or orphan indication
  - Okay to use “off-label” if on-label for reference product?
  - Reimbursement issues?
  - Institutional policy restrictions for “off-label” use?


WE'VE MODIFIED IT SIGNIFICANTLY SINCE OUR PATENT EXPIRED, SO NOW WE WANT A NEW PATENT.
M
GOOSE THAT LAYS THE GOLDEN EGGS
DRUG
CO.
WE SPENT FOUR YEARS AND NINETY MILLION DOLLARS ON THE TELEVISION ADS

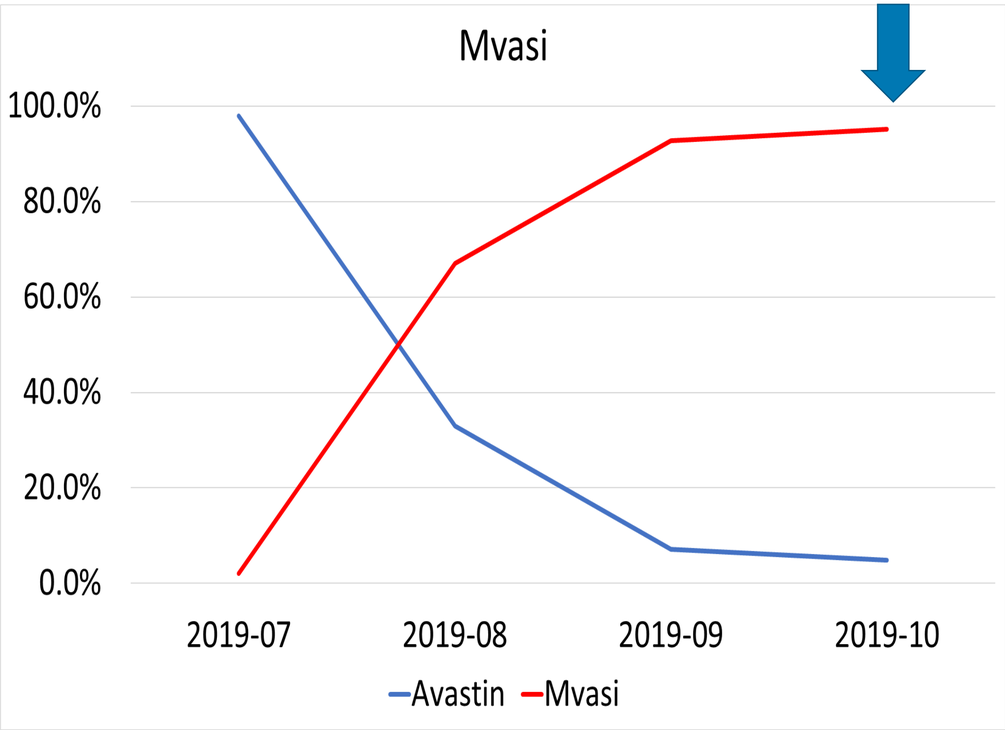
Evergreening- Manufacturer Strategies

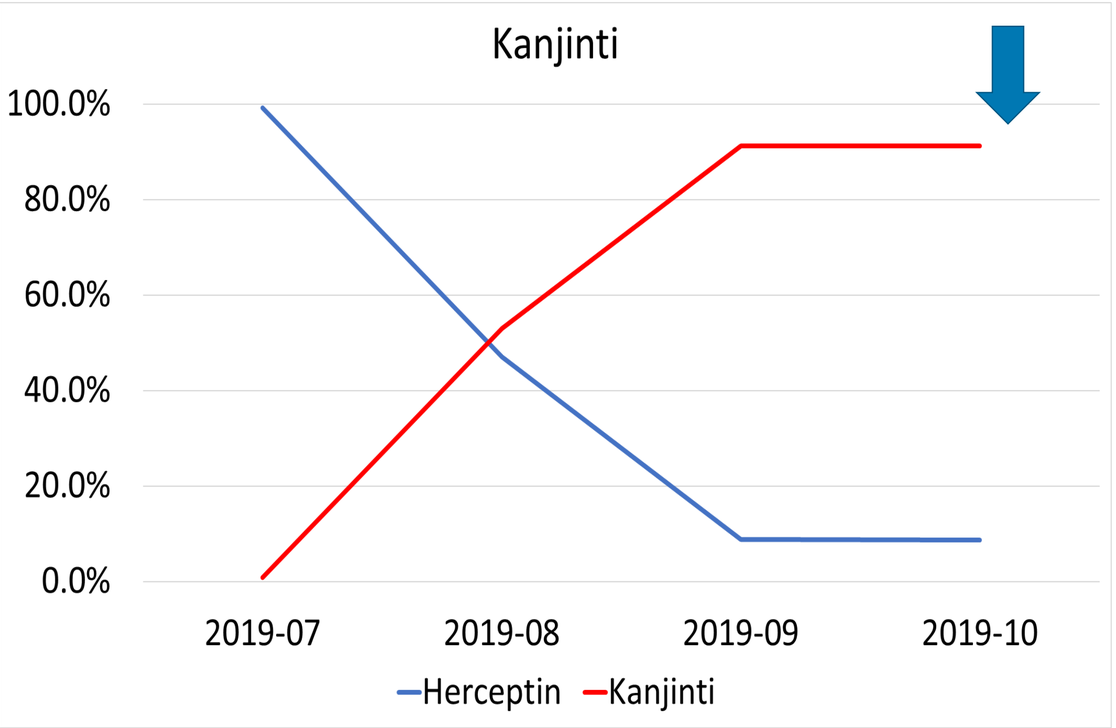
- Strategies to prolong patent royalties over highly profitable drugs
- Tactics include:
  - Taking out new patents on existing drugs
  - Launching a similar product
  - Buying out competitors
- Biosimilars have been recent targets
  - Many biosimilar patents have/will expire soon
  - Manufacturers of originator products have started evergreening to block biosimilar market

Examples of Managing Evergreening Tactics

Drug	Expected Biosimilar Date	Evergreening Tactic	KP Strategy
Herceptin (trastuzumab)	7 2019	Herceptin Hylecta (SQ)	Biosimilar preferred
Rituxan (ritixumab)	11 2019	Rituxan Hycela (SQ)	IV preferred over SQ
Soliris (eculizumab)	Q1 2021	Ultomiris (ravulizumab-cwvz) – longer acting agent	Eculizumab preferred over ravulizumab-cwvz
Humira (adalimumab)	H1 2023	Humira Citrate-Free	Original formulation preferred over citrate-free

Kaiser Permanente Early Experience with Mvasi and Kanjiti
July 2019 US Market Launch





Strategies to Address Provider and Patient Concerns

- Tap in to EU and international experience for areas where there is limited data

Non-proprietary Name	# EU of Biosimilars	First EU Approval	# of US Biosimilars	First US Approval
adalimumab	10	3/21/2017	4	9/23/2016
bevacizumab	2	1/14/2018	2	9/14/2017
enoxaparin	2	9/14/2016		
epoetin alfa	4	8/27/2007	1	5/15/2018
epoetin zeta	2	12/18/2007		
etanercept	2	1/13/2016	2	8/30/2016
filgrastim	9	9/15/2008	2	3/6/2015
follitropin alfa	2	9/27/2013		
infliximab	4	9/9/2013	3	4/5/2016
insulin glargine	3	9/6/2014		
insulin human	1	11/19/2015		
insulin lispro	1	7/18/2017		
pegfilgrastim	6	9/20/2018	2	6/4/2018
r interferon alfa-2a	1	9/5/2006		
rituximab	6	2/17/2017	2	11/28/2018
somatropin	2	4/12/2006		
teriparatide	2	1/4/2017		
trastuzumab	5	11/15/2017	5	12/1/2017
Grand Total	**64**	**4/12/2006**	**23**	**3/6/2015**

As of 10/30/2019

"The **evidence** acquired over 10 years of clinical **experience shows that biosimilars** approved through EMA **can be used as safely and effectively in all their approved indications** as other biological medicines."

"Over the last 10 years, the EU monitoring system for safety concerns has **not identified any relevant difference in** the nature, severity or frequency of **adverse effects between biosimilars and their reference medicines.**"

-- European Medicines Agency

EMA: Human Medicines. http://www.ema.europa.eu. Accessed 07/12/2019
FDA: https://www.fda.gov/media/89589/download. Accessed 07/12/2019.

Strategies to Address Provider and Patient Concerns

- Tap in to EU and international experience
- Gain support from physician leader within organization and/or national key opinion leader to help drive adoption/alleviate concerns with biosimilars
- Educate providers and patients to minimize nocebo effect
  - Nocebo effect = when placebo drug produces adverse side effect (opposite of placebo effect)
  - Well informed and confident provider→transfer confidence→confident patient

“But if thought corrupts language, language can also corrupt thought.

-George Orwell

Strategies to Address Provider and Patient Concerns

- Tap in to EU and international experience
- Gain support from physician leader within organization and/or national key opinion leader to help drive adoption/alleviate concerns with biosimilars
- Educate providers and patients to minimize nocebo effect
  - Originator products go through similar process after manufacturing changes
  - Work with biosimilars to remove misleading/inaccurate information on websites
  - Create internal materials or use FDA website: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars
- Consider transitioning patients conservatively to gain experience and support
- Monitor and/or evaluate outcomes with biosimilar conversion to enhance confidence of use
- Advocate for comparable patient assistance programs with biosimilar manufacturers

Kaiser Permanente Biosimilars Strategy

- Provide high quality, affordable care to our members
  - Generics and biosimilars are a key component
  - Biosimilars offer equivalent efficacy and safety to originator products at a reduced cost

- Kaiser Permanente is the U.S. leader in biosimilar use and strives to promote these products to enhance the viability of the biosimilars market

- Minimize usage of evergreening products whenever possible to maximize the impact of the future biosimilar market

Much appreciation to the many members of our talented physician and pharmacist teams that drive biosimilar use every day

Thank you!

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