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

Ambrose Carrejo, Pharm D.
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
- 78 Million\(^1\) Prescriptions Filled
  - [$5.4B]

Inpatient
- 38 Million\(^2\) Doses Administered
  - [$0.5B]

Clinic Administered Medications
- 10.6 Million\(^2\) Doses Administered
  - [$1.6B]

Our Member Reach

- **510** KP Pharmacy Patient Sites\(^4\)
  - 378 Outpatient and 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 – PeopleSoft, 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 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

Value
Market power
Contract negotiations
Appropriate use of formulary
Formulary development
Use of generics/biosimilars
Evidence and data
Collaboration between medical group and pharmacy
Maximizing our integrated culture
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)
THE FDA’S VIEW:

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

Clinical Safety & Efficacy (Phase 1, 2, 3)
- Clinical Pharmacology
- Non-clinical
- Analytical

“Abbreviated” Development Program, 351(k)
Goal: To demonstrate biosimilarity (or interchangeability)

Additional Clinical Studies
Clinical Pharmacology
Nonclinical
Analytical

1 FDA Slide in FDA Briefing Document for CT-P13.
**Biosimilarity: Evidence Required for Approval**

- **Analytical Data**: structural & functional characterization
- **Animal Studies**: animal study data
- **Clinical Studies**: pharmacokinetic & pharmacodynamics, clinical immunogenicity data, other clinical safety & effectiveness data
- **Mechanism of Action**
- **Conditions of Use**
- **Route, Form, Strength**
- **Fulfillment of Definition**

BPCIA
<table>
<thead>
<tr>
<th>Approved</th>
<th>Biosimilar for...</th>
<th>Biosimilar name / Mfr</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 2016-Sept 23  | 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 |
| Launch 2018+? |                   |                               |                                                                          |
| 2016-Aug 30   | 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 |
| Launch 2018+? |                   |                               |                                                                          |
| 2016-April 5  | 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 |
| Launched 2016Q4 |                   |                               |                                                                          |
| 2015-March 16 | 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 |
| Launched 2015Q4 |                   |                               |                                                                          |
KP P&T Committee Review of Biosimilars

1. Identify biosimilar for review
   - 1st biosimilars of reference product
   - Business reasons: contracts, supply
   - Clinical issues: significant new data

2. Evidence analysis by Drug Information
   - FDA review/briefing documents, PI
   - Manufacturer dossier
   - Medical literature, meeting abstracts

3. Solicit stakeholder recommendations
   - Permanente Medical Group: Regional Chiefs of Service, Specialty Consultants
   - Medical Center P&T Committees

4. Regional P&T Committee decision
# Biosimilars Usage Management: Strategies

## TARGET

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

<table>
<thead>
<tr>
<th>Discount</th>
<th>WAC</th>
<th>NET</th>
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</thead>
<tbody>
<tr>
<td>15.0%</td>
<td>$4,200.00</td>
<td>$3,570.00</td>
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</tbody>
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### Plan Use

<table>
<thead>
<tr>
<th>BrandBio™</th>
<th>Units/Yr</th>
<th>Net</th>
<th>WAC</th>
<th>Concession</th>
</tr>
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<tbody>
<tr>
<td></td>
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<td>$126,000,000</td>
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### Biosimilar Model:

#### Conversion Status

| Non-conversion | 10% |
| "Failure"      | 5%  |
| Donut Hole econ | 5%  |

#### % Converted

<table>
<thead>
<tr>
<th>% Converted</th>
<th>WAC BrandBio™</th>
<th>Savings</th>
</tr>
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<tbody>
<tr>
<td>80%</td>
<td>$4,200.00</td>
<td></td>
</tr>
<tr>
<td>30.0%</td>
<td>Biosimilar Net price</td>
<td>$2,940.00</td>
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<tr>
<td>0%</td>
<td>BrandBio™ Discount</td>
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</table>

#### Description

<table>
<thead>
<tr>
<th>Description</th>
<th>Units/Yr</th>
<th>Net Price</th>
<th>Spend</th>
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<tbody>
<tr>
<td>Biosimilar</td>
<td>24,000</td>
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<td>$95,760,000</td>
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**Savings** $11,340,000
IF the makers of BrandBio™ respond, and the conversion struggles

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<tr>
<td>BrandBio™</td>
<td>30,000</td>
<td>$94,500,000</td>
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<td>$31,500,000</td>
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Biosimilar Model:

<table>
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<tr>
<th>Conversion Status</th>
<th>% Converted</th>
<th>WAC BrandBio™ Price</th>
<th>Savings</th>
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<tbody>
<tr>
<td>Non-conversion</td>
<td>20%</td>
<td>$4,200.00</td>
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<tr>
<td>&quot;Failure&quot;</td>
<td>10%</td>
<td>$2,940.00</td>
<td></td>
</tr>
<tr>
<td>Donut Hole econom</td>
<td>5%</td>
<td>0%</td>
<td></td>
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<tr>
<th>Description</th>
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Savings: **-$6,930,000**

(vs. $18.9M to start)
## A Competitive Bid

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<tr>
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<td>$81,900,000</td>
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*(vs. $18.9M to start)*

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<tr>
<td>Donut Hole economics</td>
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<td>$47,250,000</td>
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<tr>
<td>Biosimilar</td>
<td>22,500</td>
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<td>$47,250,000</td>
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<tr>
<td>BrandBio™</td>
<td>7,500</td>
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<tr>
<td><strong>Total</strong></td>
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<td>$78,750,000</td>
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*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.