# Consumer Perspective on Biosimilars

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AARP

# Overview

- Why does this issue matter to AARP?
- Ongoing concerns
- Outlook for the future

# Biologics represent the future of the drug industry

- 40 percent of all pharmaceutical industry R&D and products in the pipeline involve biopharmaceuticals rather than traditional drugs[1]
- More than 50 percent of the US prescription drug budget is expected to be biologics by 2018[2]
- It is estimated that 21 biologics with a market value of over $50 billion will lose patent protection by 2019 in the US alone[3]

# Indications for existing biologics are expanding

*15+ approved indications for Remicade*

| | |
|---|---|
| 1998 | Crohn's disease – luminal and fistulising |
| 1998 | Rheumatoid arthritis signs and symptoms |
| 2000 | Rheumatoid arthritis structural damage |
| 2002 | Rheumatoid arthritis physical function |
| 2002 | Crohn's disease maintenance (luminal) |
| 2003 | Crohn's disease maintenance (fistulising) |
| 2004 | Rheumatoid arthritis signs and symptoms, x-ray progression, physical function |
| 2004 | Ankylosing spondylitis signs and symptoms |
| 2005 | Psoriatic arthritis signs and symptoms |
| 2005 | Ulcerative colitis |
| 2006 | Pediatric Crohn's disease |
| 2006 | Psoriatic arthritis structural damage |
| 2006 | Psoriatic arthritis physical function |
| 2006 | Chronic severe plaque psoriasis |
| 2006 | Ulcerative colitis maintenance |
| Phase III | Pediatric ulcerative colitis |

*10+ new indications in development for Avastin*

## Phase III

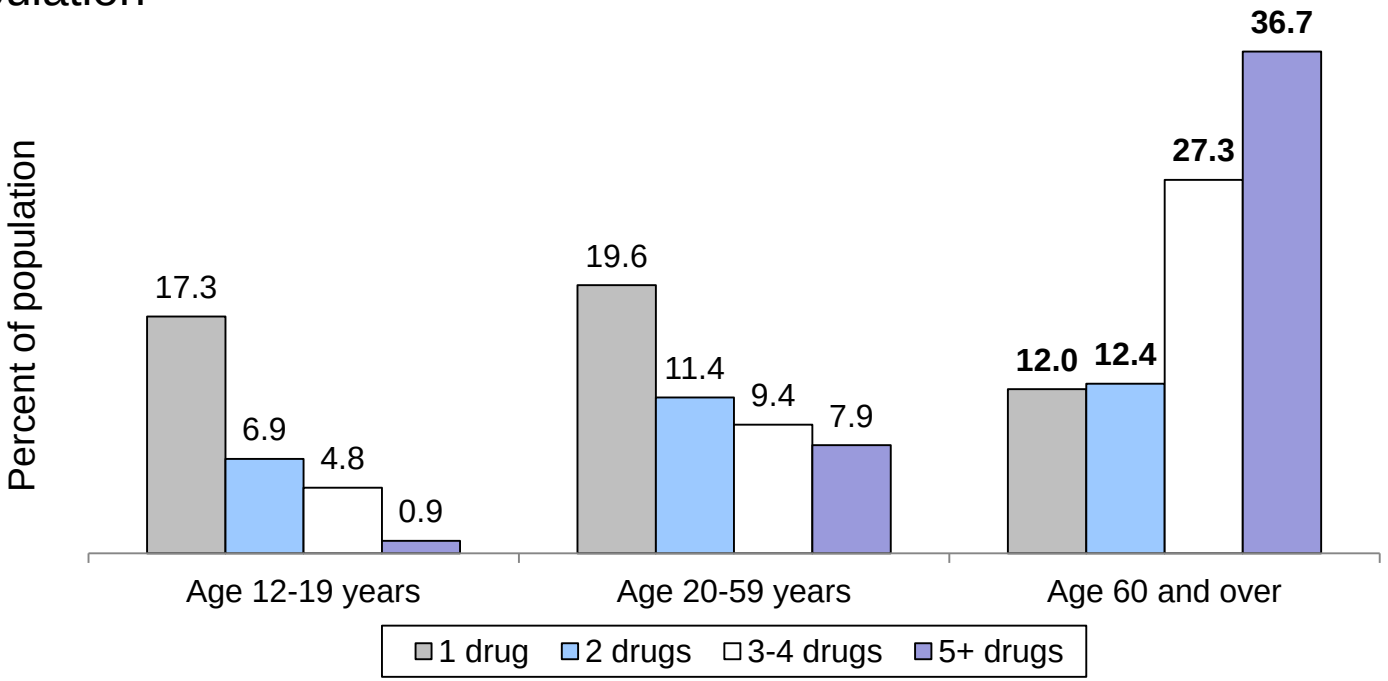
| Project ID | | Project/Product | Indication |
|---|---|---|---|
| **Oncology** | | | |
| [redacted] | RG105 | MabThera/Rituxan | NHL, fast infusion |
| [redacted] | RG105 | MabThera/Rituxan | NHL, SC formulation |
| [redacted] | RG435 | Avastin | adj breast cancer, HER2+ |
| [redacted] | RG435 | Avastin+Herceptin | mBC, HER2+, 1st-line |
| [redacted] | RG435 | Avastin | adj NSCLC |
| [redacted] | RG435 | Avastin | adj breast cancer, HER2-neg |
| [redacted] | RG435 | Avastin | adj BC, triple negative |
| [redacted] | RG435 | Avastin | relapsed ovarian cancer |
| [redacted] | RG435 | Avastin | high-risk carcinoid |
| [redacted] | RG435 | Avastin | GBM, 1st-line |
| [redacted] | RG435 | Avastin | met colorectal cancer, treatment through multiple lines |
| [redacted] | RG435 | Avastin | met breast cancer, 2nd-line |
| [redacted] | RG597 | Herceptin | BC, HER2+, SC formulation |
| [redacted] | RG597 | Herceptin | adj BC, HER2+, 2-yr treatment |

# Treatment costs are extraordinarily high

- On average, biologic drugs are 22 times more expensive than traditional drugs[4]
- The average annual cost of a branded biologic is estimated to be $34,550[5]
- Annual costs can range from $25,000 to $200,000 or more[6]

# Older adults are more likely to use biologics

- Older adults use more prescription drugs than any other segment of the population[7]




- Biologics are often used to treat conditions that are more commonly found in older adults (e.g., multiple sclerosis, cancer, rheumatoid arthritis)

# Medicare beneficiaries are not healthy or wealthy

- **Many beneficiaries live on modest incomes.** The median income among Medicare beneficiaries is roughly $22,500[8]

- **Many beneficiaries have limited financial resources.** More than one in four Medicare beneficiaries have less than $10,000 in savings[9]

- **Many beneficiaries are have multiple chronic conditions.** 68 percent of Medicare beneficiaries are being treated for at least two concurrent chronic illnesses[10]

# Medicare Part B can lead to high cost-sharing

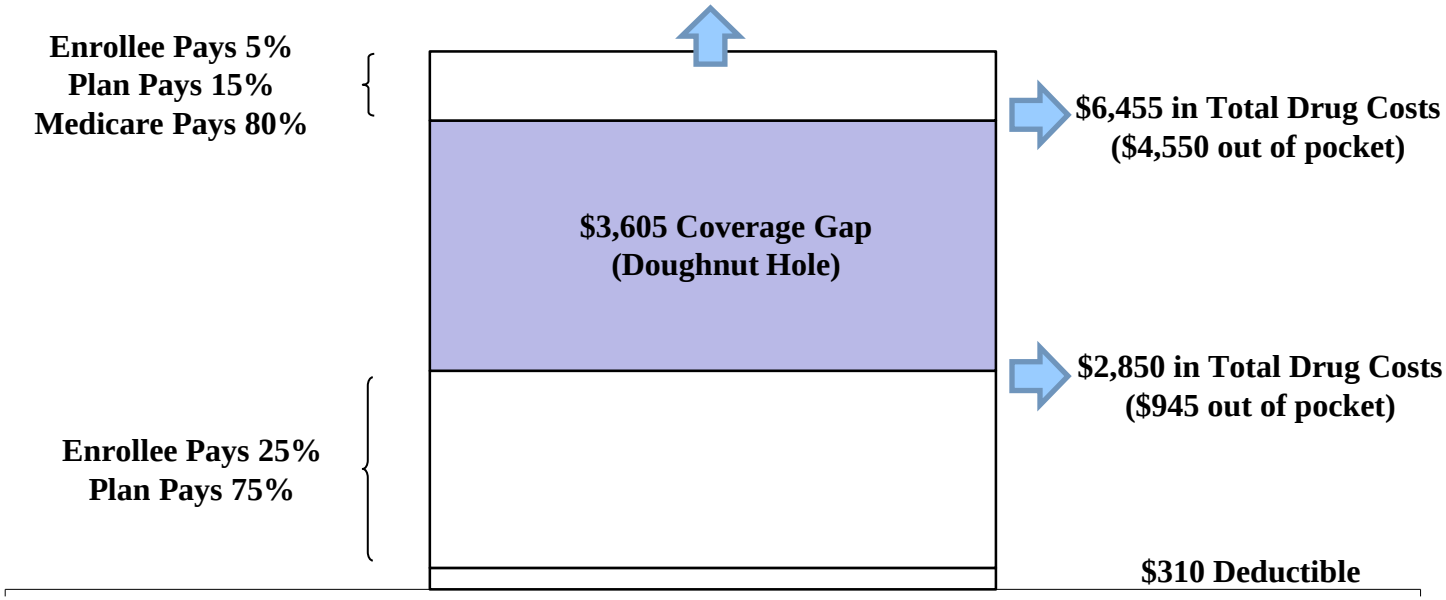
- Eight of the ten highest-expenditure Medicare Part B drugs in 2010 were biologics[11]

| Drug Name | Indication | Spending |
|---|---|---|
| Epogen, Procrit | Anemia (ESRD) | $2.0B |
| Rituxan | Cancer, rheumatoid arthritis | $1.3B |
| Lucentis | Wet AMD | $1.2B |
| Avastin | Cancer, wet AMD | $1.1B |
| Remicade | Autoimmune disorders | $0.9B |
| Neulasta | Infection prevention | $0.9B |
| Aranesp | Anemia | $0.5B |
| Epogen/Procrit | Anemia (non-ESRD) | $0.4B |

- Part B beneficiaries are responsible for 20% of their prescription drug costs
  - Part B does not cap out-of-pocket spending

# Medicare Part D cost-sharing is growing

- Part D plans are increasingly using coinsurance
- No real incentive for Part D plans to control spending on biologics
- Out-of-pocket spending is limited by catastrophic cap



# Private insurance is following Part D's lead

- An increasing number of employer-sponsored plans have created a fourth or even higher tier of drug cost sharing

- The average copayment for a fourth-tier drug is $80 and the average coinsurance is 32%[12]

- The "relatively low" cost-sharing for specialty drugs is threatening to increase cost-sharing for non-specialty drugs[13]

# Many exchange plans will have high cost-sharing

- Enrollees will benefit from new out-of-pocket maximums ($6,350/single, $12,700/family)
- However, most exchange plans will rely on coinsurance for drugs on Tier 3 and 4, which could result in extremely high cost-sharing[14]

| | Silver | | | Bronze | | |
|---|---|---|---|---|---|---|
| | **Average** | Lowest | Highest | **Average** | Lowest | Highest |
| Deductible | $2,550 | $1,500 | $5,000 | $5,150 | $2,000 | $6,350 |
| Coinsurance for Tiers 3 & 4 | **40%** | 10% | **50%** | **40%** | 20% | **60%** |

# Patient assistance programs are not a cure-all


- While helpful, programs can be less than generous
- Patient assistance programs typically do not help insured patients and have very low income thresholds
    - Some also require beneficiaries to spend a certain amount of their income before they can participate
- Each pharmaceutical company has its own qualifications, forms, processes for refills, and rules for re-qualifying
    - Companies can have a different program for every drug they manufacture with different eligibility requirements for each drug

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# The debate continues…

- Exclusivity definition(s)
- Evergreening
- Reverse payments
- State legislation
- Naming

# AARP perspective on state legislation

- Unclear why necessary given that FDA has yet to approve a biosimilar
- If we can trust FDA to approve and regulate biologics, we can trust them to approve and regulate biosimilars
- Once FDA has approved a biosimilar drug as interchangeable with the original reference biologic, there is no valid reason for the process for substituting interchangeable biosimilar products for their reference biologic counterparts to be different from the process for substituting traditional generic products for their brand-name counterparts
- If enacted, would reduce substitution and subsequent competition, increasing health care costs

# AARP perspective on naming

- Different INNs could lead to prescriber and patient confusion and possibly impact patient safety
    - Prescribers would be forced to memorize the names of multiple versions of drugs with comparable clinical effects
- Would create false impression that biosimilars have a different clinical effect from the original biologic drug
- Effectively separates biosimilar from existing safety information from the brand name biologic
- Different INNs would reduce substitution and subsequent competition, increasing health care costs

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# Many unanswered questions

- Will the stated purpose of the BPCIA  be fulfilled?
- Will the new pathway be used?
- Will adequate competition develop?
    - The more roadblocks that are put in place, the less likely it becomes that companies will be willing or able to pursue biosimilars

# Lots of opportunities for additional delays

- Innovators could kill old product and launch next generation product (with 12 more years of exclusivity) just as biosimilar competition approaches
- Innovators could constantly tweak the reference product, staying one step ahead of the biosimilar and precluding substitution indefinitely
- Innovators could compete on price as they already have a full-scale production line, reducing biosimilars' cost competitiveness
- Innovators could raise fears of reduced efficacy or increased risk of side effects

# What if the biosimilar market never develops?

- The costs associated with biologics are not sustainable for patients or payers
- Many patients will be unable to afford biologics if competition does not provide some level of price relief
- Medical advances are meaningless if no one can afford to use them

# References


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