Human Services Committee Extreme Cost Drugs

- January 11, 2022
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NORTH Dakota | Human Services

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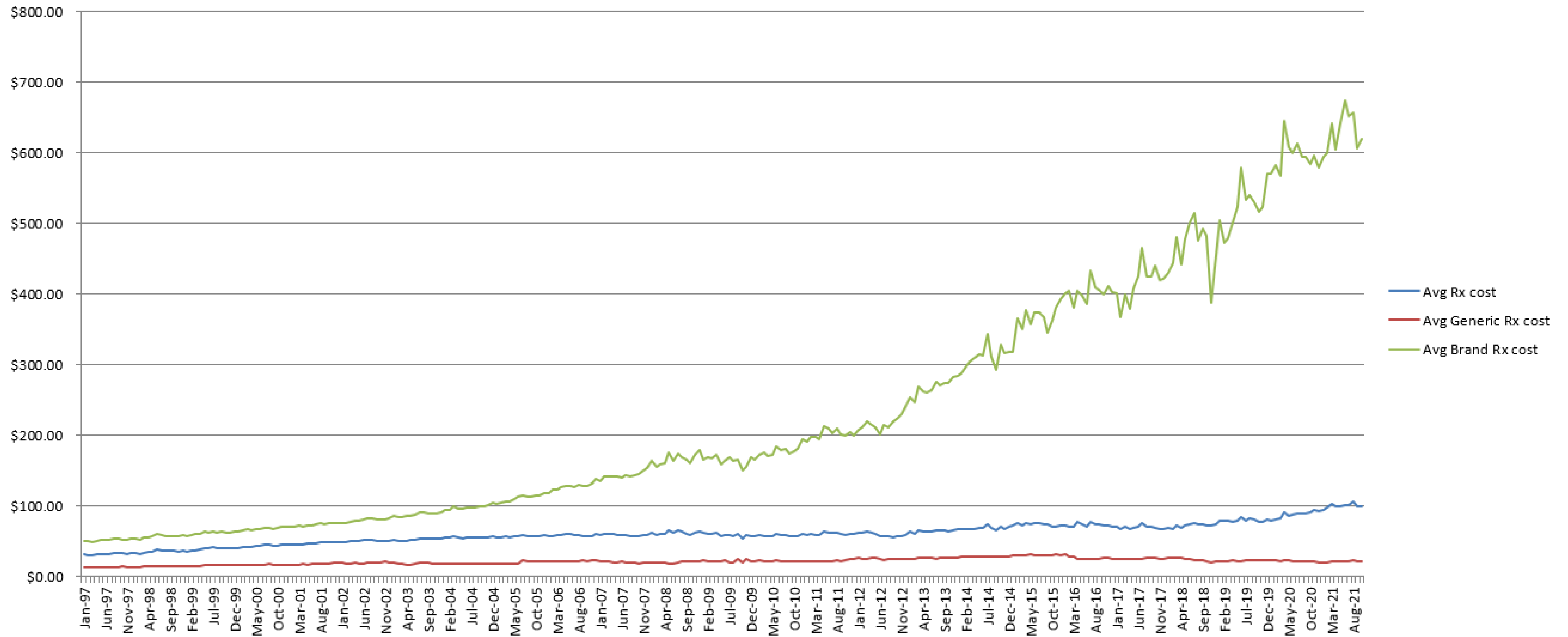
History

- Omnibus Budget Reconciliation Act of 1990 created the modern Medicaid prescription drug program
  - Medicaid Drug Rebate Program
  - Covered Outpatient Drug definition
- State Medicaid prescription drug programs
  - Required to cover FDA approved drugs for all manufacturers who have a signed Medicaid drug rebate agreement
  - Doesn’t matter if drug is orphan drug designation, accelerated approval, biologic, or otherwise; if it is approved by the FDA, Medicaid must pay

History – things have changed since OBRA ‘90



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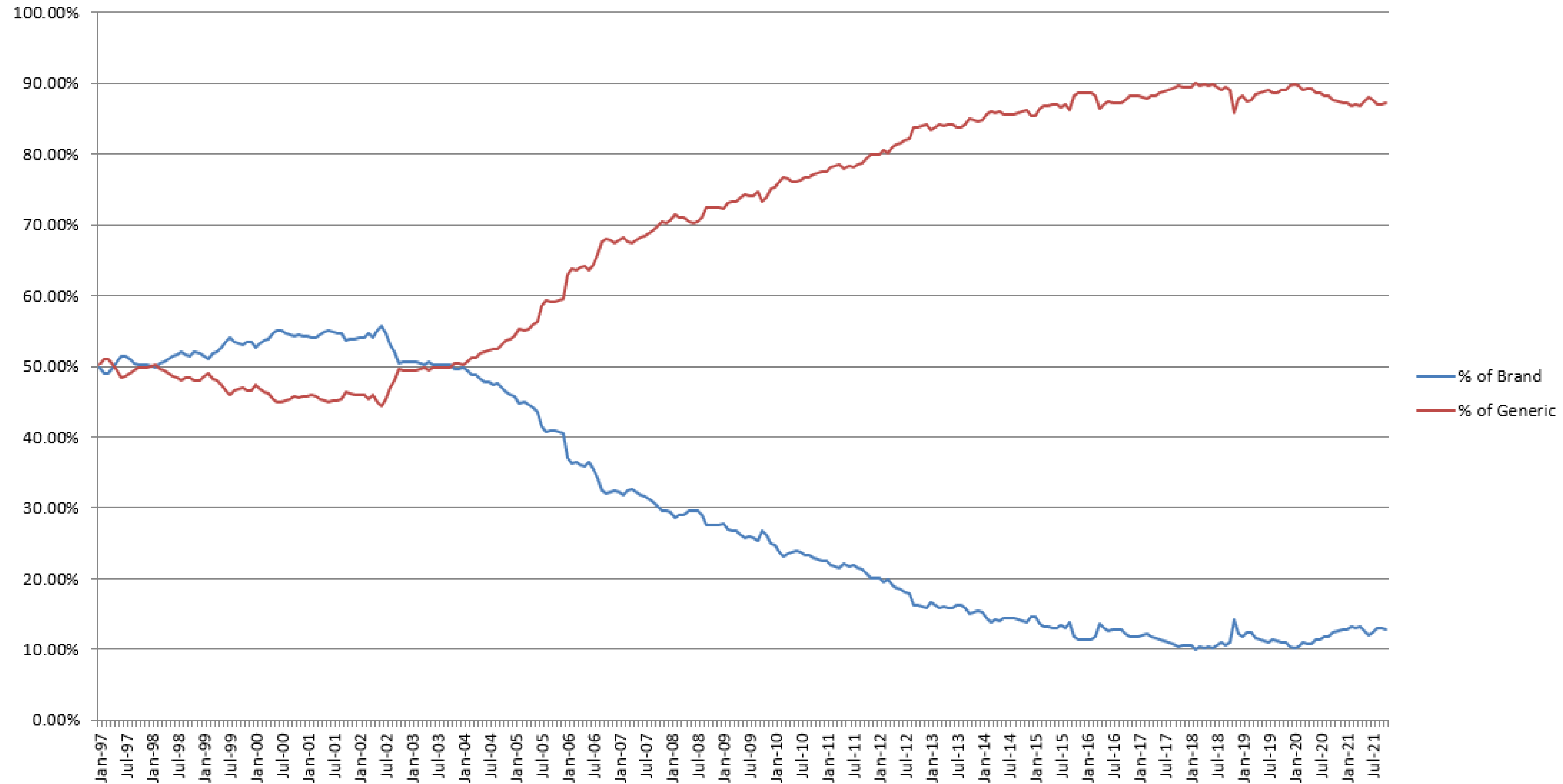


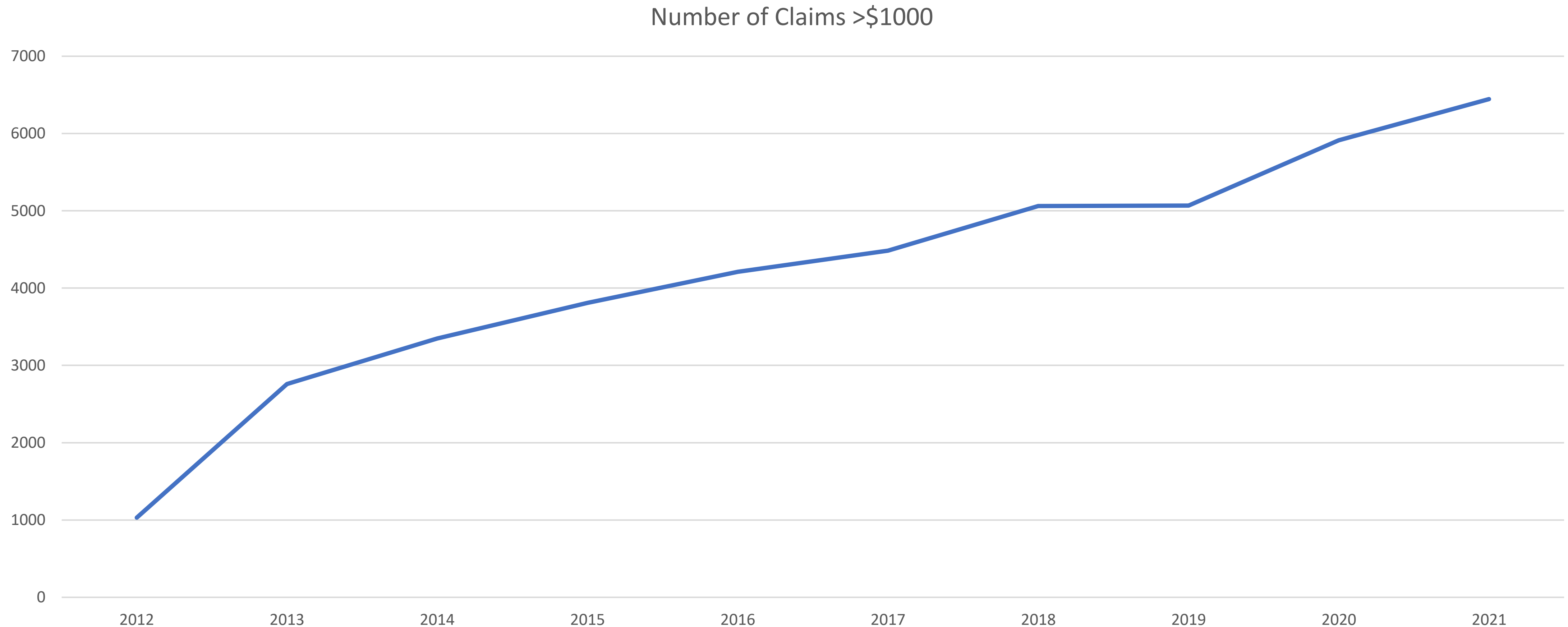
Extreme Cost Drugs

- There is no definition or actual category
- Any attempt to categorize tends to need adjustment quickly
- 1991 most expensive drug was $150,000 a year (Ceredase)
- 2010 $400,000 a year (Soliris)
- 2018 $624,000 a year (Actimmune)
- 2021 ND Medicaid paid $2.125 million for one drug claim (Zolgensma)

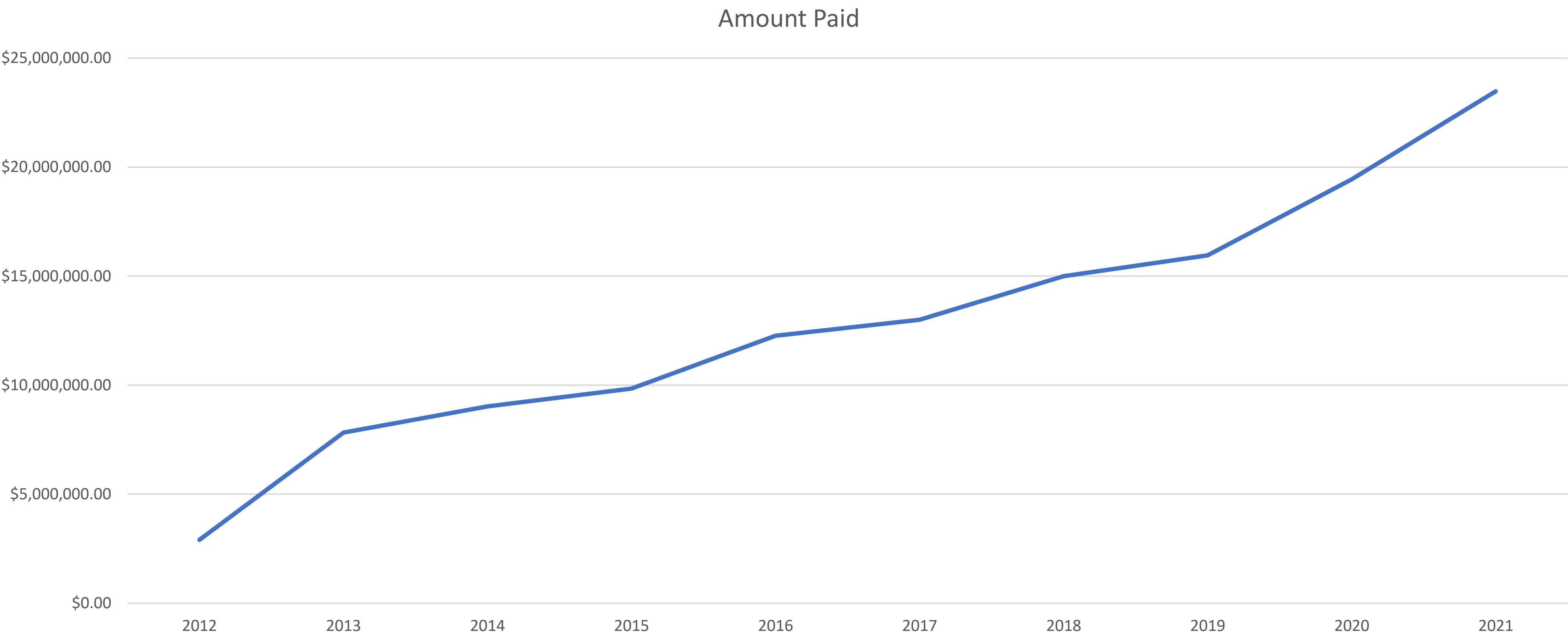
Current Extreme Cost Drugs

- 7 patients on CF drugs (6 @ $24,000 a month, 1 @ $21,000 a month)
  - $1.98 million per year
- 11 patients on high cost chemotherapy (all > $13,000 a month)
  - $2.25 million annualized
- 5 patients on seizure drugs ($9,000 to $52,500 a month)
  - $1.6 million per year
- Others at $15,000 per month, $16,000 every 2 weeks, etc.
- New the past few weeks – patient on drug at $31,900 a month
- Nothing is surprising anymore

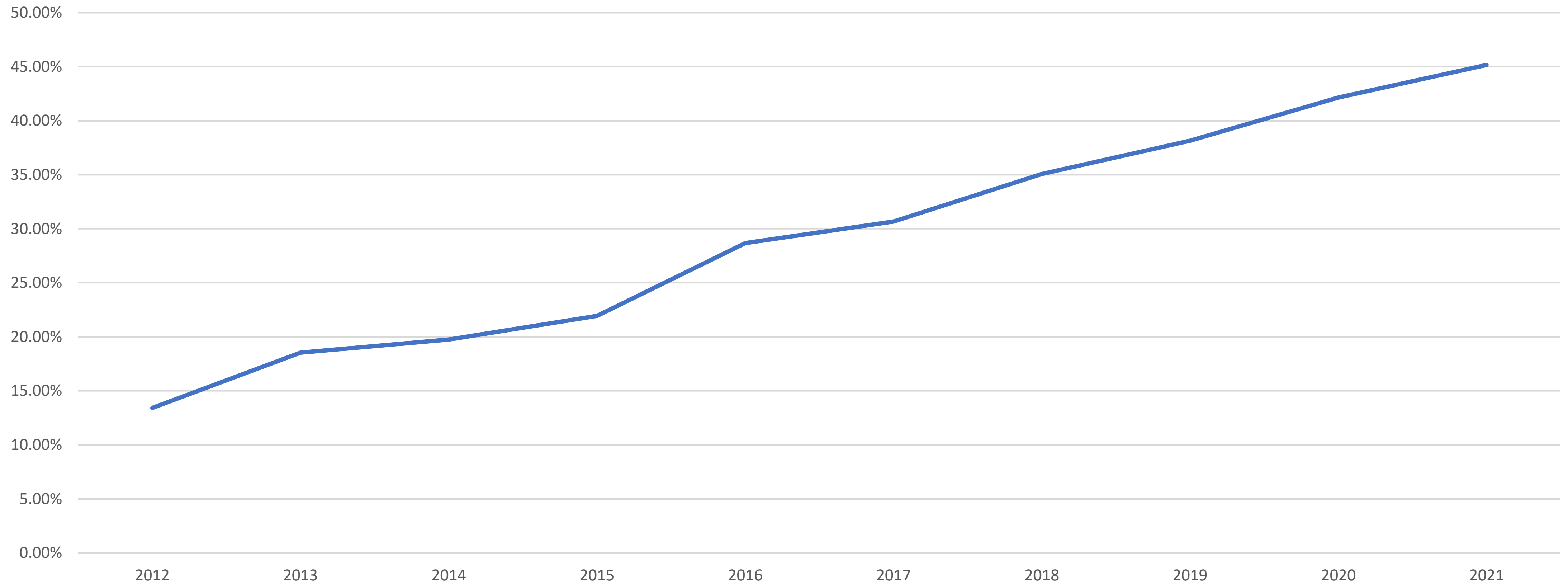
Volume of claims > $1000 (traditional Medicaid through most of November 2021)



Spend on Claims > $1000



Increasing Proportion of Pharmacy Spend



FDA Approval

- Prior to 1991, FDA approval only given if proven safe and effective
- With accelerated approval pathway in 1991, effectiveness no longer needed to be proven
  - Instead used surrogate endpoints that may hopefully predict that the drug will impact the disease in a positive way
  - Used for completely new drugs or new indications for existing drugs
- Lack of any proven efficacy hasn’t decreased demand from prescribers and families

FDA Approval – Accelerated Applications

- 40 approved 1992-1999 (2 haven't completed studies, 3 withdrawn)
- 61 approved 2000-2009 (2 haven't completed studies, 14 withdrawn)
- 93 approved 2010-2018 (41 haven't completed studies, 4 withdrawn)
- 75 approved 2019-June 2021 (1 withdrawn, 3 fully approved)
- Overall
  - 22 have been withdrawn (8.2%)
  - 116 have not completed required studies for full approval (43.1%)
    - Includes those whose follow-up studies have proven the medication is NOT effective for that indication but the FDA hasn't forced market withdrawal
  - 131 have received traditional approval after completing studies (48.7%)

Medicaid covers Accelerated Approval Drugs

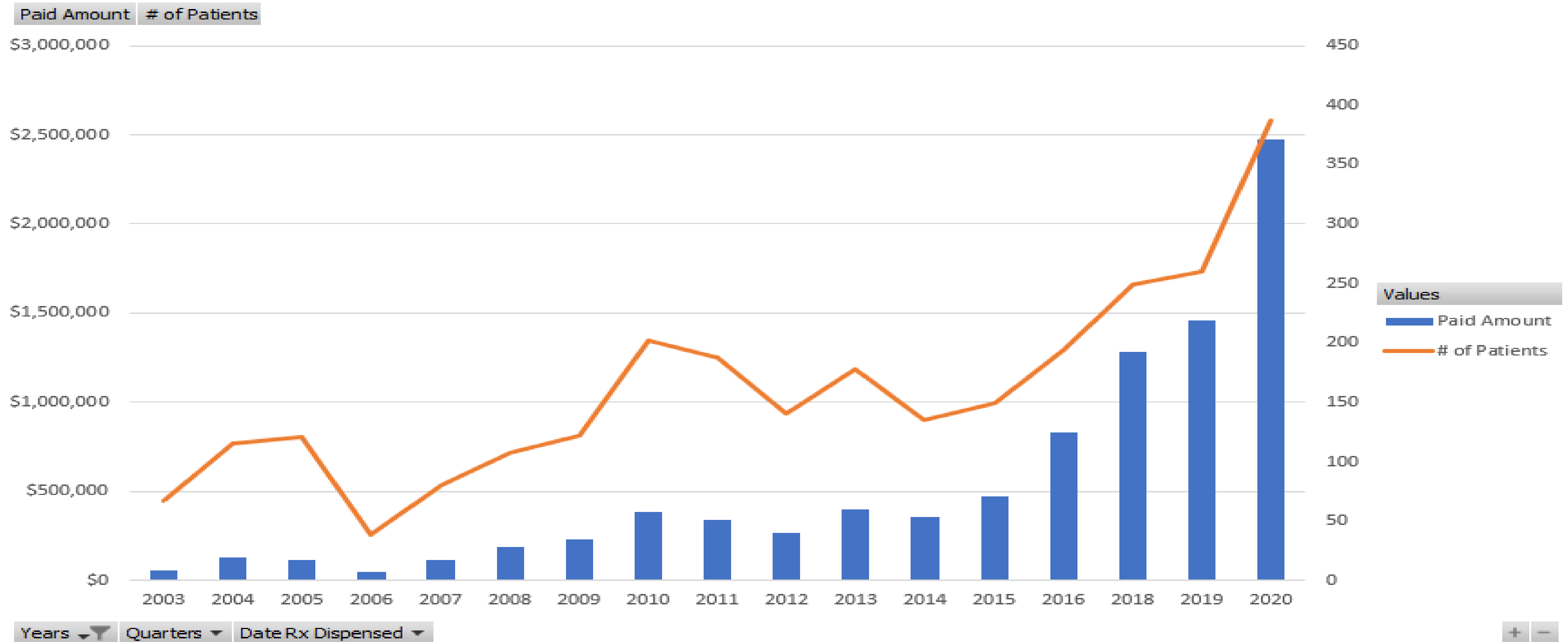
- Many cancer drugs
  - Keytruda accounts for 34 (12.6%) of all accelerated approvals
  - One Keytruda application since withdrawn and 6 converted to full approval
- Makena (prevent premature birth – has been proven to not be effective but FDA has not removed it from the market)
- Exondys (Duchenne Muscular Dystrophy)
- Aduhelm (Alzheimer’s)
- Other FDA approval options include Fast Track, Breakthrough, Priority Review, Orphan drug
  - Zolgensma, the $2.125 million drug for spinal muscular atrophy is all of these

Logic and Reason not being followed

- Medicaid is not reimbursed for all past expenditures if a drug is found to not be effective and then withdrawn (and sometimes NOT withdrawn)
  - Can only recoup if manufacturer is found to have obtained original accelerated approval through fraudulent means
- Value Based Purchasing – little incentive for manufacturers to come to a deal that results in less revenue for them
- Medications that (hopefully) stop disease progression are priced the same regardless of the patient's current disease progression
- Weight based medication pricing penalizes states for having an outlier
- Difficult for states to budget based on genetic prevalence
- Drug originally priced for small population doesn't adjust when population increases due to new or expanded indications

Humira – ever expanding indications

$1,178/Rx in 2003; $6,800/Rx in 2020 (min $5,400, max $16,680)



Risk

- Small budget states can be significantly impacted
  - One drug claim increased ND Medicaid's medical drug expenditures 84% quarter over quarter
- Genetic based diseases have higher prevalence in places where there are higher populations of those who are genetically predisposed
- Diseases with higher prevalence in colder climates cause northern tier states to be disproportionately affected
  - Copaxone for Multiple Sclerosis
    - $803/month in 2000
    - $7,114/month in 2020

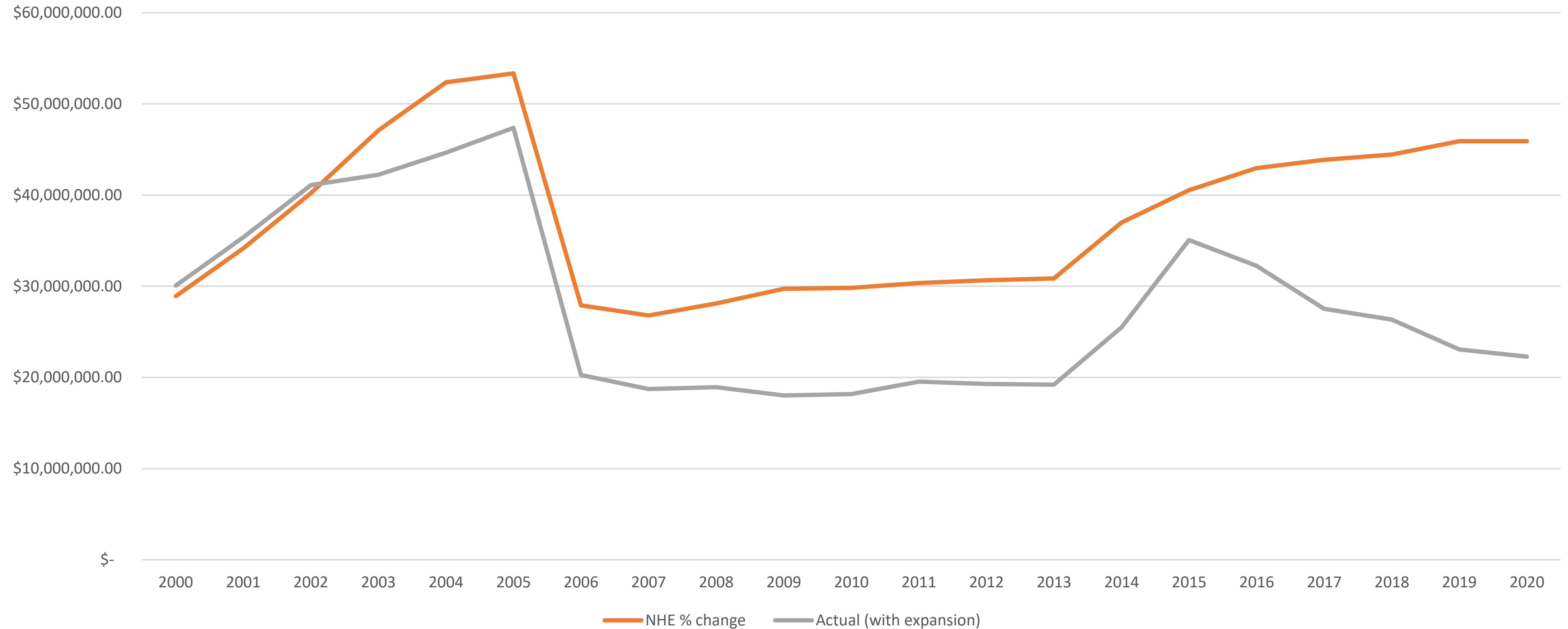
Solutions

- Congress
  - Centralize payment to minimize variability of risk to states
    - If there are only 100 people in the nation who have a genetic disease, and 20/100 live in ND because it happens most often in those of Scandinavian/German descent, ND shouldn't have to absorb those costs into their budget
  - Give FDA explicit authority and direction to remove medications from the market if they are proven ineffective
  - Remove approvals and force reimbursement for all payments if confirmatory trials are not completed timely
  - Force increased rebates when indications have expanded
- North Dakota
  - Ensure Medicaid has the flexibility to react quickly

How is ND Medicaid doing overall

- DHS works hard to be a leader in claim payment methodology leveraging Prospective Drug Use Review edits to ensure the best possible pharmaceutical care for our members
- If ND pharmacy growth matched National Health Expenditure (NHE) Medicaid pharmacy growth percentages historically since 1999, our net spend would have been $23.6 million higher for 2020*
  - *Understated as 2020 NHE growth rates not yet released so 0% growth was used

Pharmacy Growth NHE vs ND Medicaid



After Part D

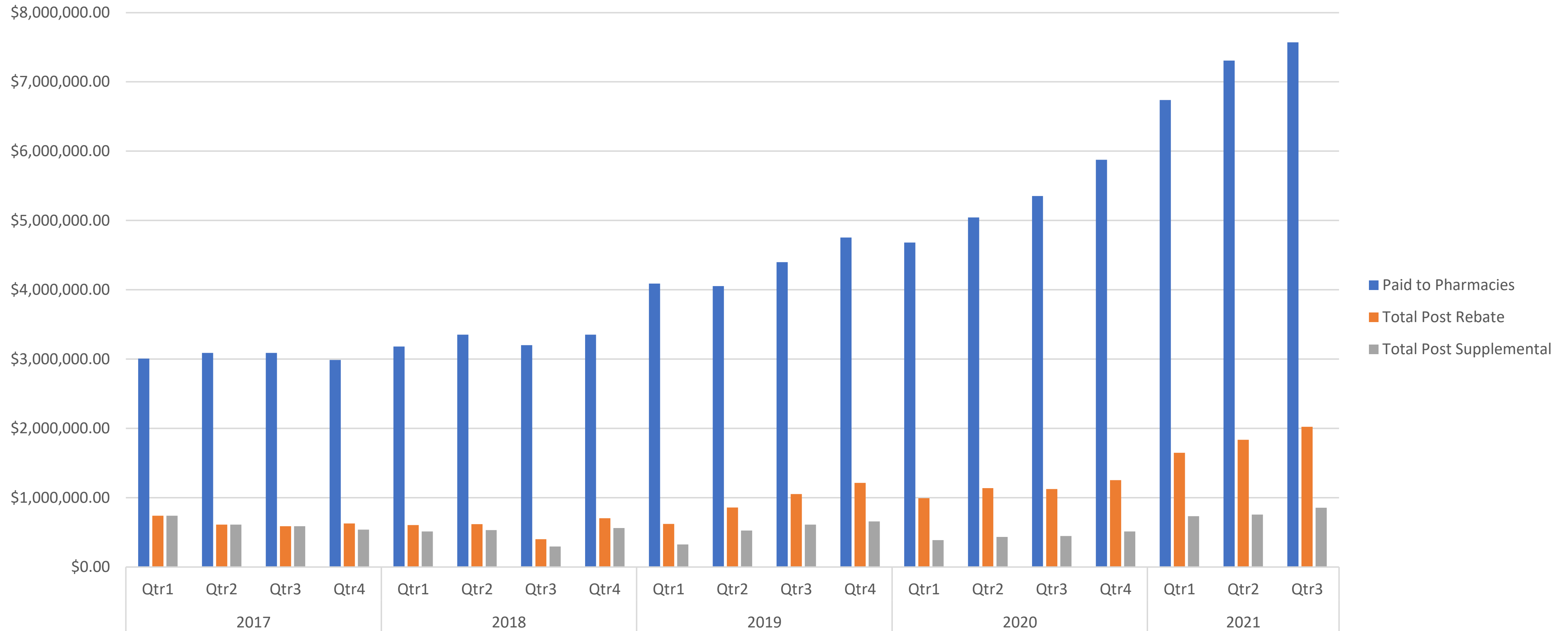
- Part D started in 2006
  - ND's drop in expenditures was larger than NHE due to high % of aged in ND and continuing program improvements
- 2007 through 2013, ND outperformed NHE % growth overall
  - $100 script in 2006 would have inflated to $110.54 vs $94.85 for ND Medicaid

Year	NHE % Growth	ND % Growth
2007	-4.0%	-7.6%
2008	4.9%	1.1%
2009	5.8%	-4.8%
2010	0.3%	0.8%
2011	1.8%	7.6%
2012	1.0%	-1.4%
2013	0.6%	-0.3%

Medicaid is Unique

- Federal law governs drug coverage
- Federal law governs drug rebates
- Rebate percent of spend was 21.5% in 2001 and 33.9% in 2007
- Rebate percent of spend was 72.1% in 2020
- Net spend traditional Medicaid 2007 (average 50,002 recipients)
  - $18.7 million
- Net spend traditional Medicaid 2020 (average 74,241 recipients)
  - $11.5 million

Medicaid is Unique – 19 classes Expansion



Final Thoughts

- Extreme cost drugs will continue to increase in volume and costs
- Congress likely won’t provide solutions
- Specialized staff and ability to manage the program (including system changes), and the legislative support for such, has led to ND Medicaid outperforming NHE growth
- ND Medicaid needs to continue to have the flexibility to react as needed

- Questions?