UCSD Skaggs School of Pharmacy; Applied Pharmacoeconomics & Outcomes Research Forum

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Kaiser Permanente

National Pharmaceutical Contracting Leader

KP PHARMACY'S FOOTPRINT

Kaiser Permanente Pharmacy

Our pharmacists and staff are often the last interaction and serve as a primary point of contact for members throughout the care delivery process

Outpatient	Inpatient	Clinic Administered Medications
78 Million[1] Prescriptions Filled [$5.4B]	**38 Million**[2] Doses Administered [$0.5B]	**10.6 Million**[2] Doses Administered [$1.6B]

$7.5 billion in annual drug expense[3]

Our Member Reach

510 KP Pharmacy Patient Sites[4]

- **378** Outpatient and
- **38** Inpatient Pharmacies
- \+
- **72** Clinic Administered Sites
  Oncology, Outpatient Infusion, & Specialty
- \+
- **22** Call Center and Central Fill Operations

Employing **13,234** KP Pharmacy Staff Members[5]

~138,000 + Daily Member Interactions[6]

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

Source: (1) KP Pharmacy Outpatient Prescription Volume, 2015; (2) National Pharmacy Acute & Transitional Care Services Leadership & Regional Operations Teams; (3) Total KP Pharmacy Drug Expense and Dispensing Costs 2014 (National Pharmacy Finance); (4) KP Pharmacy Facilities Count; (5) KP Pharmacy Employee Count – People Soft, February 2015; (6) Total KP Pharmacy Estimated Daily Member Interaction, 2014

INTEGRATED SYSTEM ENABLES AN IMPRESSIVE MARKETPLACE POSITION

Kaiser Permanente Pharmacy

We provide our patients and members with a **very high level of collaboration among the pharmacy, medical groups, and health plan** to enable accessible, high quality, and affordable medication therapy and services

Differentiators

- **Fully integrated medical record** (HealthConnect) across all patient care areas
- KP Pharmacy offers a **comprehensive range of ambulatory clinical pharmacy services,** second only in scope to the U.S. Veterans Administration (VA) program
- Kaiser Permanente's **integrated medical model** provides a unique ability to fully leverage the pharmaceutical supply chain, drug formulary management, and pharmacy benefit design to successfully manage drug cost

Competitive Position

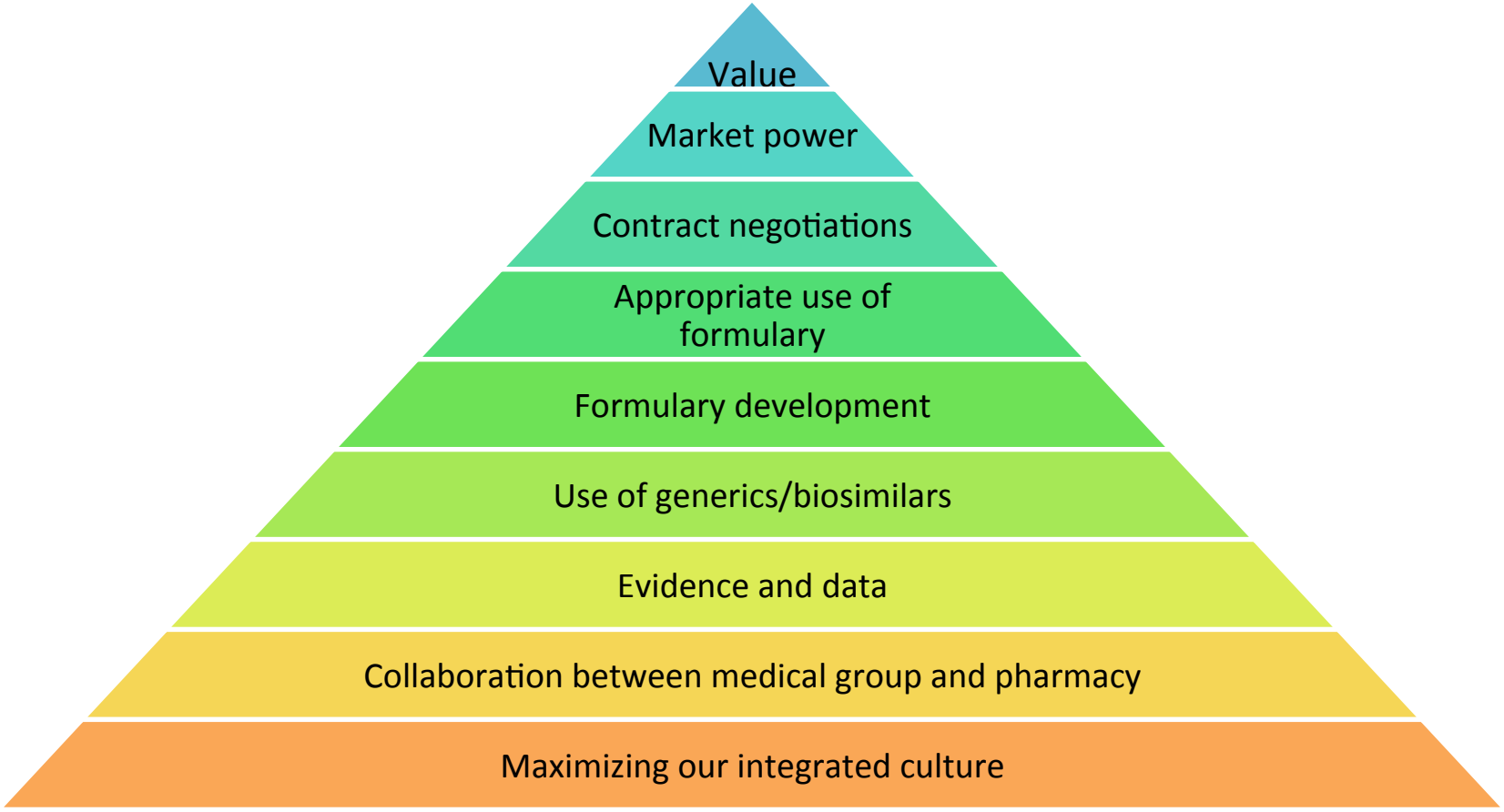
71% **more outpatient prescriptions per store daily** than Walgreens

more oncology treatments for patients every day than THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER or Memorial Sloan Kettering Cancer Center

3rd **largest non-profit acute care pharmacy** health system in the country

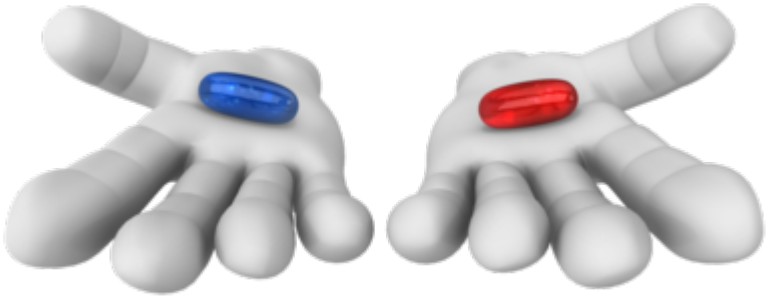
Source: Company reports

KAISER PERMANENTE'S EFFORTS TO CONTROL DRUG COSTS



Efficacy & Safety: Biosimilar Definition

Section 351(k) of BPCIA:



Biosimilarity:

- "the biological product is **highly similar** to the reference product not w/ standing minor differences in clinically inactive components" and
- "there are **no clinically meaningful differences** between the biological product and the reference product in terms of the safety, purity, and potency of the product"

Biologics Price Competition and Innovation Act (BPCIA) of 2009. (quotes)
U.S. FDA. Guidance for Industry: Biosimilars. February 2012.

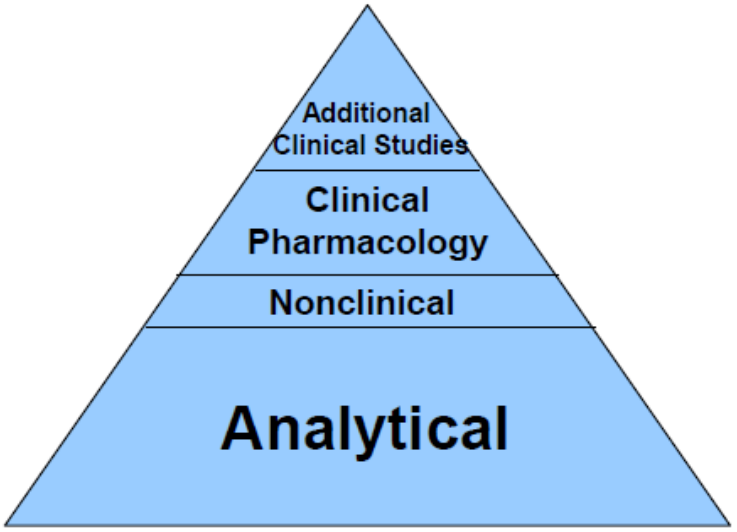
THE FDA'S VIEW:

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Key Concept #1: Goals of "Stand-alone" and Biosimilar Development are Different

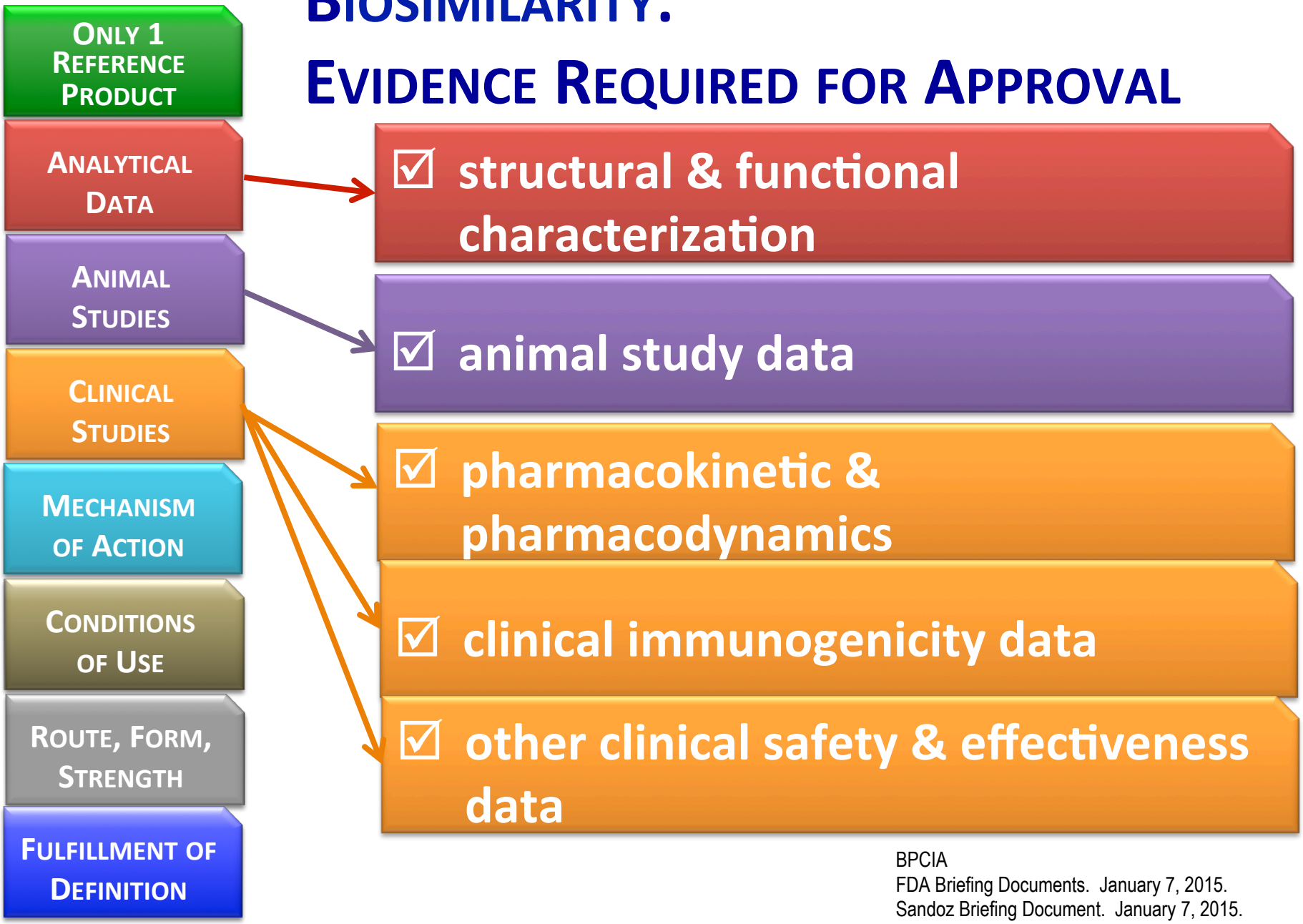
"**Stand-alone**" Development Program, 351(a)
Goal: To establish safety and efficacy of a new product

"**Abbreviated**" Development Program, 351(k)
Goal: To demonstrate biosimilarity (or interchangeability)



1 FDA Slide in FDA Briefing Document for CT-P13.

BIOSIMILARITY: EVIDENCE REQUIRED FOR APPROVAL



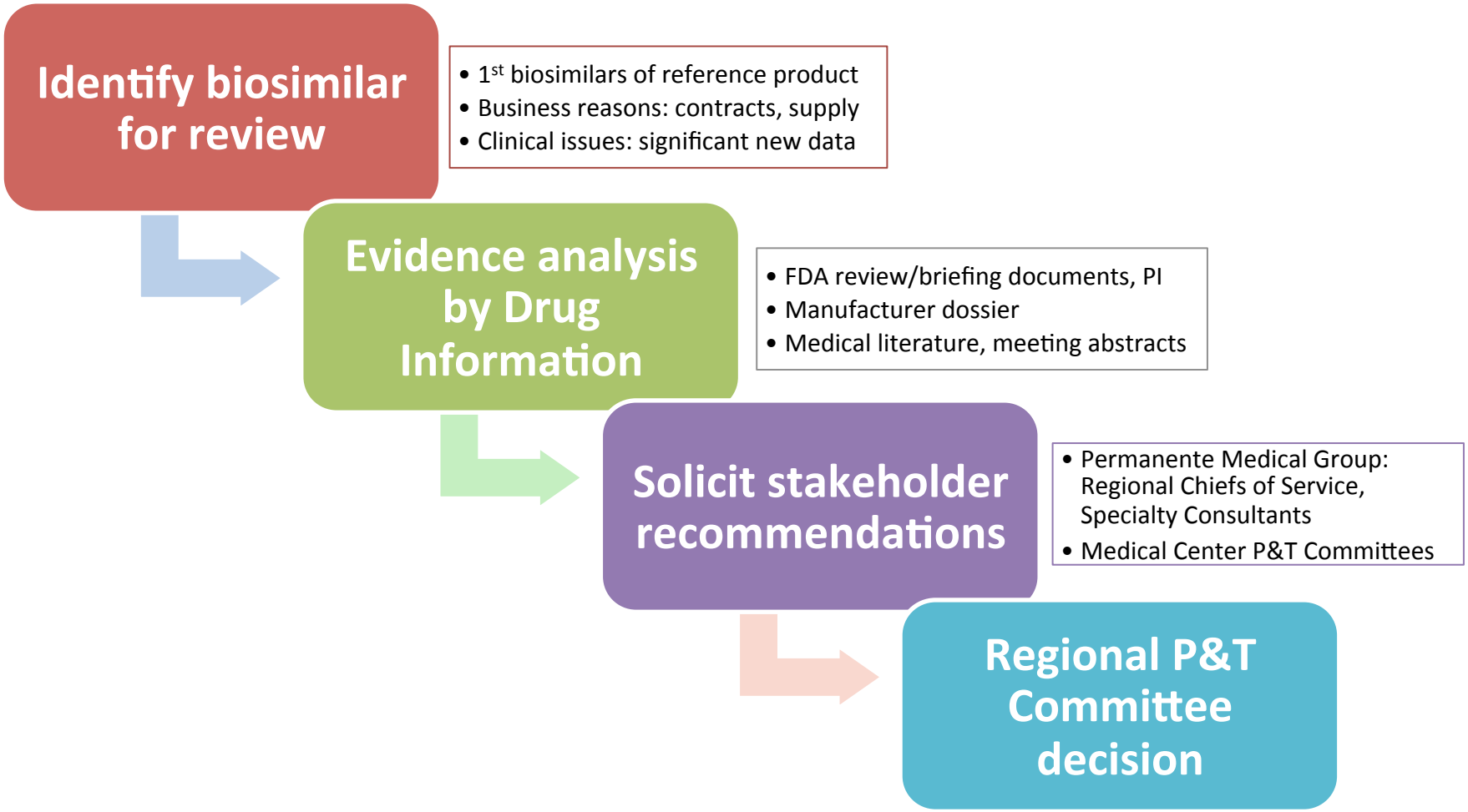
BPCIA
FDA Briefing Documents. January 7, 2015.
Sandoz Briefing Document. January 7, 2015.

BIOSIMILARS APPROVED BY THE FDA

	Approved	Biosimilar for…	Biosimilar name / Mfr	Comments
TNF-α Inhibitors	**2016-Sept 23** *Launch 2018+?*	**adalimumab** (Humira)	**adalimumab-atto** (AMJEVITA) Amgen	• 7 of 8 Humira indications at time of approval; Humira has since added 2 more indications • Abbvie claiming patent through 2022 • Unlikely to launch until 2018+ due to litigation
	2016-Aug 30 *Launch 2018+?*	**etanercept** (Enbrel)	**etanercept-szzs** (ERELZI) Sandoz	• Same 5 indications as Enbrel at time of approval; Enbrel later expanded plaque psoriasis indication in to children • Prefilled syringe/pen only; no vials • Amgen claim: patent exp. 2029 • Unlikely to launch until 2018+ due to litigation
	2016-April 5 *Launched 2016Q4*	**infliximab** (Remicade)	**infliximab-dyyb** (INFLECTRA) Pfizer	• 7 of 8 Remicade indications at time of approval; Peds Ulcerative Colitis has Orphan Exclusivity • J&J claim: Remicade patent exp. 2018 – 2027 • Launched November 2016
CSF	**2015-March 16** *Launched 2015Q4*	**filgrastim** (Neupogen)	**filgrastim-sndz** (ZARXIO) Sandoz	• 1st biosimilar approved by FDA • Same 5 indications as Neupogen at time of approval; Neupogen added an orphan indication AFTER Zarxio approval • Launched Sept 2015 • Prefilled syringes only; no vials

Pink Sheet [Subscription]

KP P&T Committee Review of Biosimilars



Biosimilars Usage Management: Strategies

Target
1. Review of Evidence
2. Education
3. Policy
4. Conversion
5. Record-keeping
6. Benefits
7. Safety

1ST BIOSIMILAR APPROVAL: APPROVAL OF ZARXIO

March 6, 2015:
"The U.S. Food and Drug Administration today approved Zarxio (filgrastim-sndz), the first biosimilar product approved in the United States."

Zarxio (by Sandoz) is biosimilar to Neupogen (by Amgen, originally licensed in 1991).

11. "FDA approves first biosimilar product Zarxio", March 6, 2015

KAISER PERMANENTE'S ZARXIO UTILIZATION

- Zarxio market share as a percentage of all Zarxio and Neupogen utilization for 2016, including Neupogen vials, was 96.1%

- Zarxio market share as a percentage of all Zarxio and Neupogen utilization for 2016, excluding Neupogen vials, was 98.1%

ZARXIO: FEBRILE NEUTROPENIA RATES

- Compared Neupogen patients in 1st quarter 2015 vs Zarxio patients in 1st quarter 2016.
- 860 Neupogen patients, 701 Zarxio patients
- Overall FN rate (all cycles) per patient was decreased with Zarxio vs Neupogen (4.2% vs 8.3%).
- The FN rate with Zarxio was numerically lower than Neupogen for cycle 1 of chemotherapy (5.7% vs 9.5%).
- Statistically, both were non-inferior in regards to FN rate.

BrandBio™
30,000 packages per Year

As is Model:

Discount	WAC	NET
15.0%	$4,200.00	$3,570.00

Plan Use	Units/Yr	Net	WAC	Concession
BrandBio™	30,000	$107,100,000	$126,000,000	$18,900,000

Biosimilar Model:

Conversion Status	
Non-conversion	10%
"Failure"	5%
Donut Hole econom	5%
	20%

% Converted	80%	WAC BrandBio™	**$4,200.00**
Biosimilar Discount	30.0%	Biosimilar Net price	**$2,940.00**
BrandBio™ Discount	0%		

Description	Units/Yr	Net Price	Spend
Biosimilar	24,000	$2,940.00	$70,560,000
BrandBio™	6,000	$4,200.00	$25,200,000
Total	**30,000**		**$95,760,000**

Savings **$11,340,000**

IF the makers of BrandBio™ respond, and the conversion struggles

As is Model:

Discount	WAC	NET
25.0%	$4,200.00	$3,150.00

Plan Use	Units/Yr	Net	WAC	Concession
BrandBio™	30,000	$94,500,000	$126,000,000	$31,500,000

(vs. $18.9M to start)

Biosimilar Model:

Conversion Status	
Non-conversion	20%
"Failure"	10%
Donut Hole econom	5%
	35%

% Converted	65%	WAC BrandBio™	**$4,200.00**
Biosimilar Discount	30.0%	Biosimilar Net price	**$2,940.00**
BrandBio™ Discount	0%		

Description	Units/Yr	Net Price	Spend
Biosimilar	19,500	$2,940.00	$57,330,000
BrandBio™	10,500	$4,200.00	$44,100,000
Total	**30,000**		**$101,430,000**

Savings **-$6,930,000**

A Competitive Bid

As is Model:

Discount	WAC	NET
35.0%	$4,200.00	$2,730.00

Plan Use	Units/Yr	Net	WAC	Concession
BrandBio™	30,000	$81,900,000	$126,000,000	$44,100,000

(vs. $18.9M to start)

Biosimilar Model:

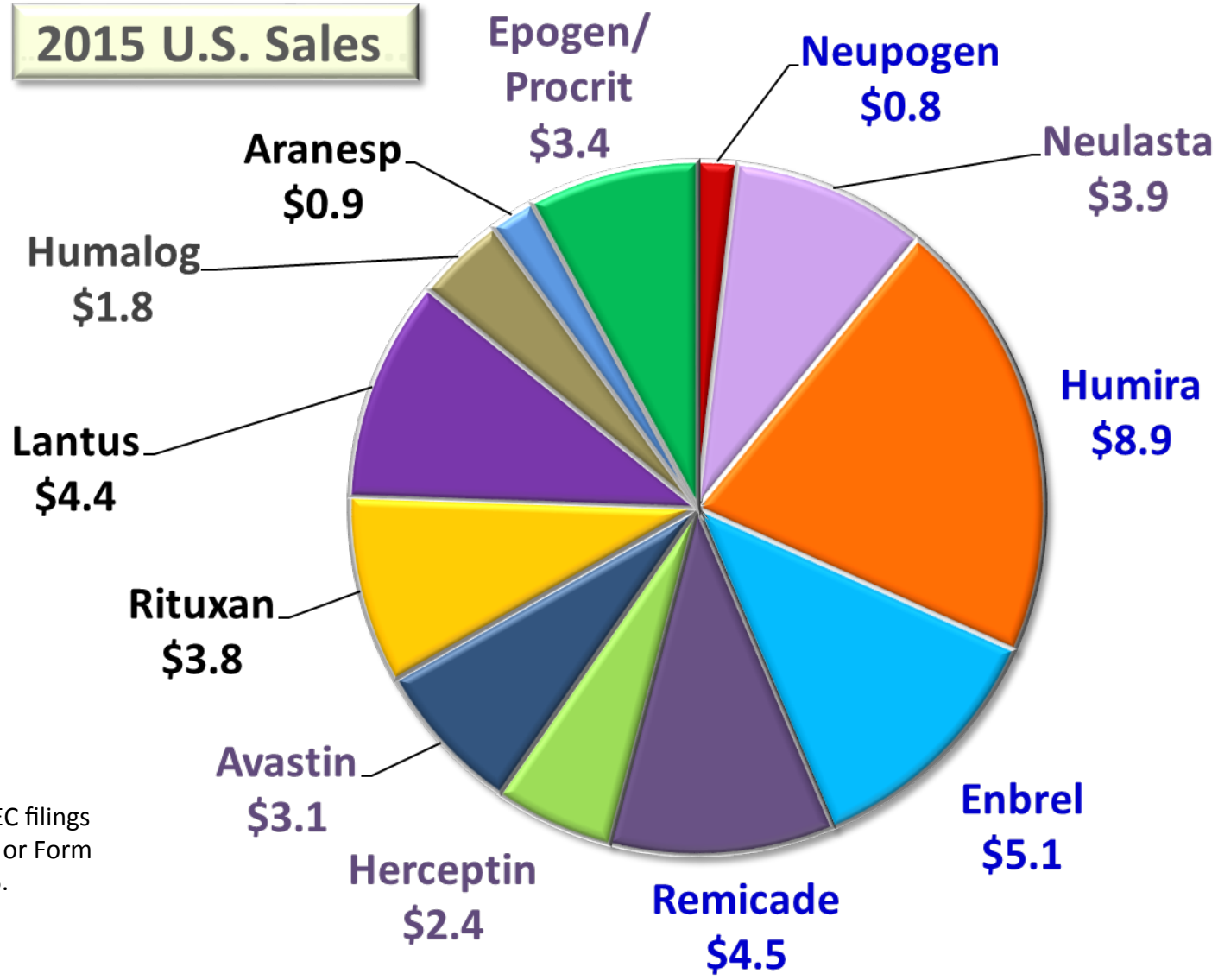
Conversion Status	
Non-conversion	10%
"Failure"	10%
Donut Hole economics	5%
	25%

% Converted	75%	WAC BrandBio™	**$4,200.00**
Biosimilar Discount	50.0%	Biosimilar Net price	**$2,100.00**
BrandBio™ Discount	0%		

Description	Units/Yr	Net Price	Spend
Biosimilar	22,500	$2,100.00	$47,250,000
BrandBio™	7,500	$4,200.00	$31,500,000
Total	**30,000**		**$78,750,000**

Savings **$3,150,000**

U.S. Sales of Possible Reference Products = >$43 Billion (U.S., 2015)



Drug sponsor SEC filings of Form 10-K or Form 20-F for 2015.