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Take 5
Diabetic Shoes

Melody Savley
Alps Pharmacy

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alps
Discount Pharmacy
always low prices
Pharmacy
Pharmacy
DROP OFF

Building relationships throughout the pandemic

COVID-19 Vaccination Clinic with Christian County Emergency Services

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Getting out in the community

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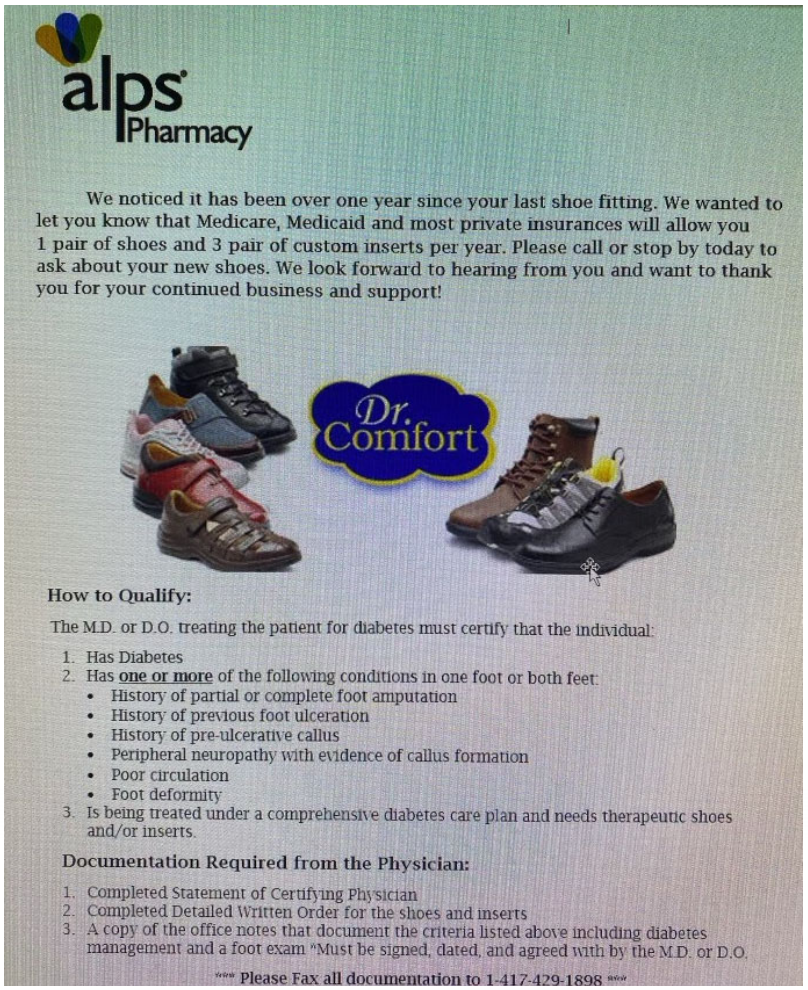
Led to unexpected opportunities

Diabetic shoes for all seniors in Christian County



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What's on the horizon…

Opportunity.

Look into the Senior Citizen's Tax Fund in your county.

NEWS

Shingles vaccine funding approved by Springfield City Council

by: Carrie Winchel
Posted: Feb 8, 2022 / 03:45 PM CST
Updated: Feb 8, 2022 / 03:45 PM CST

SHARE

SPRINGFIELD, Mo. — Springfield City Council members approved grant funding to pay for education about and administration of the Shingles vaccine. The bill was approved by everyone who attended Monday night's council meeting. Zone 2 Councilman Abe McGull was not at the meeting and did not vote.

The $97,930 is coming from the Greene County Senior Citizens' Services Fund Board and will be used by the Springfield-Greene County Health Department to pay for Shingles vaccines and supplies to administer them. According to the council bill, the largest expense will be for the vaccine itself, with around $400.00 set aside each for clinic supplies and educational materials.

supplies to administer them. According to the council bill, the largest expense will be for the vaccine itself, with around $400.00 set aside each for clinic supplies and educational materials.

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Take 5
The Suggestion Box

(Ken) Khanh-Long Thai, Pharm.D., Aph
986 Degrees Corporation

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Motivating Team Members

Communication is KEY!

Remember that all team members are differently motivated, and you can not assume those motivations factors are the same across your team!

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Motivating Team Members

Important to ASK and LISTEN and TAKE ACTION on what your individual team members want

Typical WANTS:

- Opportunity to grow/learn
- Opportunity to have a voice/to be heard in the operation
- Provided an idea of your vision/goals
- Advancement
- More money
- A trip to Disneyland?

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Suggestion Box of “WANTS”

- This can be anything
  - Supplies: Nice Pens, Note Pads
- Better accommodations in the break area
  - Keurig Machine, Donuts once a week?
- Team Event
  - If we reach goal trip to Disneyland?!!

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PIXAR PIER

Staff Engagement Events

- Staff gets to pick lunch
  - Most outstanding staff
  - Rotating on which staff gets to pick
- It should be open and fun!
- Goal is to allow for the team to get to know one another and build chemistry and a better work culture and environment

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Suggestions for Changes

- Suggestion box
- Regular time to meet and talk with staff on goals
  - Quarterly
  - Half yearly
- Opportunities for success
- Additional services

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Launching a “Specialty Lite” Service

Mark Ey
VP of Operations
CARE Pharmacies Cooperative

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Disclosure

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

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Pharmacist and Technician Learning Objectives

1. Differentiate specialty pharmacy from specialty lite.

2. Describe strategies for offering specialty pharmacy services without the need for accreditation.

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126 locations in 23 states, >900M in sales in 2021

77% of CARE purchases are in specialty or specialty lite drugs

72% of prescriptions filled are traditional

22 URAC or multiple accredited pharmacies

Members specialize in

HIV, Hep C, MS, CF, RA, pediatrics, fertility, pain management, dermatology, hospice, oncology, compounding, veterinary, infusion suites and many others

Specialty Lite Concept

While the price tag for traditional specialty products continues to surge with an average annual wholesale acquisition cost (WAC) of $75,000, specialty lite products carry a much lower price point.

Specialty lite is generally defined by WAC, which is typically within the guardrails of $400 per month to $800 per month, as well as service level requirements. CARE focuses on drugs in the $500 to $4000 a month price range

CMS defines "Specialty" as >$600/month for formulary purposes, for Specialty Pharmacies to make this level of high-touch service economically feasible, they typically look to take on products with a WAC of >$1500/month. This specialty

WAC price gap leaves a gray area for products that could benefit from SP services, but their gross-to-net just isn't able support such a program.

(Corsica Life Sciences)

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The Vision

Physicians do not get paid after the prescription leaves their office and often are looking for help with the administrative burden of payor driven issues including restricted distribution networks, prior authorizations, copay assistance, benefits mitigation.

Patients with specialty prescriptions often have multiple prescriptions that can be filled locally but often leave the retail location with all of their prescriptions if the specialty prescription can not be filled.

CARE positions itself as the “gate keeper” for referral sources taking on the administrative burden of assisting the patients and prescribers navigate payor hurdles and clinical management of patient.

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Why the Gate Keeper

In a 2020 Survey conducted by AMA, physicians noted*

PA issues contribute to 94% of care delays

80% of physicians reported that PA's led to patient abandoning their recommended treatment

The National Board of Prior Authorization Specialists, a division for the Accreditation Council for Medical Affairs has recently added a Prior Authorization Certified Specialist Program for pharmacy staff.

* The Pharmacists Role in Prior Authorizations Pharmacy Times Feb 1 2022 Kiana Dixson PharmD BCMAS

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Specialty Lite Drugs

Thru 2019, the FDA approved over 140 new specialty drugs since 2013 and approximately two-thirds of the 48 novel therapies approved in 2019 were specialty drugs.

About 60% of new molecular entities awaiting FDA approval through 2021 can be classified as specialty pharmaceuticals as late-stage pipelines are dominated by specialty therapies led by oncology indications and niche products across a range of classes.

Wholesaler economics becoming more and more of a challenge as they exclude many of these products from standard cost of goods calculations and “net price” on specialty lite items.

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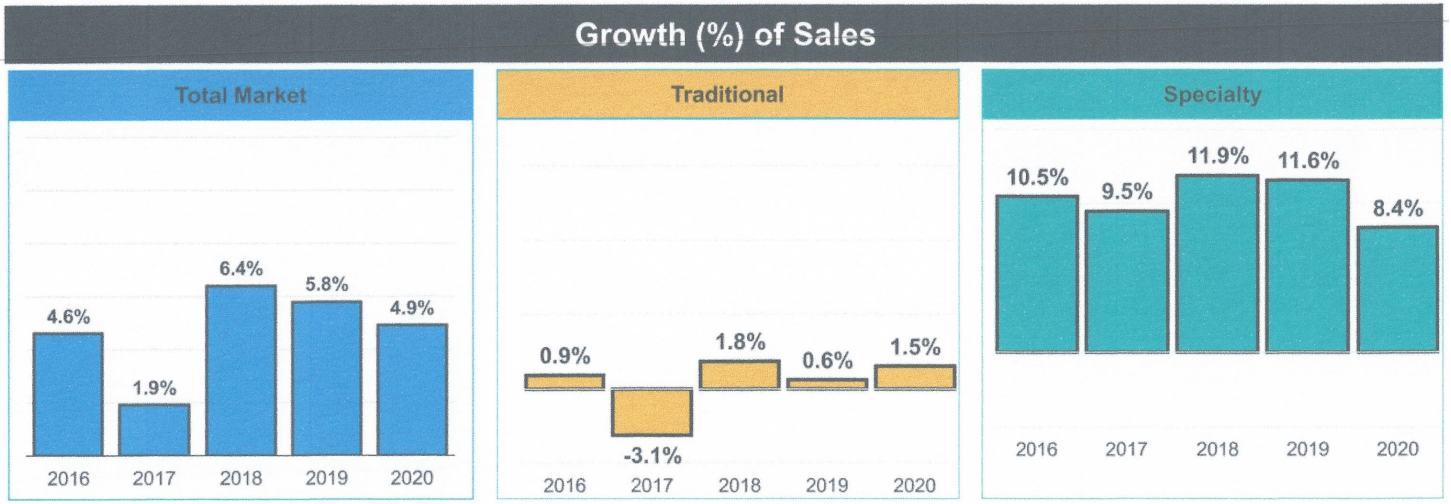
2020 Specialty vs Traditional Growth

Specialty dollar growth has been very strong and stumbled slightly in 2020 after topping 10% in the prior 2 years



Source: IQVIA, National Sales Perspectives, November 2020
Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail

IQVIA

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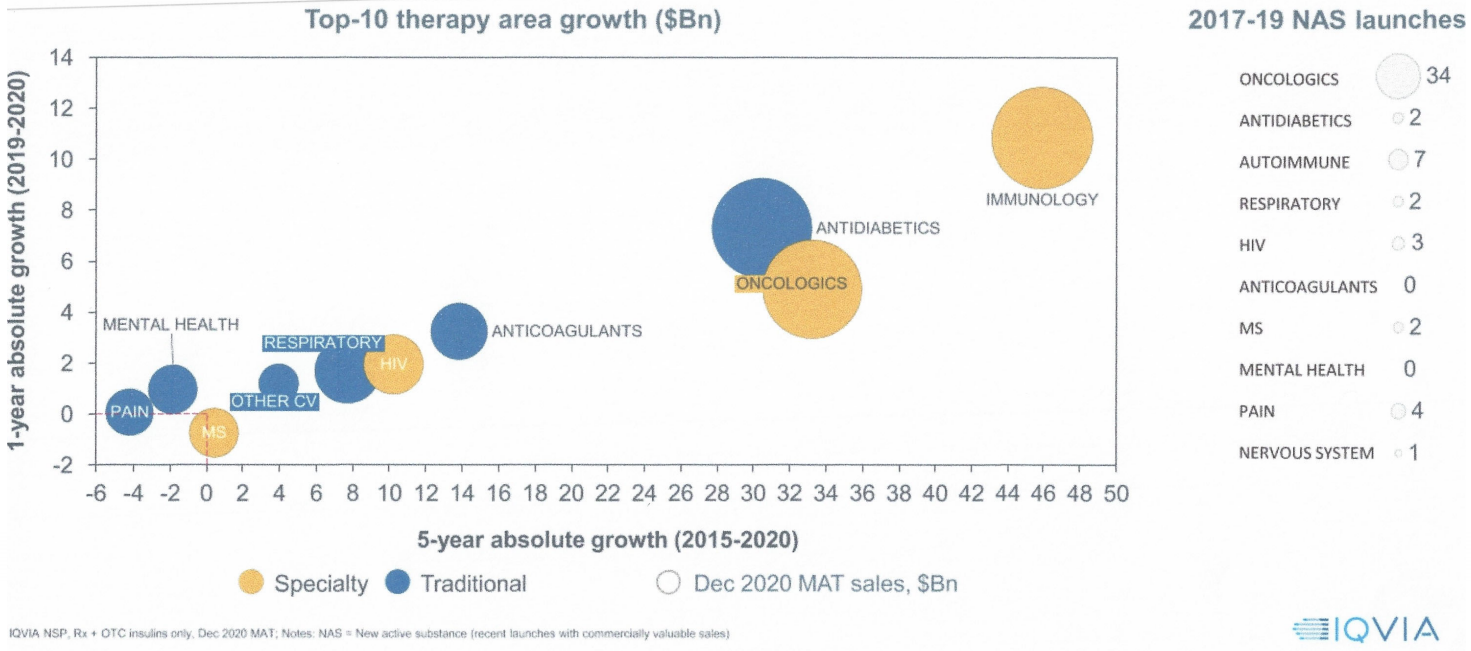
2020 Therapy Growth Sectors

Just three therapy areas are responsible for 60% of positive absolute growth in the US and 40% of recent launches

US total market absolute growth, $Bn



IQVIA NSP, Rx + OTC insulins only, Dec 2020 MAT; Notes: NAS = New active substance (recent launches with commercially valuable sales)

IQVIA

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Specialty Lite Products

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CARE Solution

- CARE required a solution that:
  - Kept specialty drug dispensing internal to CARE or its partners
  - Provided back-end solutions for specialty, hybrid, and traditional retail pharmacies
  - Provided assistance in accreditation, data collection, and potential for increased access to products
  - Assisted with just in time inventory management

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CARE Solution

CARE did not want a partner that:

- Simply took all Rxs a single CARE pharmacy could not fill without looking at member access
- Had the potential to “pilfer” non-specialty Rxs and patients
- Provided distribution only
- Did not have solutions for every pharmacy

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Set Up Considerations

- Payor classification Retail vs Specialty
    - Licensing and NCPDP
- Wholesaler and alternative distribution
    - Net pricing
- Specialty divisions
- Secondary distributors and spec buyers

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Non-Dispensing Revenue Opportunities

Injector Networks

Data Agreements

CPA provider opportunities

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THANK YOU

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Retail Pharmacy Biosimilar Opportunities

Sonia T. Oskouei, PharmD, BCMAS, DPLA
Vice President, Biosimilars
Cardinal Health

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Disclosure

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Pharmacist and Technician Learning Objectives

1. Discuss current U.S. biosimilar market dynamics and products in the pipeline.
2. Explain the unique implications and considerations for retail and interchangeable biosimilars.

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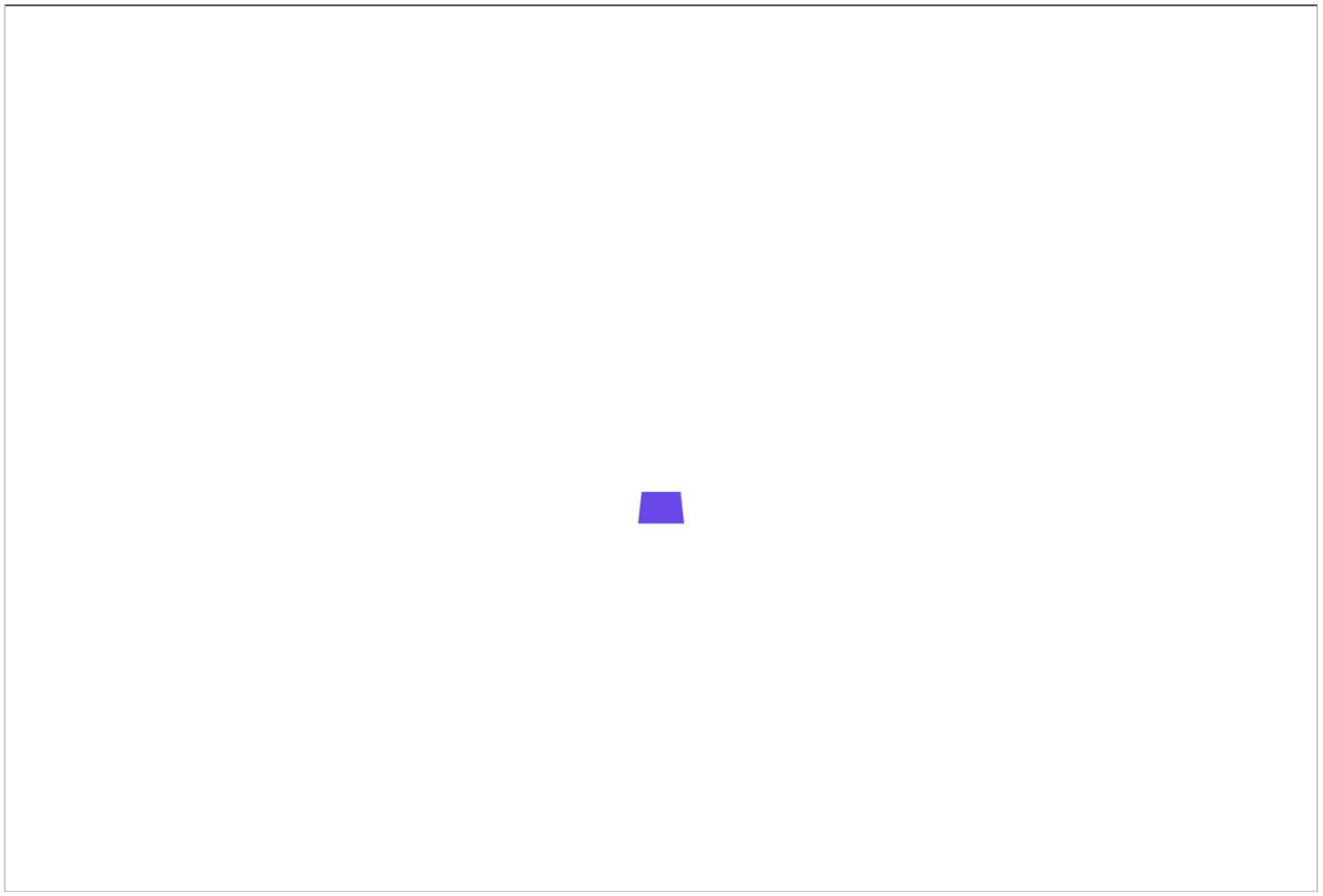

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Understanding Biologics and Biosimilars

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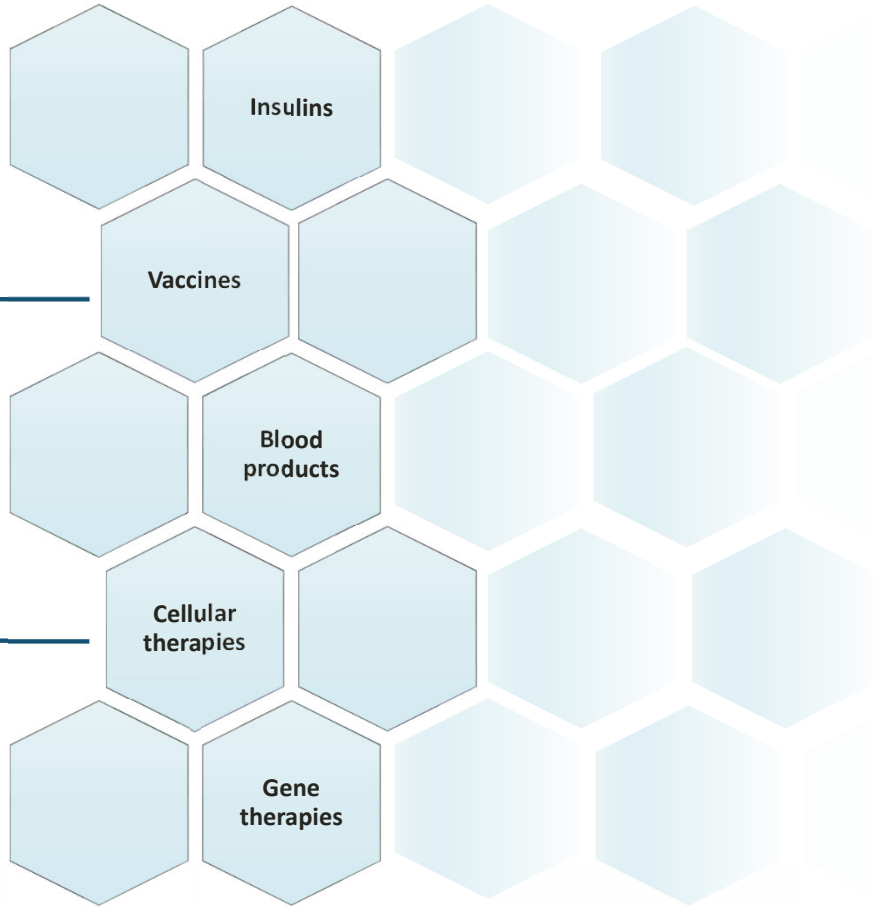
Understanding biologics

Biologic medications consist of large, complex molecules that are created from **living cells** that are used to treat, prevent or diagnose chronic and advanced illnesses



What is a biological product? U.S. Food & Drug Administration. https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm. Updated May 31, 2016. Accessed March 29, 2017.

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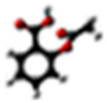
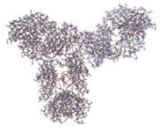
Biologic vs Chemical drug production





	Chemical/Small molecule drugs	Biological drugs
Structure	Small and simple; well-defined	Large and complex; heterogenous
Molecular weight	<500-900 Daltons	4000 to > 140,000 Daltons
Manufacturing	Predictable chemical process to make **identical** copy	Specialized biological process to make **similar** copy
Immunogenicity[1]	Lower potential	Higher potential
Manufacturing quality test	≤ 50	≥ 250
Product examples	Advil (ibuprofen), Lipitor (atorvastatin)	Avastin (bevacizumab), Remicade (infliximab)

[1]Immunogenicity is the potential for a therapeutic protein to elicit an immune system response or adverse effect. Immunogenicity studies are conducted between reference and biosimilar products during their approval process with FDA to assess potential differences between the products in eliciting immune system responses

Biosimilars vs generics: important distinctions between Biosimilars and generics. Amgen Biosimilars. http://www.amgenbiosimilars.com/the-basics/biosimilars-versus-generics/. Accessed March 24, 2017.

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What are biosimilars?

Biosimilars are a type of biological product that are highly similar to an already FDA-approved biological product

- Have no clinically meaningful differences in terms of the safety, purity and potency
- Only minor differences in clinically inactive components are allowed

Biosimilars are not considered generics

- Generic medications have ***identical*** active ingredients to the reference product
- Since biologics have **inherent variability** (due to being made from living cells), biosimilars must demonstrate they are **highly similar** to the reference product

Biosimilars are approved through an abbreviated pathway under section 351(k) of the Public Health Service Act for biological products shown to be biosimilar or interchangeable with an FDA-licensed reference product

- FDA Purple Book: contains information about all FDA-licensed biological products including biosimilars and interchangeable biological products

1. Information on biosimilars. U.S. Food & Drug Administration. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/. Updated May 10, 2016. Accessed March 29, 2017. 2. Ventola CL. Evaluation of Biosimilars for Formulary Inclusion: Factors for Consideration by P&T Committees. *Pharmacy and Therapeutics*. 2015;40(10):680-689.; Burich M. Potential unintended consequences of CMS' policy for Biosimilars reimbursement. Biosimilar Development website. https://www.biosimilardevelopment.com/doc/potential-unintended-consequences-of-cms-policy-for-biosimilars-reimbursement-0001. Accessed March 20, 2017.

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Production costs between small molecule generics and biosimilars vary greatly

	Production costs	Production time
Generic drug	*$3 to $4 million*	*3 to 4 years*
Biosimilar	***$200 to $300 million***	***6 to 7 years***

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Burich M. Potential unintended consequences of CMS' policy for Biosimilars reimbursement. Biosimilar Development website. https://www.biosimilardevelopment.com/doc/potential-unintended-consequences-of-cms-policy-for-biosimilars-reimbursement-0001. Accessed March 20, 2017.

Why Biosimilars Matter to the U.S. Healthcare System

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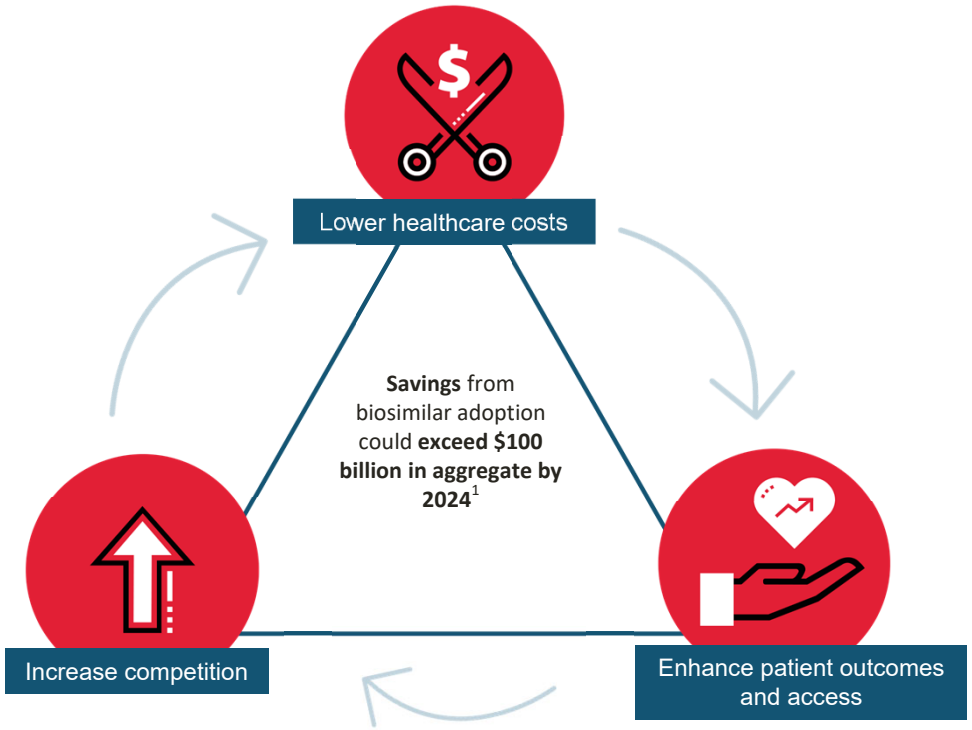
Biosimilars target drugs with highest spending



There are more than 100 biosimilars in development across 22 molecules

	Name	Category	2019 Expenditures ($ Thousands)	% Change from 2018
1	**Humira (adalimumab)**	Immunology	22,164,601	15.7
2	**Eliquis (apixaban)**	Anticoagulant	9,835,751	39.2
3	**Lantus (insulin glargine)**	Diabetes	9,470957	1.3
4	**Enbrel (etanercept)**	Immunology	8,020,696	0.7
5	**Stelara (ustekinumab)**	Immunology	6,592,410	31.3
6	**Keytruda (pembrolizumab)**	Oncology	6,548,036	54.0
7	**Trulicity (dulaglutide)**	Diabetes	6,467,525	43.7
8	**Januvia (sitagliptin)**	Diabetes	6,019,585	5.4
9	**Novolog (insulin aspart)**	Diabetes	6,018,135	1.0
10	**Xarelto (rivaroxaban)**	Anticoagulant	6,000,798	16.0
11	**Humalog (insulin lispro)**	Diabetes	5,763,766	0.5
12	**Biktarvy (bictegravir/ emtricitabine/tenofovir)**	HIV	5,108,139	285.7
13	**Remicade (infliximab)**	Immunology	4,993,790	-8.3
14	**Victoza (liraglutide)**	Diabetes	4,986,939	3.9
15	**Immune globulin**	Blood	4,704,431	6.6
16	**Rituxan (rituximab)**	Oncology	4,424,900	3.1
17	**Opdivo (nivolumab)**	Oncology	4,376,356	5.2
18	**Neulasta (pegfilgrastim)**	Supportive care	4,123,228	-3.6
19	**Epinephrine**	hormone	3,899,709	-9.6
20	**Symbicort (budesonide formoterol)**	Respiratory	3,872,353	10.7

= has biosimilar approved or in pipeline

Reference: 1. Aitken M, Kleinrock M, Muñoz E. Biosimilars in the United States 2020-2024: competition, savings, and sustainability. IQVIA. September 29, 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024 2. Tichy EM, Schumock GT, Hoffman JM, et al. National trends in prescription drug expenditures and projections for 2020. *Am J Health Syst Pharm*. 2020;77(15):1213-1230. https://pubmed.ncbi.nlm.nih.gov/32412055/

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Biosimilars are key to helping lower costs and improve access to critical treatments in the U.S.

Example opportunities with products primarily dispensed in community/retail pharmacy site of care:

Insulins	Adalimumab
• First discovered in 1923 • Average list price of insulin increased 11% annually from 2001 to 2018 • ~87% of long-acting insulin prescriptions dispensed within Retail or Mail Order channel • Increasing price scrutiny around insulins and demand for more affordable diabetes care in U.S.	• World's best- selling drug • Entered the market in 2003 • Currently accounts for >$20B in sales/year • 7% price increase in 2020; ~19% price increases in previous years

The market entrance of biosimilars can help increase competition, lower costs, and enhance patient access to critical treatments

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1. Retail Chain, Food Store, Independent, and Mail Order Class of Trade as defined by IQVIA 2. https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends/; 2. https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends/#:~:text=The%20average%20list%20price%20of,insulin%20costs%20now%20nearing%20%246%2C000.; 3. https://www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f_story.html

Biosimilars Regulatory Approval Pathway and Key Terms

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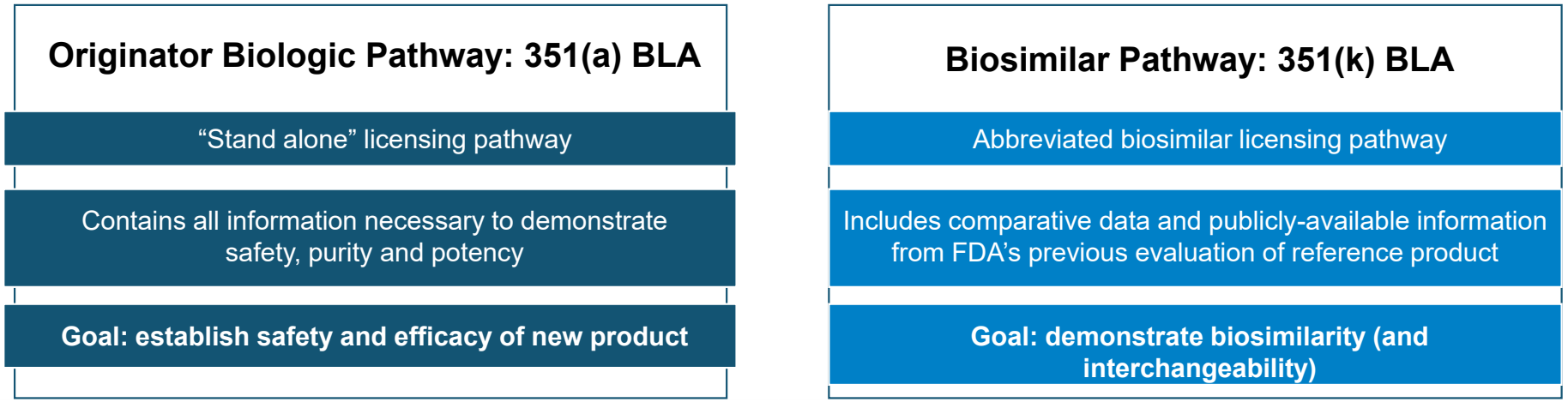
Biologics Price Competition and Innovation Act (BPCIA)

- BPCIA signed into law on March 23, 2010
- Created abbreviated licensure pathway under 351(k) of Public Health Service Act (PHS Act) for biological products shown to be biosimilar or interchangeable with an FDA-licensed reference product



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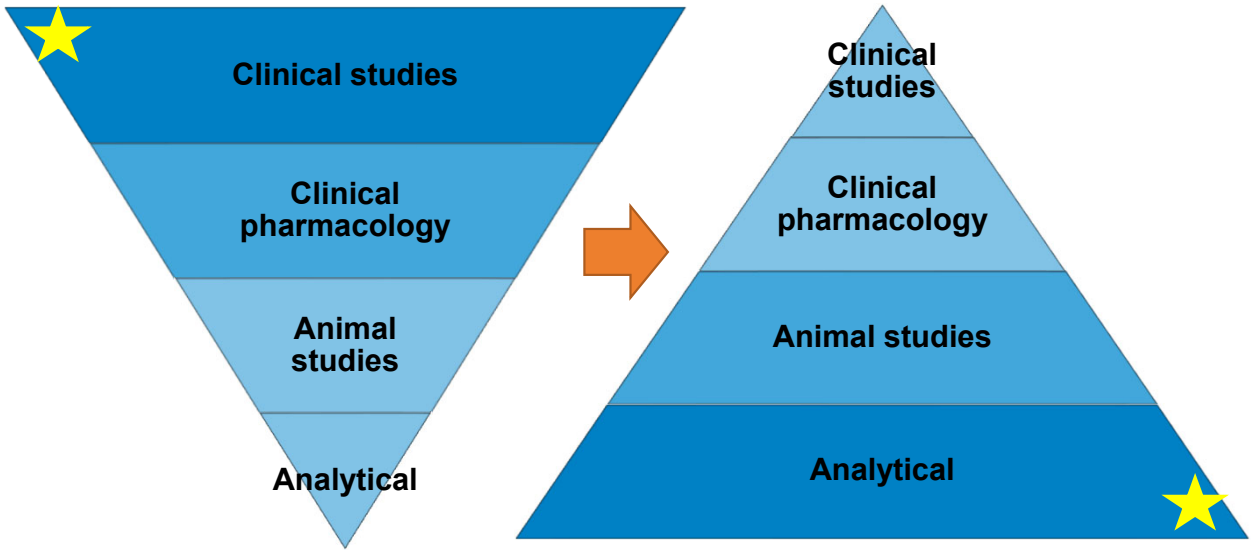
Overview of the regulatory pathway and FDA's guidance for the development and approval of biosimilar products in the US. U.S. Food & Drug Administration. https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/arthritisadvisorycommittee/ucm513087.pdf.

351(a) BLA vs 351(k) BLA



351(a) BLA
Originator biologic pathway

351(k) BLA
Biosimilar pathway

= Greatest regulatory weight

How Does a Manufacturer Demonstrate Biosimilarity? Biosimilars Resource Center. 2017. Accessed July 20, 2020. https://www.biosimilarsresourcecenter.org/faq/how-does-a-manufacturer-demonstrate-biosimilarity/

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Transition of insulins to biologics regulatory approval pathway

March 2020: small subset of biological products approved under the FD&C Act, such as insulin and human growth hormone, transitioned to being regulated as biologics

- The transition of insulins to be regulated as biologics enabled a pathway for insulin biosimilars to come to market
- FDA released guidance stating that switching studies will generally not be needed for interchangeable designation for insulins

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https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition

Interchangeability

FDA criteria for interchangeability designation:

Biosimilar to FDA-approved biologic/reference product

Expected to produce same clinical result as reference product in any given patient

Generally achieved through submission of additional data (e.g., **switching studies**)

1st interchangeable biosimilar approved: Viatris' Semglee (insulin glargine- yfgn); officially (re)launched Nov 2021

2nd interchangeable biosimilar approved: Boehringer Ingelheim's Cyltezo (adalimumab-adbm); anticipated launch July 2023

Interchangeable ≠ Superior

The U.S. is the **only** country that has interchangeability as a **regulatory designation**

Allows **pharmacist-level substitution**, per state laws

Most **relevant for pharmacy benefit** biosimilars (e.g., insulins, Humira)

First official interchangeable biosimilar in U.S. granted in 2021

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https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition

U.S. Biosimilar Market Dynamics and Pipeline

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Overall U.S. biosimilars market share

Product	Category	1st Biosimilar Launch	Current # Biosimilar Competitors	Biosimilar Market Share (Nov '21)
Neupogen (filgrastim)	Supportive Care	2015	3[1]	91%[1]
Remicade (infliximab)	Immunology	2016	3	32%
Epogen/Procrit (epoetin Alfa)	Supportive Care	2018	1	53%
Neulasta (pegfilgrastim)	Supportive Care	2018	4	39%[2]
Avastin (bevacizumab)	Oncology	2019	2	75%
Herceptin (trastuzumab)	Oncology	2019	5	56%
Rituxan (rituximab)	Oncology	2019	3	65%
Lantus (insulin glargine)	Diabetes	2020*	2[3]	2%
8 Product Classes		--		--
Lucentis (ranibizumab)	*Ophthalmology*	*2022*	*1*	*Not Launched*
Humira (adalimumab)	*Immunology*	*2023*	*7*	*Not Launched*
Enbrel (etanercept)	*Immunology*	*2029*	*2*	*Not Launched*

[1]Includes Granix
[2]Neulasta biosimilars excluding Onpro adoption is 76% (e.g., the syringe market only)
[3]Rezvoglar is the 2nd approved Lantus biosimilar but has not launched yet
*Semglee launched as an originator in Aug 2020, but transitioned to an interchangeable biosimilar in July 2021

IQVIA accessed February 2022

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What is going on with the insulin biosimilars?

Here's the story…

Product	Company	Originator Biologic	Biosimilar to Lantus	Interchangeable Biosimilar to Lantus
Lantus (insulin glargine)	Sanofi	x		
Basaglar (insulin glargine)	Lilly	x		
Semglee (insulin glargine- yfgn)	Viatris		x	x
Insulin glargine- yfgn	Viatris		x	x
Rezvoglar (insulin glargine- aglr)	Lilly		x	

As of February 2022

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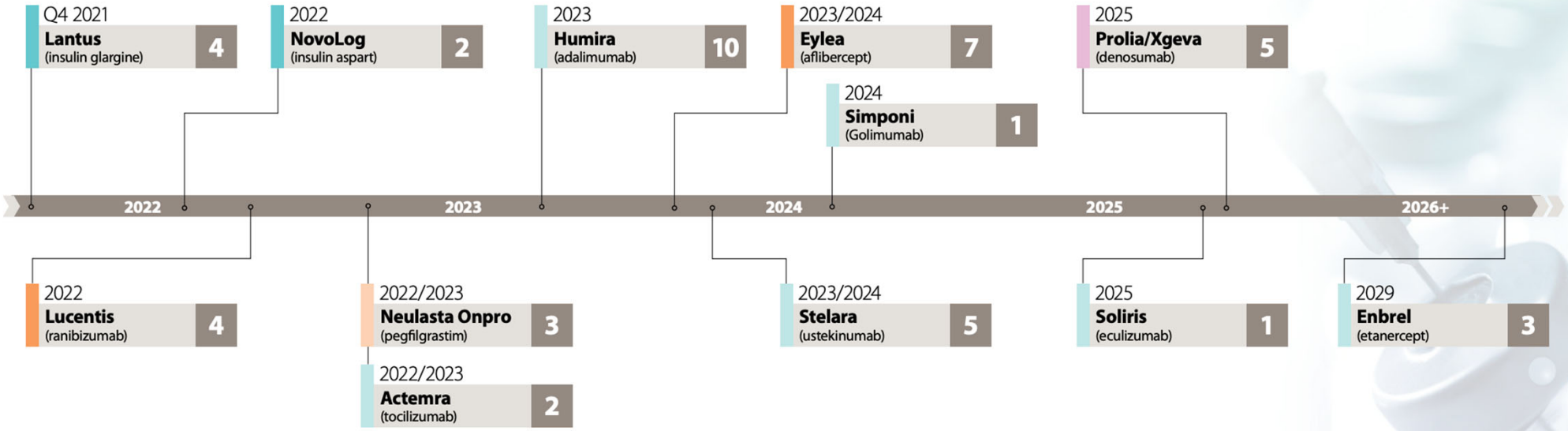
Upcoming new biosimilars pipeline



Source: IPD Analytics. Market & Financial Insights. December 2021.

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Implications of retail and interchangeable biosimilars

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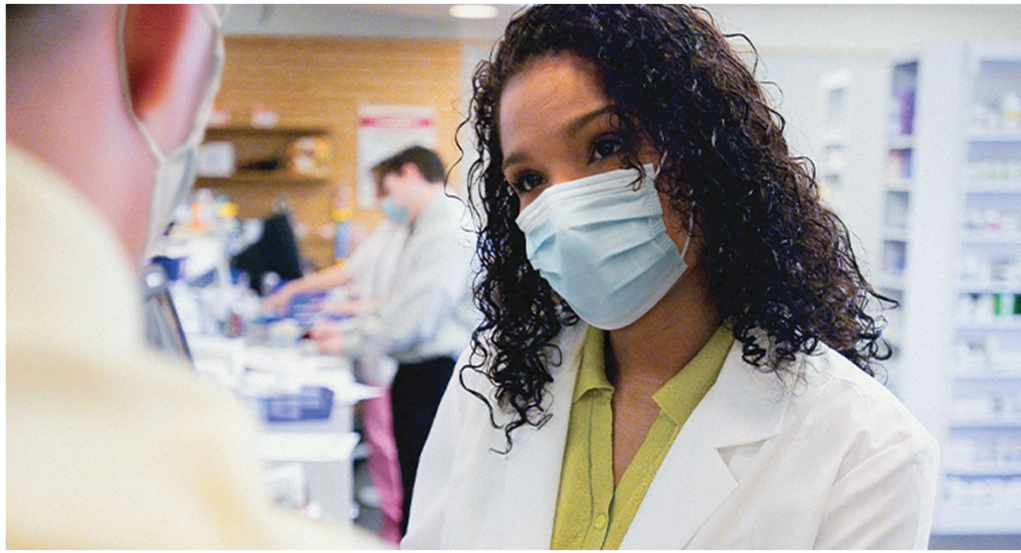
Managing retail and interchangeable biosimilars

With interchangeable biosimilars entering the market, community pharmacists and pharmacy technicians will be further positioned to support biosimilar adoption and champion the education process within communities.

As the most accessible and frequently visited healthcare providers, community pharmacists can play a significant role in ensuring clinical confidence with biosimilars.



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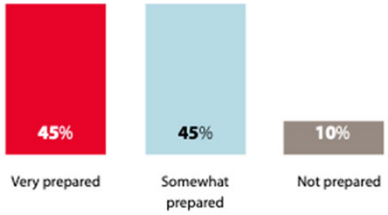
Biosimilars market research with retail pharmacists and physicians/endocrinologists (winter 2021)

Less than half of participating pharmacists said they are "very" prepared for discussing biosimilars with patients.

Figure 26. **How prepared do you feel to have conversations with patients on their options for insulin biosimilars?**
(Surveys conducted in 2021) N = 115



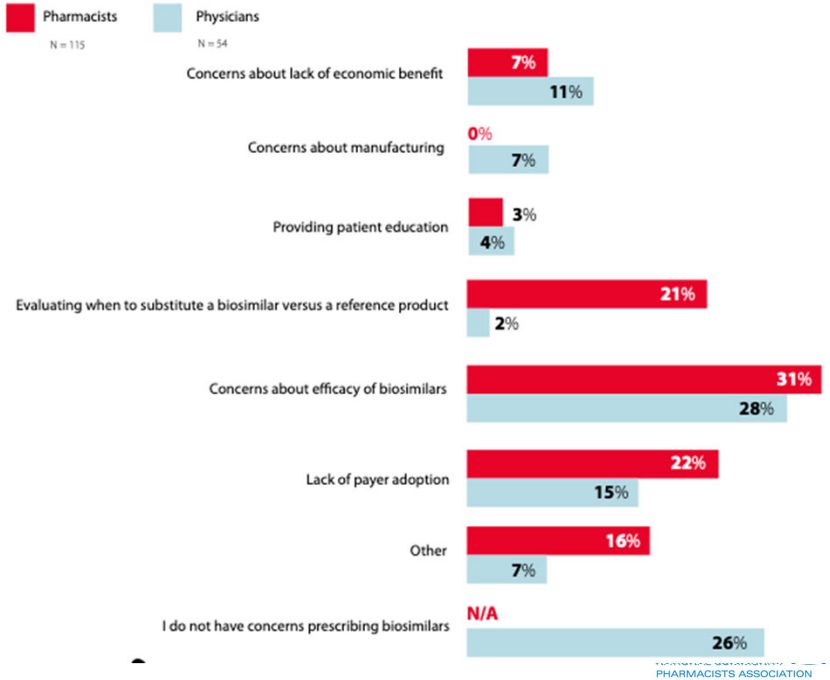
Less than 20% of participating pharmacists were "very familiar" with interchangeability designation.

Figure 33. **How would you describe your familiarity with the interchangeability designation for biosimilars?** (Surveys conducted in 2021) N =115

Half of participating pharmacists (**51%**) said they are "very comfortable" substituting a biosimilar for a reference product if the biosimilar would **deliver a lower out-of-pocket cost for the patient.**

Efficacy of biosimilars is the top concern for both physicians and pharmacists.

Figure 32. **What is your top concern about substituting a biosimilar product for the reference product?**
(Surveys conducted in 2021)



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www.cardinalhealth.com/BiosimilarsReport.

Considerations for retail biosimilars

Financial

- Product purchase cost
- Reimbursement (e.g., PBMs)
- Patient out of pocket costs and/or co-pay assistance programs
- Opportunities with cash pay, underinsured, or uninsured population

Clinical

- Patient counseling/education
- Pharmacist familiarity and confidence with biosimilar scientific principles
- Medication adherence support (e.g., MTM)

Operational

- Interchangeability requirements per individual state laws
-
- Procurement and inventory management (e.g., product storage/ refrigeration)
- Prior authorization process
- Workflow efficiencies

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Navigating state specific biologic substitution laws for interchangeable biosimilars

- While interchangeability is granted by the FDA, biologic substitution is handled by each state's Board of Pharmacy
- Cardinal Health partnered with regulatory advisors to develop an interactive map that details state-by-state interchangeability laws
- Most state laws detail pharmacist communication/documentation requirements for conducting a biologic substitution
  - Patient/Provider notification
  - Document retention policy
  - Methods of acceptable communication

Interchangeability Resource:
www.cardinalhealth.com/biosimilars/statelaws

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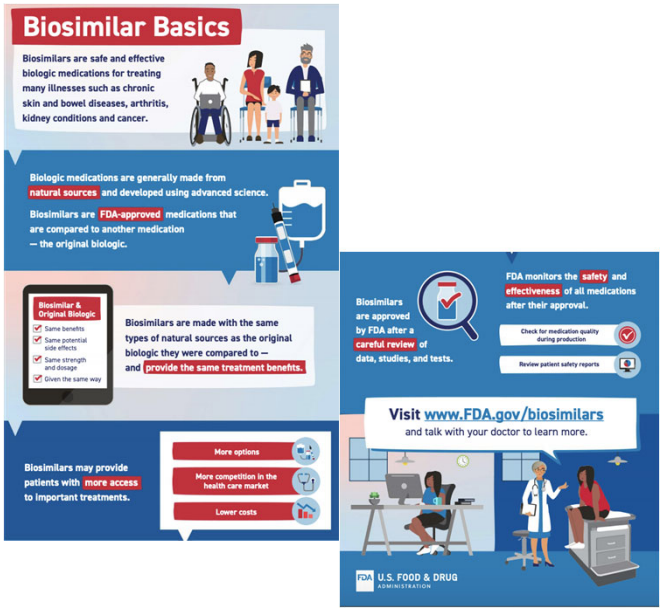
Biosimilar resources



FDA educational resources for both providers and patients: [FDA biosimilars website]

Cardinal Health biosimilars resources: [CardinalHealth.com/biosimilars]

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Conclusion

- Biosimilars are biologic products that undergo a rigorous approval process with the FDA, and have no clinically meaningful differences in terms of safety, purity, and potency from their reference products
- Biosimilars serve as valuable tools to increase competition and lower costs for some of the most expensive treatment options in the U.S.
- Interchangeability is an FDA regulatory designation in the U.S. that enables automatic, pharmacist-level biosimilar substitution, per state laws
- Arrival of biosimilars (and interchangeable biosimilars starting with insulins) predominately dispensed in the retail/community pharmacy setting will require management of various clinical, operational, financial, and regulatory implications for pharmacies and patients
- Continued educational efforts will be critical to close knowledge gaps and strengthen clinical confidence in biosimilars to enable successful adoption by community pharmacies and patients

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Thank You

Please reach out with any additional questions!

Sonia.oskouei@cardinalhealth.com

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Leveraging the Disruption

B. Douglas Hoey, Pharmacist, MBA

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Disclosure

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

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Pharmacist and Technician Learning Objectives

1. Identify at least three trends in the pharmacy marketplace that will enhance patient care.
2. Discuss the evolution of primary care services available to health care consumers.

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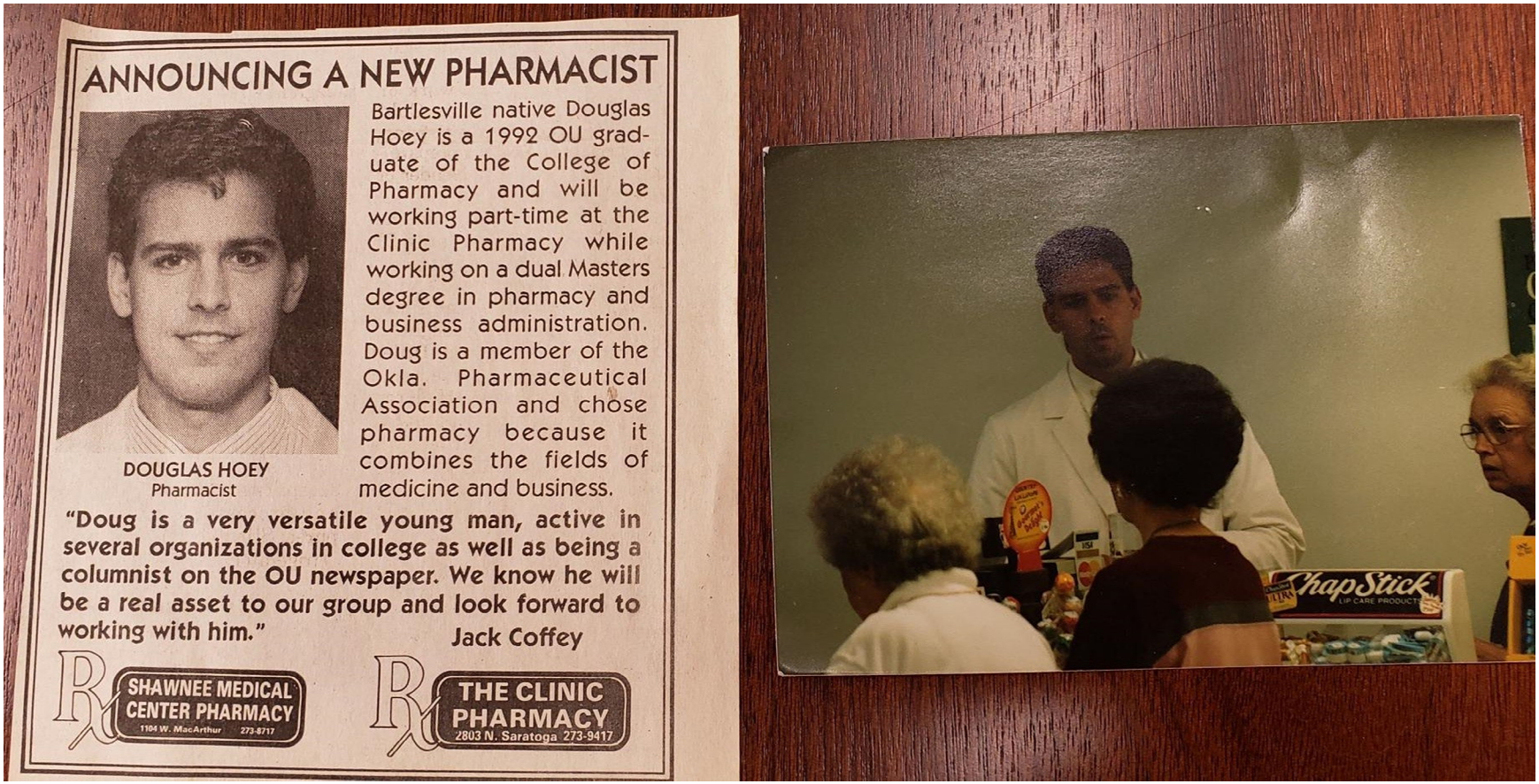
Quick Background



ANNOUNCING A NEW PHARMACIST

DOUGLAS HOEY
Pharmacist

Bartlesville native Douglas Hoey is a 1992 OU graduate of the College of Pharmacy and will be working part-time at the Clinic Pharmacy while working on a dual Masters degree in pharmacy and business administration. Doug is a member of the Okla. Pharmaceutical Association and chose pharmacy because it combines the fields of medicine and business.

"Doug is a very versatile young man, active in several organizations in college as well as being a columnist on the OU newspaper. We know he will be a real asset to our group and look forward to working with him."

Jack Coffey

Rx SHAWNEE MEDICAL CENTER PHARMACY
1104 W. MacArthur 273-8717

Rx THE CLINIC PHARMACY
2803 N. Saratoga 273-9417

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Changing the Pharmacy Payment Model

- The U.S. government is the only gov't in the world that has outsourced the prescription drug benefit. Not coincidentally, the U.S. pays the highest drug prices in the world!

NCPA.2024 Strategic Planning.De
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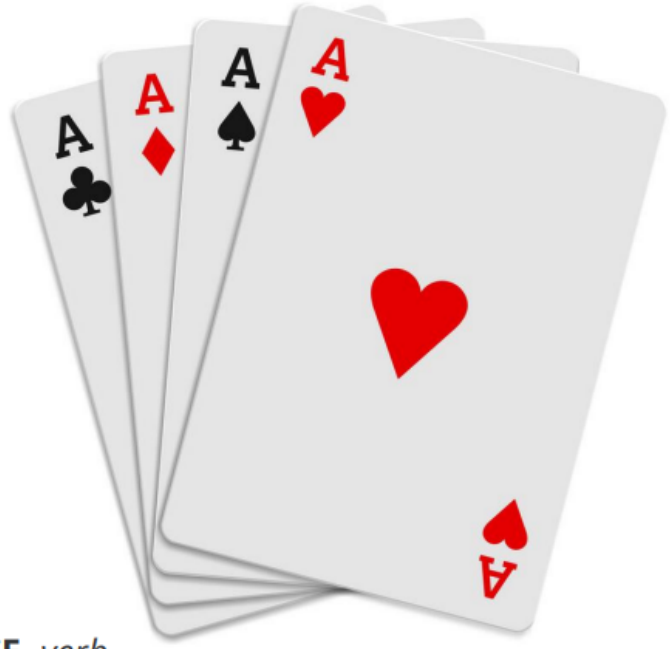
2024 STRATEGIC PRIORITIES

- Advocate
- Communicate
- Educate



ACE, *verb*

- to perform extremely well, high quality

Type here to search
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2/23/2022

To what end…

NCPA's Strategic Plan results in a payment model and practice environment where pharmacy owners have the opportunity to thrive

- Recent examples
  - Payment for pharmacist services and fair payment for dispensing medications to patients
  - COVID vaccinations, testing, centerpiece of test and mask distribution
  - Supreme Court lawsuit—spurring state legislation
  - Lawsuits in ND, IA, Okla, and LA
  - NADAC Plus (plus)
  - Payment for vaccines and mAb infusion therapy is fair

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Vertical Integration of Primary Care

- Primary care provider shortage—The Association of American Medical Colleges (AAMC), expects the U.S. to face a shortage of primary care physicians **ranging from 21,400 to 55,200 by 2033**.
- CVS-Aetna investing in their Health Hubs
- *HealthHUB will expand primary care for lower risk patients. Pharmacies will serve as the next step. M&A activity to support primary care. HealthHUB and MinuteClinics serve roughly 45% of the US population.*
- Walmart building primary care clinics

Walmart to Open 4,000 Healthcare 'Supercenters' by 2029 That Include 'Comprehensive' Clinical Laboratory Services

Vertical Integration of Primary Care

- Walgreens investing in Village MD

- Walgreens Boots Alliance is becoming the majority owner of VillageMD, as it opens hundreds of doctor offices with the primary-care company.
- It plans to have at least 600 primary-care clinics in more than 30 U.S. markets by 2025 and 1,000 by 2027.
- The deal is part of an effort to turn neighborhood drugstores into health-care destinations with doctors who provide care, write prescriptions and draw traffic to the retail locations.

- Independents response? CPESN aggregates local networks of independent pharmacies (4th largest single signator)

Eyes on the skies?

- Amazon
- Pressure on prescription pricing
- Specialty/Biologics consolidation
- 340B reform
- Rx acquisition cost discrimination
- Government intervention—national healthcare?
- Continued health system mergers
- Cash pricing; cash card programs (e.g. GoodRx, etc)
- Drones
- “Made in America”?

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Reshaping Pharmacy Practice

Ronna Hauser, PharmD
Senior Vice President, Policy and Pharmacy Affairs

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Disclosure

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Pharmacist and Technician Learning Objectives

1. Summarize how recent legal decisions and ongoing litigation could impact your pharmacies
2. Discuss current community pharmacy legislative and regulatory issues

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Advocacy Dividends

- PPP loans helped pharmacies survive
- Authority to order and administer COVID tests, vaccines, and therapies
- Access to COVID vaccines - FRPP
- Vax Administration up from avg of $23 to $40 + At-Home Payment

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Advocacy Dividends

- Supreme Court unanimous ruling
- Support/leadership in state court cases
- Model PBM legislation in the states
- Reforming Medicaid Managed Care

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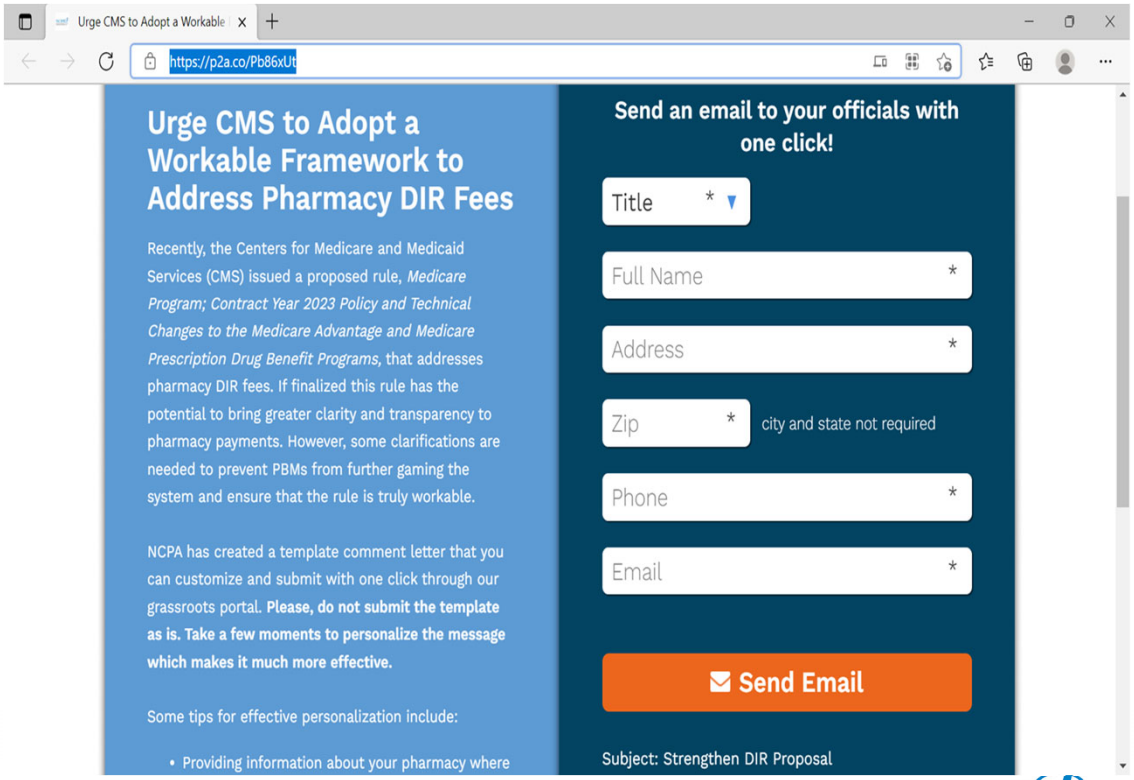
Medicare Part D Proposed Rule for 2023

- NCPA has identified areas of concern that CMS should address:
  - All price concessions attributable at the claim level
  - Coverage gap loophole
  - Smoothing process to prevent cashflow issues during transition
  - Network Access/Quality measures
- Comment period on proposed rule closes March 7
- NCPA is asking members to submit comments; over 2,000 comments have been submitted
- Final rule should be issued in April or May

NCPA's Grassroots Campaign for Comment Submission to the CMS Docket

- ✓ **Provide information about your pharmacy (how long you have served your community, services that you provide, number of Part D beneficiaries you serve)**
- ✓ **Discuss the harm that will come to your patients, pharmacy, and employees if DIR fees are not addressed (examples: the sickest patients pay more at the pharmacy counter because of DIR fees, reduced pharmacy hours, stopped providing free home delivery of medications to seniors, closed your pharmacy)**
- ✓ **Provide examples of how DIR fees have increased and how they have impacted your business (examples: reduce staff, reduce charitable/community donations)**



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NCPA's Grassroots Campaign for Comment Submission to the CMS Docket

https://ncpa.org/cmsdir2022

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Other Federal Priorities

Build Back Better

- Inclusion of drug pricing provisions-NADAC reporting

Payments and Prescriptive Authority for Oral Antivirals

- Outreach to Hill, CMS, and FDA by NCPA and other national associations

Antitrust

- Outreach to FTC, comments on mergers/anticompetitive practices by PBMs

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State Government Affairs

2022 Priorities:

1) **Medicaid Managed Care Reform**
   - **Focus on fair and transparent reimbursements (i.e. NADAC plus pdf)**
2) **PBM Reform**
   - Includes State DOI enforcement of existing PBM regulations
3) **Scope of practice and compensation for services**
   - Focus on state's adopting HHS authorizations post PHE
     - Adopted so far: Arkansas, California, Florida, Illinois, New York, Ohio, Oklahoma, Wisconsin, and Virginia
     - Currently working with Nebraska, Minnesota and Missouri

Snapshot of 2022 Activities:

- Since January 1, NCPA has provided legislative assistance to 22 states!
- Working with Ohio to ensure fair reimbursements in new Medicaid managed care single PBM model
- Working with states and their DOIs regarding lack of enforcement of PBM regulations: NCPA will have a resource for DOI complaints for lack of enforcement
- Working with CMS and state pharmacy associations to get state Medicaid programs to pay enhanced fees (above fee for service fees) for dispensing oral antivirals

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Legal Update

- DIR lawsuit – NCPA v. Becerra
  - Stayed pending the outcome of the CMS proposed DIR rule changes
- Washington State – SPA lawsuit – NACDS v. Becerra
  - Remanded back to CMS - stalled, WA Legislator Pressure
- PCMA v Wehbi
  - PCMA petitioned the court for an en banc (full panel) rehearing
  - The court denied that petition on 2/11
  - PCMA has 90 days to appeal to the Supreme Court
- FTC Engagement
  - Continue to engage FTC and DOJ staff
  - FTC advocacy encouraging it to undertake a 6(b) study of PBMs/ First vote failed on 2/17
- United Health Group acquisition of Change Healthcare
  - Met with DOJ to express objections
  - Sent DOJ a letter explaining the issues and encouraging close work with the FTC on this potential acquisition

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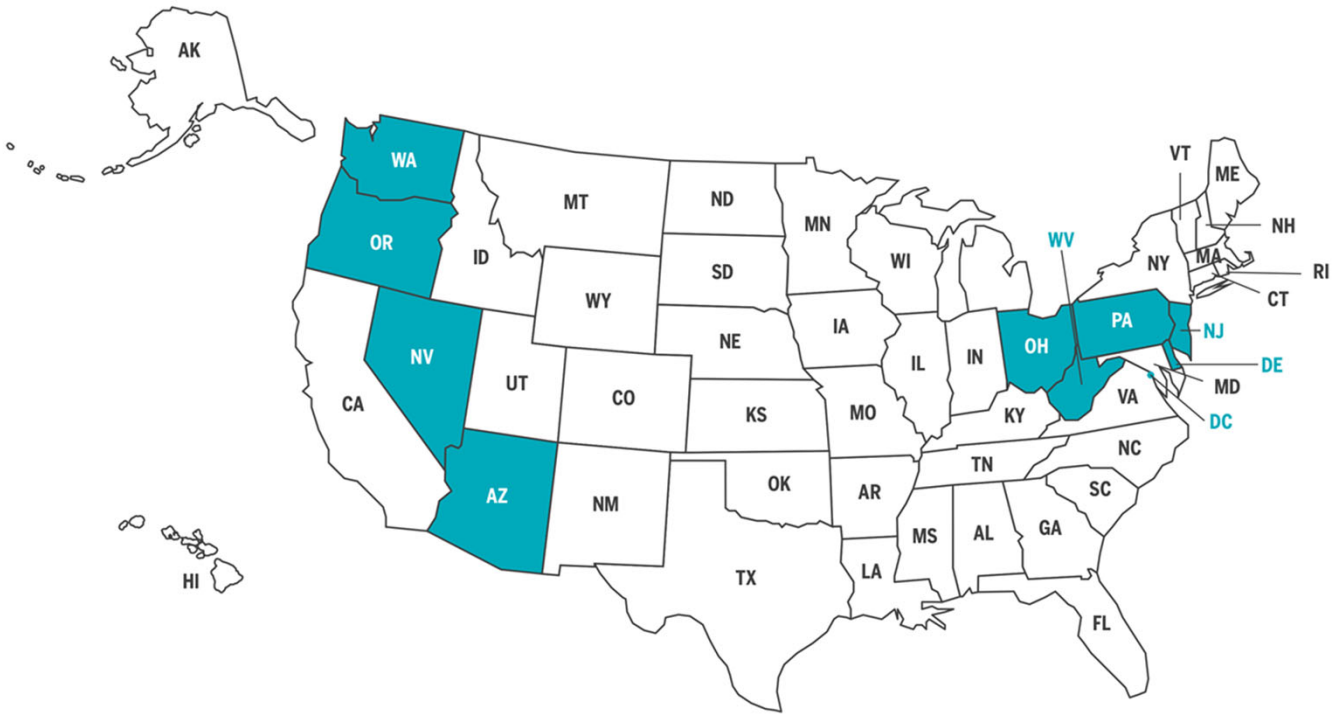
The Truth 2 Campaign

- $2 Million Total Buy
- 4 Weeks
- Targeting senators who are favorable to PBM reform
- Aim is to encourage senators to weigh in with CMS to ensure DIR rule meets our objectives
- New ad cites “unfair and discriminatory” fees instead of “backdoor” fees



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The Truth 2 Campaign

National Community Pharmacists Association PAC

Get into politics or get out of pharmacy

The NCPA PAC is fighting for our profession in Washington, DC by demonstrating the vital role pharmacists play in heatlh care

If every NCPA member gave **$1** a day to the PAC

WE'D RAISE

$4.5M

A YEAR

LEGISLATIVE TOP PRIORITIES:

- Prohibition of onerous retroactive pharmacy DIR Fees
- Prohibition of spread pricing in Medicaid managed care
- Pharmacy choice under Medicare Part D
- Medicare Payment for enhanced pharmacist services

2 pharmacists and 1 pharmacy owner serving in 117th Congress:

Reps. Buddy Carter (R-Ga.), Diana Harshbarger (R-Tenn.) and Jerry Carl (R-Ala.)

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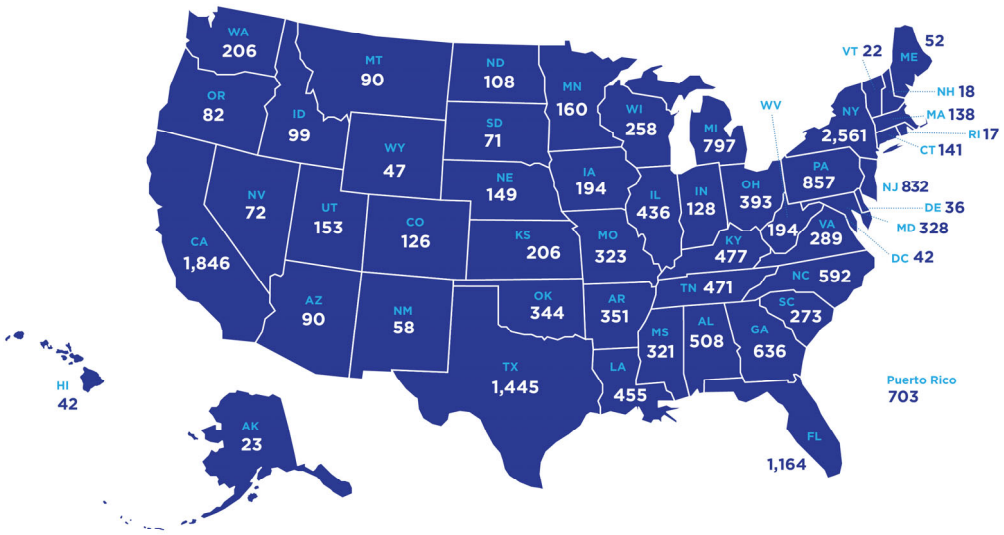
has the largest pharmacy industry trade association PAC

INDEPENDENT PHARMACY **FOOTPRINT**



NCPA® PAC
POLITICAL ACTION COMMITTEE

If you have any questions or want to learn more about the NCPA PAC **please visit our website ncpa.org/pac or email pac@ncpa.org.**

National Community Pharmacists Association LDF

The Legislative/Legal Defense Fund: Defending Community Pharmacy

What does LDF do?

The LDF **funds** NCPA's **federal** and **state government affairs** activities **on your behalf.**

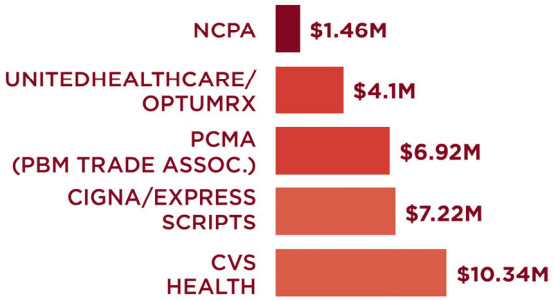
Community pharmacy is subject to pervasive federal regulation. The government plays the **leading** role in reimbursement policy for Medicare and Medicaid patients.

NCPA's **Legislative/Legal Defense Fund (LDF)** funds all of NCPA's **advocacy work on behalf of community pharmacies**. From the White House, to the US Capitol, to the State House to the Court House, the **NCPA LDF is at work for you fighting for pharmacy DIR reform**, **fair and transparent** reimbursements, and a **fair marketplace free from PBM steering** .This all **requires significant resources**, but **if every community pharmacist invested $100/month** into the LDF, we'd have a **significant** war chest to **rival the PBMs**.

Running an **effective** legislative and regulatory affairs program can be **quite costly.**

A fully-funded government affairs operation **is necessary to keep the tide turning** in our favor and can cost over **$3 million** a year.

The health care industry alone spends $300+ **million annually on lobbying.**



Despite being outspent, NCPA and the **grassroots efforts of members stopped giant PBM initiatives.**

NCPA® LDF
LEGISLATIVE/LEGAL DEFENSE FUND

If you have any questions or want to learn more about the NCPA LDF **please visit our website ncpa.org/ldf or email ldf@ncpa.org.**

Recent Pharmacy Visits by Elected Officials

Senate Finance Committee Chairman Ron Wyden, (D-Ore.) visits NCPA President Michele Belcher at Grants Pass Pharmacy

Rep. Cathy McMorris Rodgers (R-Wash.), Ranking member of the House Energy & Commerce Committee and NCPA SVP of Government Affairs, Karry La Violette visit owner Jeff Bray at MedQuest Pharmacy

Gov. Roy Cooper (D-N.C.) receives vaccination at Health Park Pharmacy

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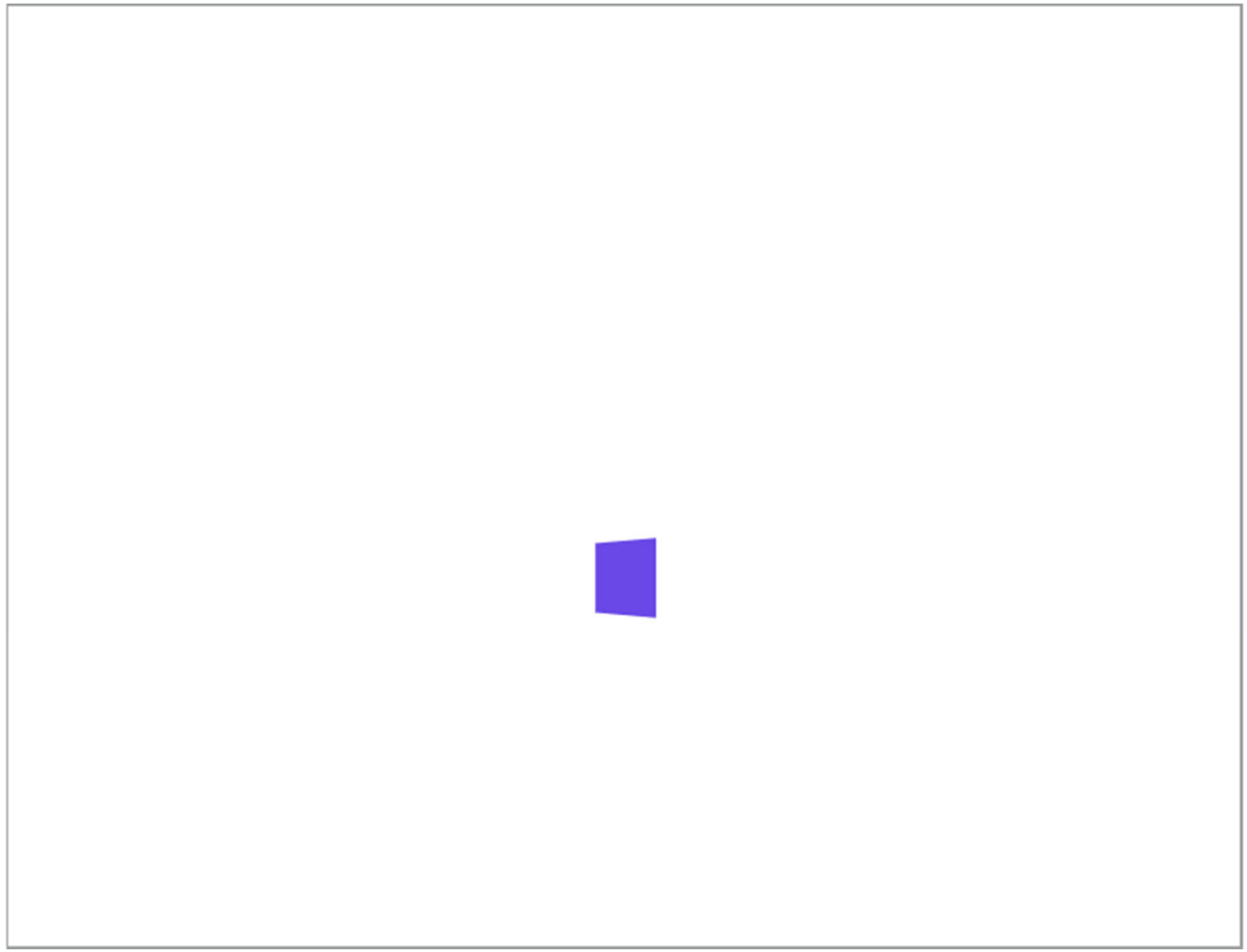

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