Health Care Policy For Today's Oncologist

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MSH and The US Oncology Network

Dell Medical School at The University of Texas at Austin

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Creating Aha! Moments In Healthcare

Agenda

Federal

- IRA
- CMMI Demo Announcement
  - Part B Demo on Accelerated Approval Drugs coming soon: potential reimbursement cuts
  - Medicaid Demo on Cell & Gene Therapy coming soon
- Part D Protected Classes
  - CMS Deputy Administrator Jon Blum implies 6PCs are safe, for now
- PBMs
  - Senate Commerce Hearing
  - Bills introduced
- EOM
  - The latest

State

- Biomarkers
- Access
- Prior Authorization
- PBMs

Federal Policies

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IASLC INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER
Conquering Thoracic Cancers Worldwide

Inflation Reduction Act 2022

The prescription drug provisions included in the Inflation Reduction Act will

- Require the federal government to negotiate prices for some drugs covered under Medicare Part B and Part D with the highest total spending, beginning in 2026
- Require drug companies to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries, beginning in 2023
- Cap out-of-pocket spending for Medicare Part D enrollees and make other Part D benefit design changes, beginning in 2024
- Limit monthly cost sharing for insulin to $35 for people with Medicare, beginning in 2023
- Eliminate cost sharing for adult vaccines covered under Medicare Part D and improve access to adult vaccines in Medicaid and CHIP, beginning in 2023
- Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program, beginning in 2024
- Further delay implementation of the Trump Administration's drug rebate rule, beginning in 2027

CMMI: Report on Models for Testing in Response to the EO on Lowering Prescription Drug Costs for Americans

Feb. 14, 2023: Department of HHS released "A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans" (link), intended to lower drug costs, including new Medicare coverage options for drugs cleared under accelerated approval.

Area	Model	Test Question	Design
Medicare Part D	**Medicare High-Value Drug List** 	What is the impact of standardizing the Part D benefit for high-value generic drugs on beneficiary affordability, access, health outcomes, and Medicare spending?	Part D plans would be encouraged to offer a low, fixed co-payment across all cost-sharing phases of the Part D drug benefit for a standardized Medicare list of generic drugs.
Medicaid	**Cell & Gene Therapy Access** 	Does a CMS-led approach to administering outcomes-based agreements for certain cell and gene therapies improve beneficiary access and equity and reduce health care costs?	State Medicaid agencies would assign CMS to coordinate and administer multi-state outcomes-based agreements with manufacturers for certain cell and gene therapies.
Medicare Part B	**Accelerating Clinical Evidence** 	Do targeted adjustments in Part B fee-for-service payments for drugs approved by the Food and Drug Administration (FDA) under the accelerated approval pathway improve timely confirmatory trial completion and reduce Medicare spending, while maintaining or improving quality of care?	CMS would develop payment methods for drugs approved under accelerated approval, in consultation with FDA, to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data.

Potential New Areas of Interest

- In addition to three selected for testing, CMMI highlights areas for additional research:
  - Accelerating Biosimilar Adoption
  - Data Access Changes to Support Price Transparency
  - Cell & Gene Therapy Access in Medicare Fee-for-Service

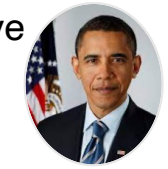
Next Steps

- Secretary directs CMS to begin developing the Part B Accelerating Clinical Evidence Model and the Medicaid Cell & Gene Therapy Access Model in 2023
- Secretary gives further direction to launch the CGT Access model as early as 2026
- Report noted CMMI may use rulemaking for feedback

Part D's Six Protected Classes:
Not Longer a Risk in the Biden Administration?

The following threats were never finalized/implemented due to significant stakeholder pushback

2014



- CMS proposed to remove protected status from:
  - Antidepressants
  - Antipsychotics
  - Immunosuppressants classes

2018

- CMS proposed to allow plans to exclude protected-class drugs from their formularies if list price increases in the previous 3 years outpaced CPI-U

2021

- **Jan. 19**: CMMI announced that in 2022 plans participating in the Part D Modernization Model could:
  - Treat 5 of the 6 Protected Classes (anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics) as they would other Part D drug classes
  - Cover only 1 drug per class instead of 2
- **March 16**: CMMI reversed course; announced it would not move forward with the changes

Despite speculation about CMMI efforts to address the six protected classes, at the Feb. 13 Biopharma Congress, **CMS Deputy Administrator Jon Blum** responded to questions about CMS/CMMI plans to make changes to the 6 Protected Classes.

- Blum said **Congress has made it clear that they want these classes protected and "we have to respect Congress…. this is settled policy for Congress and CMS, and for the country."**

Pharmacy Benefit Managers

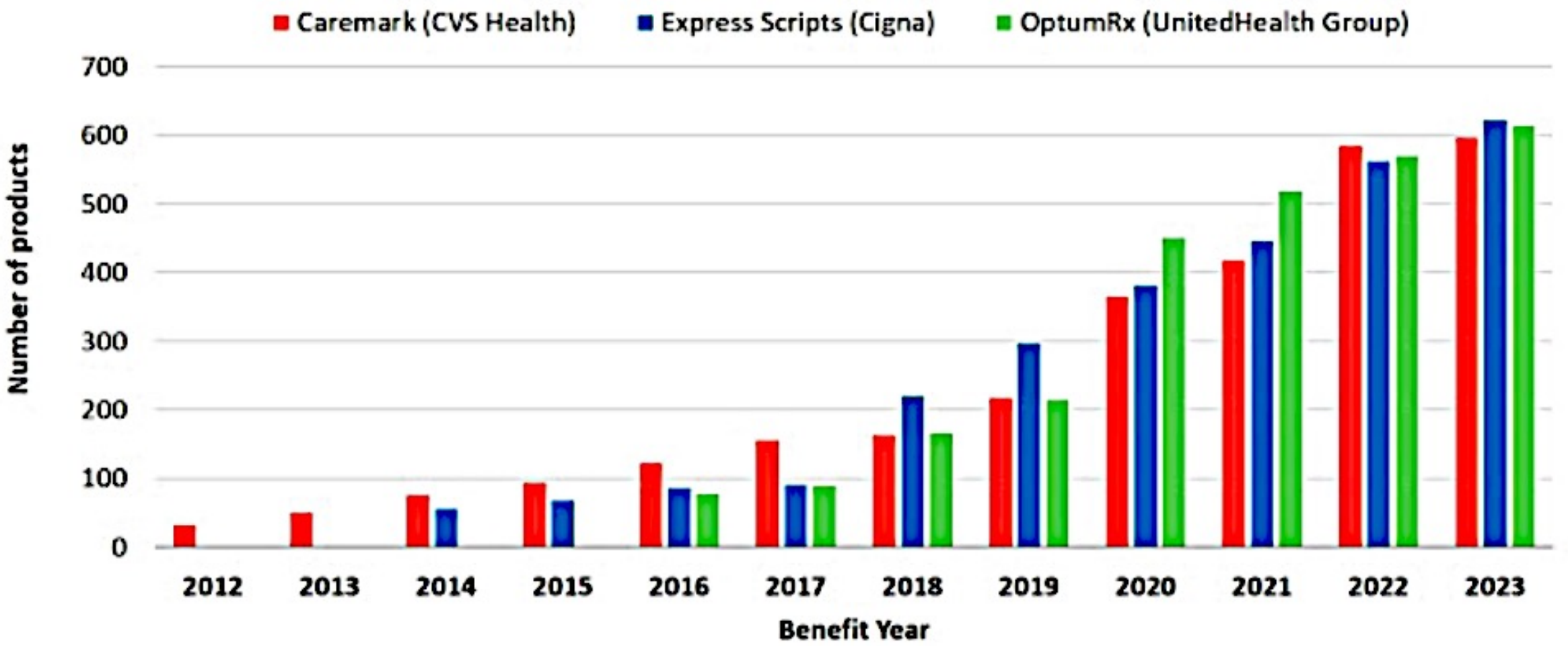
Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2022

1. In September 2022, CVS Health announced its acquisition of Signify Health. The transaction is expected to close in 2023.
2. Since January 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Prime for mail and specialty pharmacy services. On Dec. 31, 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest in AllianceRx Walgreens Prime, so this business has no PBM ownership in 2022. Effective June 2022, the company has been known as AllianceRx Walgreens Pharmacy.
3. In 2021, Centene has announced its intention to consolidate of all PBM operations onto a single platform and outsource its PBM operations to an external company.
4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
6. Cigna also partners with providers via its Cigna Collaborative Care program.
7. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. In 2022, Kindred at Home was rebranded as CenterWell Home Health.

Source: [The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](), Exhibit 212. Companies are listed alphabetically by insurer name. Published on Drug Channels (www.DrugChannels.net) on October 18, 2022.

DRUG CHANNELS INSTITUTE

Number of Products on PBM Formulary Exclusion Lists, by PBM, 2012 to 2023



Source: Drug Channels Institute analysis of company reports; Xtenda. Note that some data have been restated due to midyear additions to exclusion lists. Express Scripts did not publish exclusion lists before 2014. OptumRx did not publish exclusion lists before 2016. Note that PBMs may exclude many of the same medications, so certain products may appear on multiple lists.

Published on *Drug Channels* (www.DrugChannels.net) on January 10, 2023.

Senate Commerce Hearing: PBM Transparency and Accountability

U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE, & TRANSPORTATION

TEXAS LUNG CANCER CONFERENCE AUSTIN 2023

Feb. 16, 2023: Senate Committee on Commerce, Science, and Transportation held a hearing (link) titled, “Bringing Transparency and Accountability to Pharmacy Benefit Managers.”

Witnesses

- Debra Patt, MD, PhD, MBA, Oncologist, Texas Oncology

- **Ryan Oftebro**, PharmD, FACA, CEO of Seattle-based independent pharmacy Kelley-Ross Pharmacy Group

- **Erin Trish**, PhD, Co-Director, Leonard D. Schaeffer Center fo Health Policy, USC

- **Casey Mulligan**, Program Director of The Initiative on Enabling Choice and Competition in Healthcare, University of Chicago

PBM Transparency	DIR Fees/Clawbacks	Consolidation/Vertical Integration with Health Insurers	Care Delays & Drug Wastage	Rebates	Drug Pricing
• Senators Grassley (R-IA), Cantwell (D-WA), Warnock (D-GA), and Klobuchar (D-MN) stated their support for the PBM Transparency Act of 2023 (link). • Sen. Cruz (R-TX) does not support the PBM Transparency Act, citing concerns over giving the FTC more authority. • Sen. Tester (D-MT) said that holding pharmaceutical companies accountable is not reasonable as there is no transparency in PBMs. • Sen. Hickenlooper (D-CO) highlighted on the importance of PBM transparency, remarking on the importance in knowing where the money is going.	• Sen. Welch (D-VT) said that clawbacks are a rip-off for the local pharmacist, crushing the ability for pharmacists to help those in their community. • Sen. Grassley (R-IA) mentioned that PBMs claim to pass on savings to consumers or through lowering premiums, but their pricing and clawback tactics prove otherwise.	• Sen. Cantwell (D-WA) opposes the concentration of power among the largest PBMs. • Dr. Trish (USC) commented on how there has been a considerable degree of integration in the PBM industry resulting in the three biggest PBMs to be integrated or owned by a health plan or health insurer. • Dr. Patt (Texas Oncology): “Due to the power of the top PBMs, the majority of oral cancer drugs... are steered by the PBMs to their corporate-affiliated specialty mail order pharmacies. PBMs tell you that this is a cost saving measure, but in reality it allows them to effectively control the practice of medicine. We urgently need PBM transparency and accountability.”	• Dr. Patt (Texas Oncology): “PBMs frequently delay and detour appropriate and timely therapy for patients. This is difficult to anticipate and limit a doctor’s ability to effectively control cancer, and delays can lead to poorer disease control, morbidity, and mortality.” • Dr. Patt (Texas Oncology): “When patients receive oral cancer drugs at our office-based medically integrated pharmacy, we can see a patient, check labs, and made dose modifications prior to the refill. That does not happen when the drug is filled by a PBM vertically integrated specialty mail order pharmacy. Routine refilling usually happens from PBMs at the same dose, without real time modifications. This leads to wastage of a month’s supply or the patient taking the incorrect dose that will make the therapy more toxic. For Verzenio (abemaciclib), that could result in >$10,000 of waste per month.”	• Dr. Trish (USC) said that rebates drive a wedge between a drug’s list price and its net price and that increasing rebates are one of the key drivers of increasing list prices over time. • She also noted PBMs have deflected blame for rebate practices by passing through most of the rebates they collect to health plans, who may then use them to keep premiums low for beneficiaries.	• Sen. Warnock (D-GA) cited a recent article (link) on NPR stating that manufacturers have increased the price of insulin by more than 600% in the last two decades. • Sen. Klobuchar (D-MN) stated that her bill with Sen. Grassley (R-IA), the Preserve Access to Affordable Generics and Biosimilars Act (link), passed out of the Judiciary Committee for a second time last week. • Dr. Trish (USC) pointed out that over time, PBMs have been seen to be effective at lowering the net prices that insulin manufacturers are receiving.

Source: ADVI Memo (link)

Growing interest in PBMs

Prices paid at the pharmacy are drawing congressional scrutiny.
PHOTO: GABBY JONES FOR THE WALL STREET JOURNAL

https://www.wsj.com/articles/drug-prices-investigation-focused-on-middlemen-opens-in-congress-f5a7fd25?st=v2tayisx7ybsde4&reflink=desktopwebshare_permalink

Drug-Prices Investigation Focused on Middlemen Opens in Congress

Panel asks CVS Caremark and other pharmacy-benefit managers about fees

PBM Investigation and Transparency Bills

Pharmacy Benefit Manager Transparency Act (S. 127)

- Sponsored by Sen. Cantwell and co-led by Sen. Grassley
- **Makes it illegal for PBMs to engage in "spread pricing", in which they charge health plans and payers more for a prescription drug than what they reimburse to the pharmacy, and pocket the difference-the "spread"-as profit**
- Prohibits PBMs from increasing fees or lowering reimbursements to offset reimbursement changes in federally-funded health plans
- Authorizes the FTC and state attorneys general to enforce its mandates, including by seeking civil penalties from PBM companies for each violation, plus an extra penalty of up to $1 million
- Protects whistleblowers from being fired or reprimanded for bringing violations to light

Prescription Pricing for the People Act (S. 113)

- Sponsored by Senators Grassley, Cantwell, Blackburn, Blumenthal, Braun, Capito, Lankford, Tillis, Tuberville
- **Directs the FTC to issue a report within one year** addressing whether PBMs:
- Charge certain payers, including Medicare and Medicaid, a higher price than reimbursement rates for competing pharmacies while reimbursing pharmacies in which the PBMs have an ownership interest at the rate charged to payers; Steer patients to pharmacies in which the PBM has an ownership stake;
- Audit or review proprietary data of pharmacies not owned by the pharmacy benefit manager and use such data for competitive advantage
- Use formulary designs to depress the market share of low-cost, lower rebate prescription drugs

COA in Support

- "COA strongly supports the two bills and commends the Senators for taking this latest important step to rein in abusive PBM practices that are increasingly crippling our healthcare system. For too long, unchecked PBM consolidation and deceptive practices have had a negative impact on patients, physicians, employers, pharmacies, and our entire health care system"

Jan. 31, 2023: S.127 Legislative Text (link), S.127 Summary (link), S.113 Legislative Text (link), S.113 Summary (link), COA (link)

Enhancing Oncology Model (EOM)

CMMI Announced 6/27/22

EOM

Next iteration of OCM based on 6 years of shared learnings

5 year

program starting July 1, 2023

Promotes private payers to engage CMMI & participants

Participation

- *Open application process*
- *Voluntary participation*
- *Selection & agreements winter/spring*

8 Required Redesign Activities

6 redesign activities are identical to OCM

2 new activities:

- *Identify beneficiary health-related social needs using a health-related social needs screening (HRSN) tool*
- *Gradually implement electronic patient reported outcomes (ePROs)*

EOM Concepts of Change

Patient Navigation*

Practice Reported & Claims Based Quality Measures

Patient Experience, Social Needs* & Health Equity*

Institute of Medicine Care Management Plan*

24/7 Access to Care*, ePROs*, & CEHRT*

Total Cost of Care

Drug Utilization & Evidence-based Pathways*

State Policies

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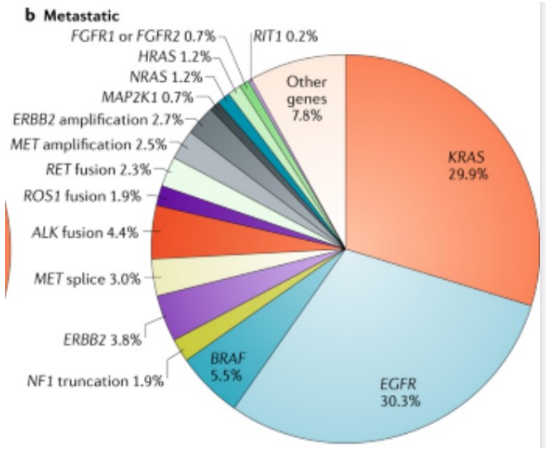
State Policies

Biomarkers	PBMs	Access	Prior Authorization



Skoulidis, Nature Reviews Cancer, 2019

Thank you!
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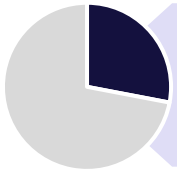
McKESSON
Alcohol Prep P
STERILE | SATURATED WITH
70% v/v ISOPROPYL ALCOHOL
M
MEDIUM
1
PREP PAD
1.2" x 2.6"
(3 cm x 6.5 cm)

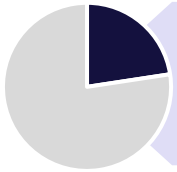
- **Appendix**

Accelerated Approval: Background & Timeline Context

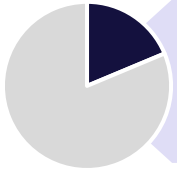
Percent of Drugs Approved via Accelerated Approval



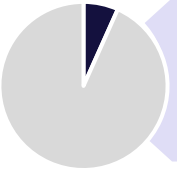
2021
28% (14 of 50 drugs)



2020
22.6% (12 of 53 drugs)



2019
18.7% (9 of 48 drugs)



2018
6.7% (4 of 59 drugs)

Time from Accelerated Approval to Traditional Approval

No specific timeline required

- FDA regulations do not stipulate a specific timeline for conversion to traditional approval
- Manufacturers are required to complete trials with "due diligence" and provide annual reports to HHS

Average timeline varies by indication

- Non-oncology indications
  - FDA granted AA to 48 drugs for 57 non-oncology indications from 1992 to 2018 with a median time to regular approval of 4.4 years
- Oncology indications
  - FDA granted AA to 64 malignant hematology and oncology products for 93 new indications between Dec. 1992 - May 2017, with a median time to verified benefit of 3.4 years

Average timeline: 2.5 years

- Average time to confirm clinical benefit for drugs that converted from AA to traditional approval between Dec. 1992 – Dec. 2021:
  - 2012-2021: 2.5 years
  - 1992-2011: 5 years
- Since Dec. 1992: half of AA drugs converted to traditional approval in a median time of 3.2 years
- As of Dec. 2021: FDA has converted 50% of AA to traditional approval

Time span can vary widely

- In some cases, manufacturers can use the same trial used to show a surrogate endpoint to show clinical benefit (i.e., HIV treatment: viral load (surrogate) could be shown in 24 weeks and viral load suppression (clinical) could be shown in 1 year)
- ADVI's review of AA drugs:
  - **Shortest conversion: 5.5 months** (Pharmacyclics/Abbvie: Imbruvica)
  - **Longest conversion: 17.6 years** (Genzyme/Sanofi: Clolar)

Sources: 21 CFR 314.510 (link); 21 U.S. Code § 356b (link); Regulatory Focus (link); CDER 2021 Report (link); Beakes-Read et al., 2022 (link); Omae et al., 2022 (link); Beaver et al., 2018 (link); FDA Guidance (link); FDA Accelerated Approval CDER/CBER Reports (link)