Merck vs. Pfizer:

Searching for the Superior Investment

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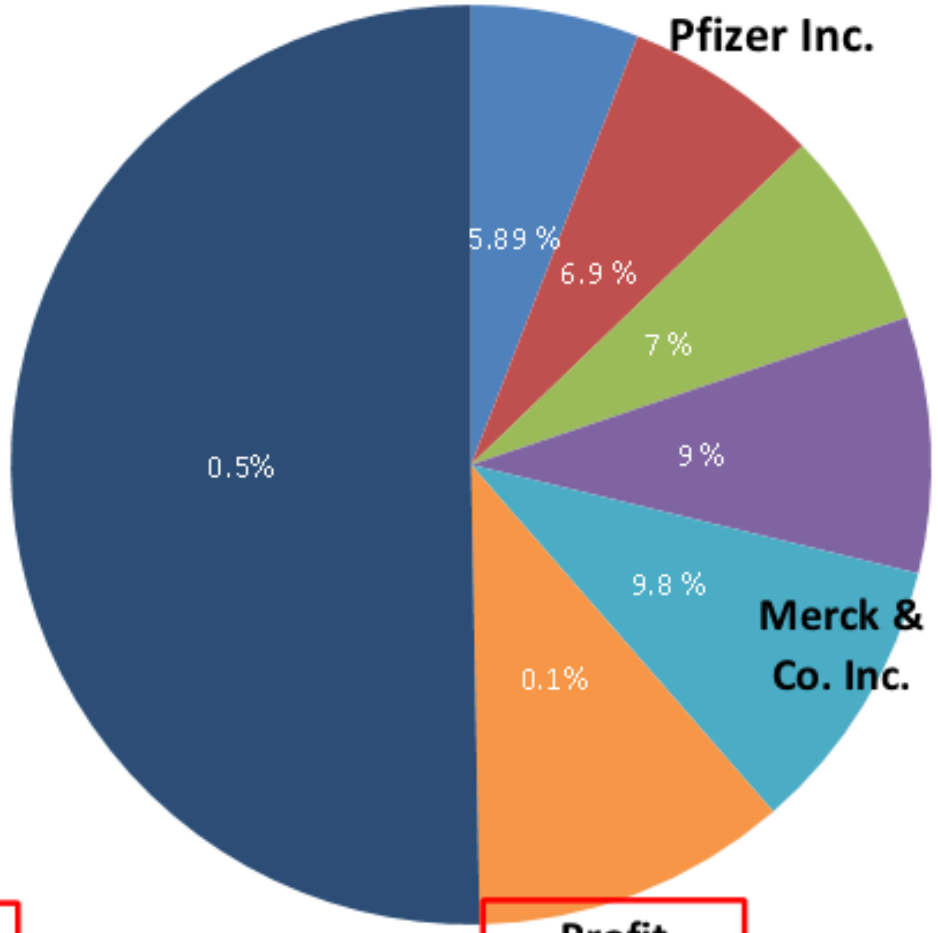
Major Players in Pharmaceutical Industry



Market Share %

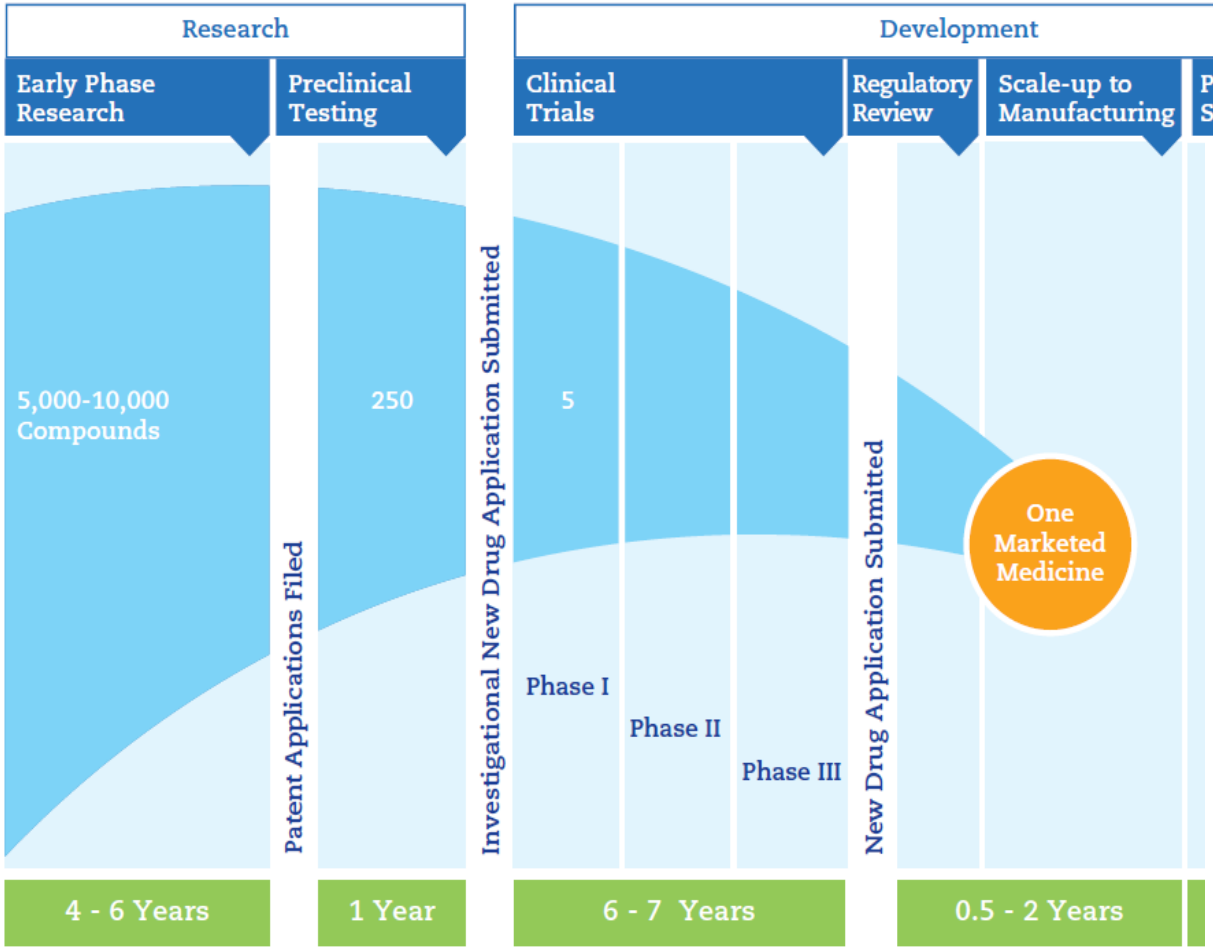
- Eli Lily & Co.
- Pfizer Inc.
- Abb Vie Inc.
- Merck & Co. Inc.
- Amgen
- J & J
- Others

Revenue
$158.7 B

Profit
$31.1 B

Annual Growth
$1.2- 1.5% %

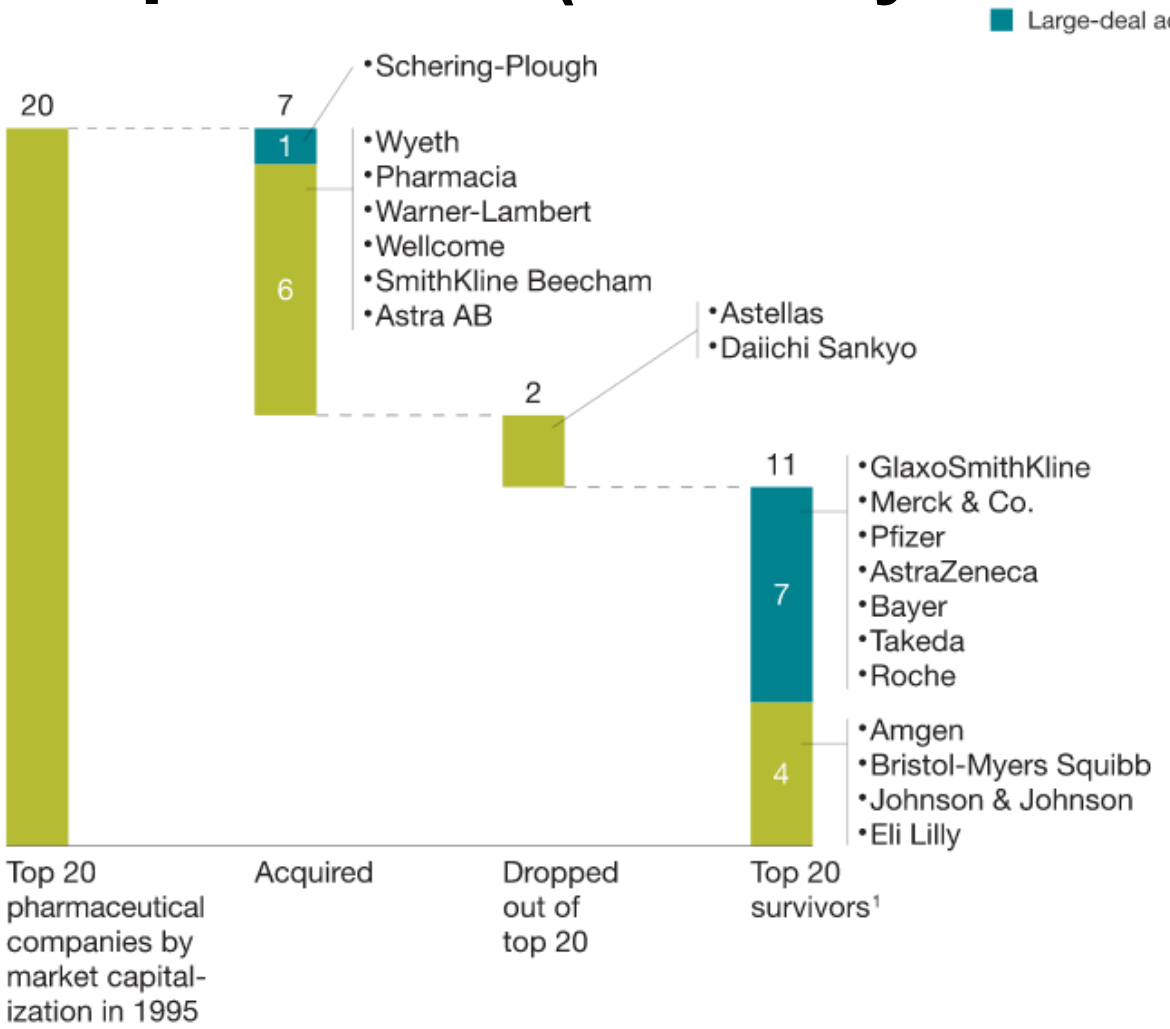
Research & Development



- 10-15 Years to develop
- 1975 - USD 138 million
- 2014 - USD 1.5 **BILLION**
- Very high per-Drug development cost
- Heavily Regulated
- 2011 - 35 new pharmaceuticals launched out of 3,200 compounds
- 2015 – Revenue to contract 0.4% due to high R&D costs
- Shifting to less lucrative or niche product segments
- 38 B – Phase III

HIGH Risk = HIGH Rewards

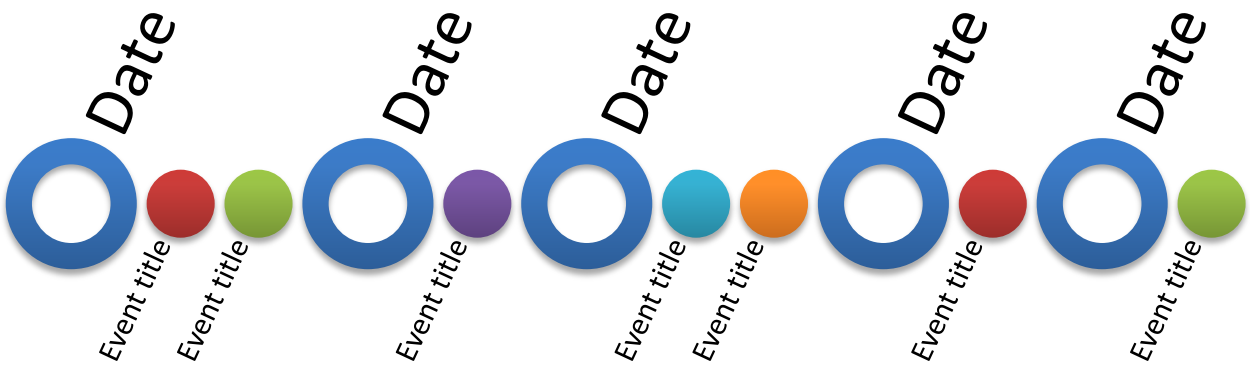
Acquisitions (Industry Consolidation)



- **High R&D costs**
- **Expectation of fast growth**
- **Keep up with Revenues**
- **Patent Cliff**
- **Addition to product portfolio**
- **Threat from generic and biosimilar products**
- **Diversification**
- **Stronger positioning in existing markets**
- **Enter new markets**
- **Cost savings through Synergies**

About Merck

- Jacob Friedrick Merck acquired The Angel Pharmacy in 1668 which led to the beginning of Merck & Co.
- Known as Merck in US and Canada
- Known as Merck Sharp & Dohme Corp (MSD) rest of the world
- Four Operating Divisions
- 7th largest Company in the Industry as per Revenue Ranking
- 2014 R&D Expense - $6.5 billion



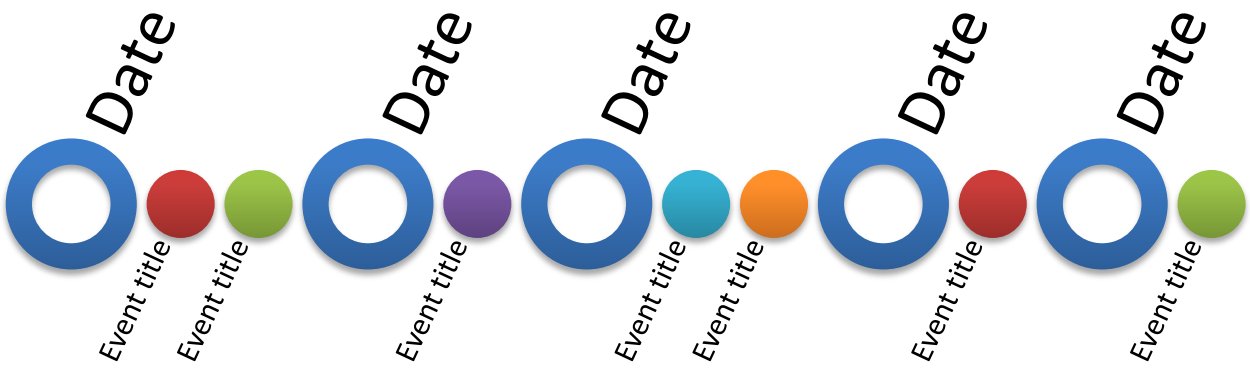
Merck's Acquisition Of Schering-Plough

Acquisition completed on November 3, 2009

Purchase Price	$49.6 Billion or $28.19 per SP common share
Cash/ Share Mix	$10.50 Cash and 0.5767 of SP share
Funding	Combination of Cash, Debt and Equity
Ownership	Old Merck - Merck Sharp & Dohme Schering-Plough – Merck & Co. Inc.
Products added	Pfizer originally 27 in phase III which increased to 34 after merger

About Pfizer

- Founded in 1849 and has been in the industry more than 150 years.
- Largest Biopharmaceutical Company (Giant)
- Nine principal operating divisions
- 4th largest Company in the Industry as per Revenue Ranking
- History of Acquisitions



Pfizer's Acquisition of Wyeth

- Acquisition completed on October 15, 2009

Purchase Price	$68.2 Billion or $50.40 per Wyeth CS
Cash/ Share Mix	$33.00 Cash and 0.985 of Pfizer share
Funding	Combination of Cash, Debt and Equity
Ownership	Wyeth – Wholly owned Subsidiary Pfizer – approx. 84% rest minority S/H
Products added	Pfizer originally 27 in phase III which increased to 34 after merger

Pfizer's Acquisition of Wyeth

Pfizer's Strategic Goals Advanced by Wyeth merger

Strong Positioning	Increased Product portfolio
New and Existing Markets	Enters the new Vaccines market – Prevnar Leader in Biologics - Enbrel
Complementary Business	Added Consumer and Nutritional divisions Strengthen Animal Health division
Financial Benefits	EPS Growth outpaced Revenue Growths Adj. Income and Diluted EPS Increased
Cost Savings	Expected savings due to synergies and combined workforce up to $4.0 B by 2012

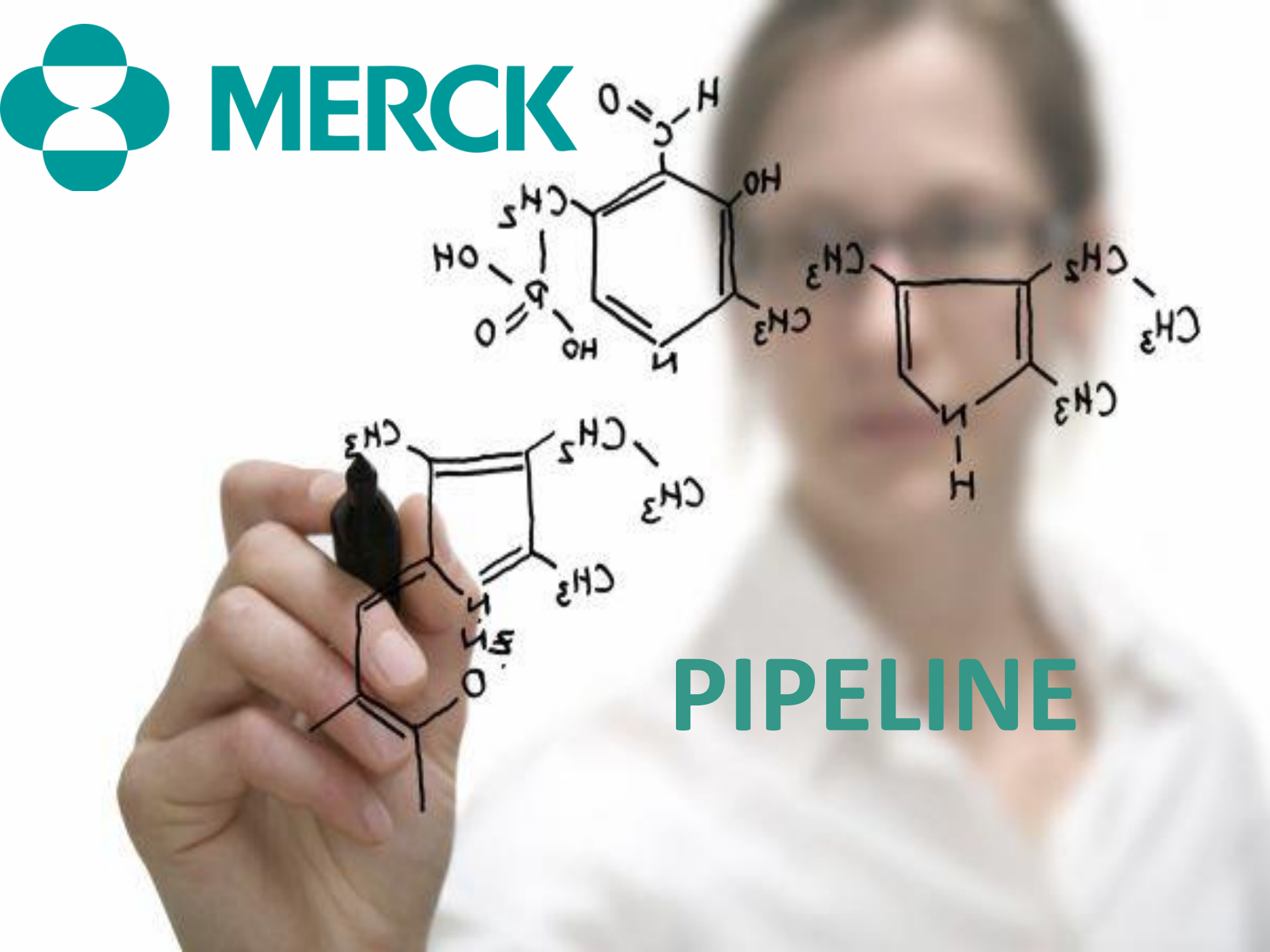
Merger delivered Value to Shareholders and Stakeholders

Areas of Analysis:

1. Pipeline Showdown
2. Research & Development (accounting focused)
3. Regulatory Compliance

Conclusion:

Final Investment Decision


MERCK
PIPELINE

Breakdown

1. Areas of Focus/Specialties

2. Current Products

3. Future Products/Drug Pipeline

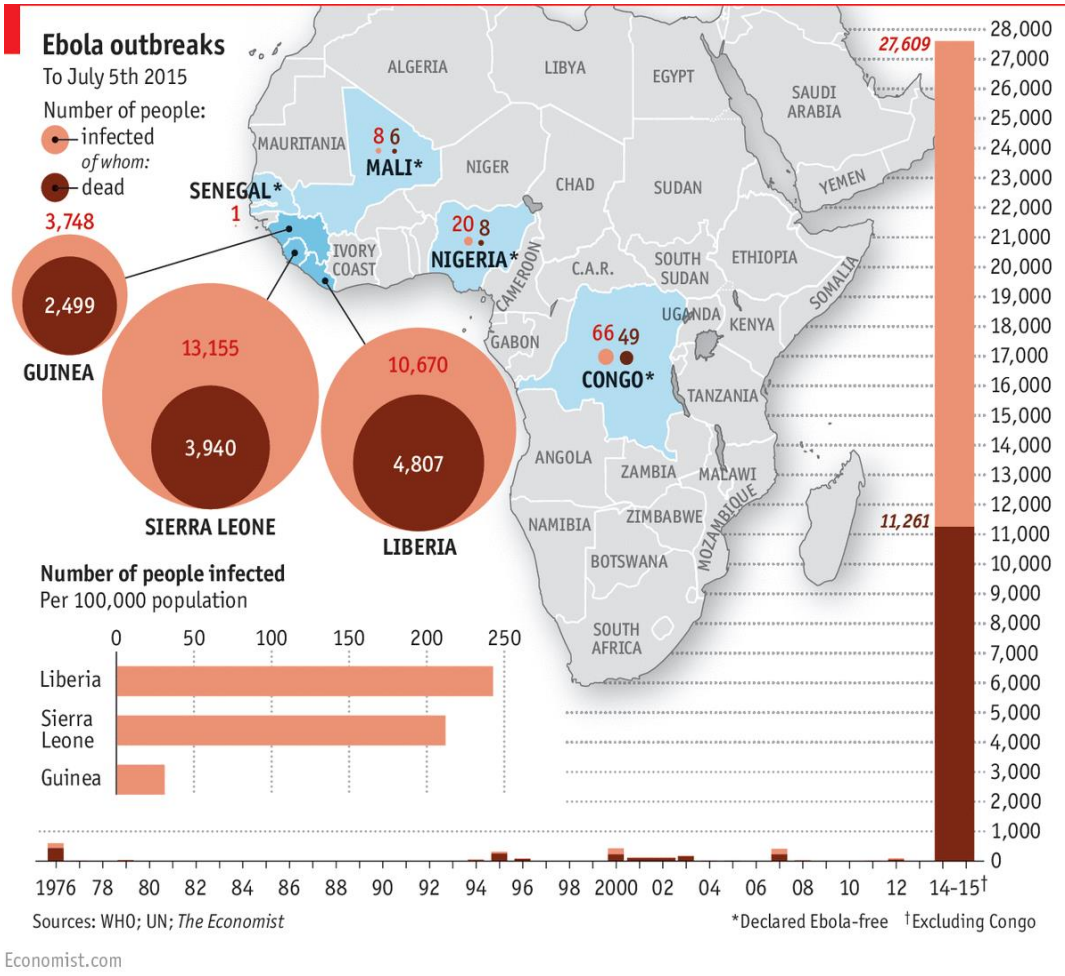
Areas of Focus

- **Primary Care** (Diabetes, Cardiovascular)
- **Women's Health**
- **Hospital and Specialty** (Hepatitis, HIV, Acute Care, Immunology)
- **Vaccines**

Ebola Vaccine

- **April 2015:** Merck's Ebola vaccine entered Phase III testing in Sierra Leone

- Shown to be 100% effective in preventing Ebola, according to an interim look from a late-stage study



- *"Our motivation to pursue this opportunity was to address a public health need," Merck Vaccines' Mark Feinberg said in a telephone interview. "We did not believe this was a commercial opportunity."*

Top Selling Products

($ in millions)	2014	2013	2012
Total Sales	**$ 42,237**	$ 44,033	$ 47,267
Pharmaceutical	**36,042**	37,437	40,601
Januvia	**3,931**	4,004	4,086
Zetia	**2,650**	2,658	2,567
Remicade	**2,372**	2,271	2,076
Janumet	**2,071**	1,829	1,659
Gardasil	**1,738**	1,831	1,631
Isentress	**1,673**	1,643	1,515
ProQuad/M-M-R II/Varivax	**1,394**	1,306	1,273
Nasonex	**1,099**	1,335	1,268
Singulair	**1,092**	1,196	3,853
Animal Health	**3,454**	3,362	3,399
Consumer Care[(1)]	**1,547**	1,894	1,952
Other Revenues[(2)]	**1,194**	1,340	1,315

Patent Protection

- *"The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product, as lower priced generic versions of the drug become available"*

- Singulair patent expired in 2012
  - **2011 Sales:** $5.5 billion
  - **2012 Sales:** $1.34 billion

Product	Year of Expiration (in the U.S.)[1]
Integrilin[2]	2015 (use/formulation)
Emend	2015
Follistim AQ	2015
Invanz	2016 (compound)/2017 (composition)
Cubicin[3]	2016 (composition)
Zostavax	2016 (use)
Dulera	2017 (formulation)/2020 (combination)
Zetia[4]*/Vytorin*	2017
Asmanex	2018 (formulation)
Nasonex[5]	2018(formulation)
NuvaRing	2018 (delivery system)
Emend for Injection	2019
Noxafil	2019
RotaTeq	2019
Intron A	2020
Recombivax	2020 (method of making/vectors)
Januvia/Janumet/Janumet XR	2022 (compound)/2026 (salt)
Isentress	2023
Nexplanon	2026 (device)/2027 (device with applicator)
Grastek	2026 (use)
Ragwitek	2026 (use)
Zontivity	2027 (with pending Patent Term Restoration)
Gardasil/Gardasil 9	2028
Keytruda	2028
Zerbaxa	2028 (with pending Patent Term Restoration)
Sivextro	2028 (with Patent Term Restoration)
Belsomra	2029

Januvia

- Treats Type-2 Diabetes
- Introduced in 2006
- Low side effects and easy to use
- **Past three years:** Over $12 billion in revenue
  - **2014 Sales:** $3.93 billion
- Patent protection until 2022

Remicade

- Treats chronic inflammatory diseases

- Costs between $19,000 and $22,000 per year
  - **2014:** $2.372 billion
  - **2013:** $2.271 billion
  - **2012:** $2.076 billion

- Marketing rights in Eastern Europe, Russia and Turkey
- Patents have expired or set to soon
  - 10% decline in sales for the fourth quarter of 2014

Pipeline

- **Phase I:** Testing on a small number of healthy human volunteers in order to find any possible side effects
  - **Emphasis** = Safety
- **Phase II:** Testing on a larger number of humans who are suffering from the illness
  - **Emphasis** = Effectiveness
- **Phase III:** Larger scale. Tested on different populations, in different dosages and in combinations with other drugs
- **Under Review**

INTERACT WITH OUR PIPELINE

Phase | Category | Therapeutic Areas | Advanced Since Last Update | CLEAR SELECTIONS

PHASE II
12 programs

- Alzheimer's Disease
  MK-7622
- Asthma
  MK-1029
- Bacterial Infection
  relebactam,
  MK-7655
- Cancer
  MK-2206

PHASE III
19 programs
1 have advanced

- HABP/VABP[3] bacterial pneumonia
  SIVEXTRO®, MK-1986
- Allergy, House Dust Mite
  MK-8237 [1,2]
- Alzheimer's Disease
  MK-8931
- Atherosclerosis
  anacetrapib,
  MK-0859

UNDER REVIEW
6 programs

- cIAI & cUTI[7]
  ZERBAXA™, MK-7625A (EU)
- Diabetes Mellitus
  omarigliptin,
  MK-3102 (Japan)
- HPV-related cancers
  HPV vaccine (9 valent)
  V503 (EU)[8]
- Melanoma
  KEYTRUDA®
  MK-3475 (EU)

Keytruda

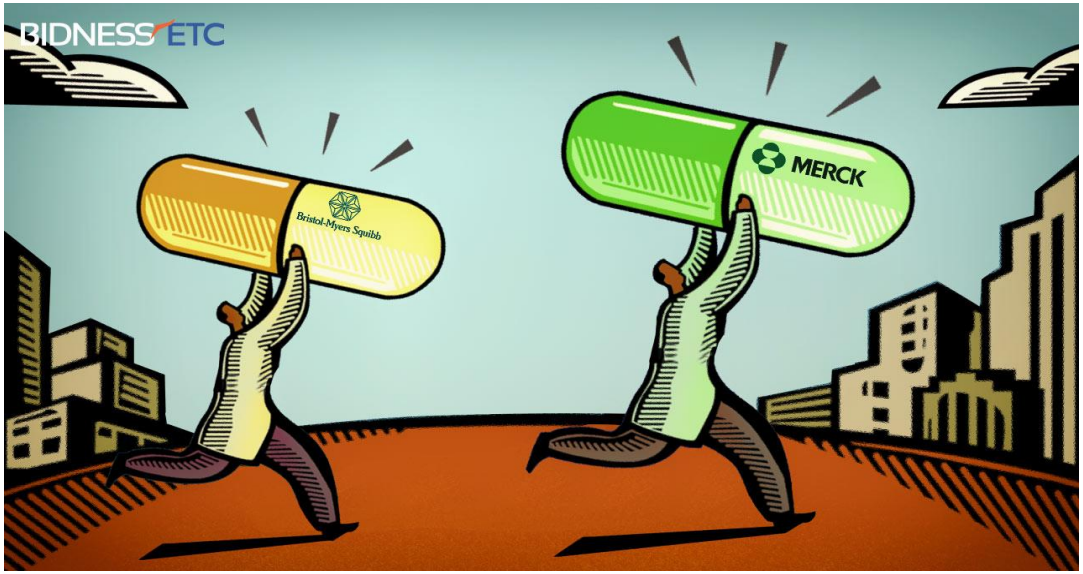
- **Under review** by the European Medicines Agency for the treatment of advanced melanoma

- Keytruda clinical development program also includes studies in more than 30 cancers including: **bladder, colorectal, gastric, head and neck, non-small-cell lung, among others**

- Received **priority-review status** from the FDA for non-small-cell lung cancer

Keytruda

- **September 2014:** FDA approved Keytruda at a dose of 2mg/kg every three weeks for the treatment of patients with certain types of melanoma



- Cost patients around $12,500 a month

- Projected to reach $5 billion in annual revenues once fully approved

- Patent protection until 2028

Reasons to be Optimistic

- Efficient in responses to emerging medical issues
- Top products under patent protection
  - Except Remicade
- Pipeline is extremely promising
- Roger Perlmutter
- Revenue declining
  - **2014:** $42.237 billion
  - **2013:** $44.033 billion
  - **2012:** $47.267 billion

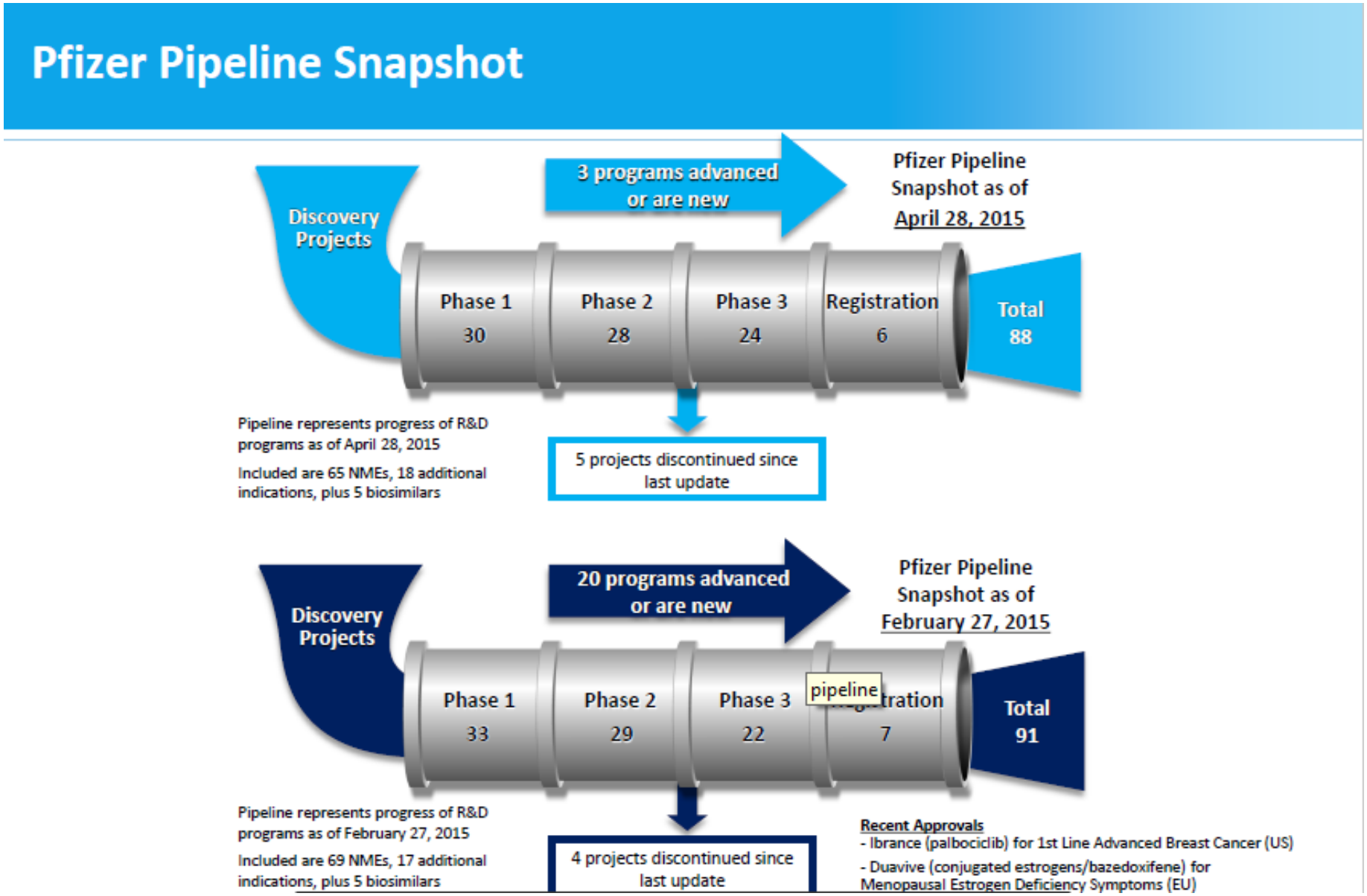
Pfizer pipeline

Pfizer is divided into 2 main businesses:

1. **<u>Innovative Products</u>** (divided into 2 sectors)
   - → **Global Innovative Pharmaceutical segment (GIP)**
   - → **Global Vaccines, Oncology and Consumer Healthcare segment (VOC**)
   - → Very specialized fields of medicine
2. **<u>Established Products</u>**

   Mostly, the popular drugs we know, that cater to more traditional problems, like high cholesterol

Pfizer pipeline of April 28.2015



Oncology is crucial area:

Pfizer Pipeline – April 28, 2015 (cont'd)

New Molecular Entity

New Indication or Enhancement

Therapeutic Area	Compound Name	Mechanism of Action (Phase 2 through regulatory approval)	Indication	Phase
★	Xalkori (crizotinib)	c-MET-ALK Inhibitor	ALK-Positive 1st Line Non-Small Cell Lung Cancer (EU), *Cancer	Registration
	► avelumab (PF-06834635) (MSB0010718C)	Anti PD-L1 Inhibitor	2nd Line Non-Small Cell Lung Cancer (Biologic)	Phase 3
	Bosulif (bosutinib)	Abl and src-family Kinase Inhibitor	1st Line Chronic Myelogenous Leukemia (ORPHAN - U.S.)	Phase 3
	dacomitinib (PF-00299804)	pan-HER Inhibitor	1st Line EGFR mutant Non-Small Cell Lung Cancer (ORPHAN - U.S.), *Cancer	Phase 3
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	1st Line Advanced Breast Cancer (E.U.), *Cancer	Phase 3
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	Recurrent Advanced Breast Cancer	Phase 3
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	High Risk Early Breast Cancer	Phase 3
	Inlyta (axitinib)	VEGF Tyrosine Kinase Inhibitor	Renal Cell Carcinoma Adjuvant, *Cancer combo w/ Merck's Keytruda (PD-1, pembrolizumab)	Phase 3
	inotuzumab ozogamicin	CD22-targeted cytotoxic agent	Acute Lymphoblastic Leukemia (Biologic) (ORPHAN - U.S., E.U.)	Phase 3
	Sutent (sunitinib)	Multiple Tyrosine Kinase Inhibitor	Renal Cell Carcinoma Adjuvant	Phase 3
	avelumab (PF-06834635) (MSB0010718C)	Anti PD-L1 Inhibitor	Metastatic Merkel Cell Carcinoma, *Cancer (Biologic)	Phase 2
	glasdegib (PF-04449913)	SMO (smoothened) antagonist	Acute Myeloid Leukemia, *Cancer	Phase 2
	PF-03084014	Gamma-Secretase Inhibitor	Triple Negative Breast Cancer	Phase 2
	gedatolisib (PF-05212384)		Cancer	Phase 1
	PD-0325901		Cancer (in combination with PF-05212384)	Phase 1
	PF-05082566		Cancer (Biologic), Combo w/ Merck's Keytruda (PD-1, pembrolizumab)	Phase 1
	PF-06263507		Cancer (Biologic)	Phase 1
	PF-06463922		Cancer	Phase 1
	PF-06647020		Cancer (Biologic)	Phase 1
	PF-06647263		Cancer (Biologic)	Phase 1
	PF-06650808		Cancer (Biologic)	Phase 1
	PF-06664178		Lung Cancer (Biologic)	Phase 1

Future success of major cancer drug partially attributed to Merck*

Pfizer

Top 50 pharmaceutical products by global sales:

17	Prevnar 13	4464	3974	490	12
18	Nexium	4442	4551	-109	-2
19	Symbicort	4262	3929	333	8
20	Lucentis	4254	4184	70	2
21	Copaxone	4237	4328	-91	-2
22	Januvia	3931	4004	-73	-2
23	Xarelto	3679	2083	1596	77
24	Truvada	3528	3304	224	7
25	Atripla	3470	3649	-179	-5
26	Olmesartan franchise	3187	3761	-574	-15
27	Eylea	3034	2072	962	46
28	Avonex	3013	3006	7	0
29	NovoRapid	3012	2908	104	4
30	Gilenya	2934	2337	597	26
31	Tecfidera	2909	876	2033	232
32	Velcade	2881	2852	29	1
33	Zetia	2866	2879	-13	0

Top 50 pharmaceutical products by global sales:

2014 | 2013 | 2012

#	Product	2014 ($m)	2013 ($m)	Growth ($m)	Growth (%)
1	Humira	13021	11105	1916	17
2	Sovaldi/Harvoni	12410	139	12271	8828
3	Remicade	10151	9900	251	3
4	Enbrel	9120	8894	226	3
5	Lantus	8152	7343	809	11
6	MabThera/Rituxan	7356	7410	-54	
7	Avastin	6841	6667	174	
8	Seretide/Advair	6700	8356	-165	
9	Herceptin	6690	6481	209	
10	Crestor	6617	6960	-343	
11	Abilify	6416	9502	-308	
12	Lyrica	5435	4838	597	
13	Revlimid	4980	4280	700	
14	Gleevec/Glivec	4746	4693	53	
15	Spiriva	4722	4564	158	3
16	Neulasta	4596	4392	204	5

A joint project with Amgen and Takeda (how much of this number is being shared with the other two companies?)

Top 50 pharmaceutical products by global sales:

34	Alimta	2792	2703	89	3
35	Humalog	2785	2611	174	7
36	Lipitor	2766	3097	-331	-11
37	Celebrex	2699	2918	-219	-8
38	Plavix	2601	2644	-43	-2
39	Levemir	2454	1993	461	23
40	Rebif	2364	2396	-32	-1
41	Diovan/Co-Diovan	2345	3524	-1179	-33
42	Victoza	2318	2008	310	15
43	Olysio	2302	23	2279	9909
44	Cialis	2291	2159	132	6
45	Erbitux	2257	2204	53	2
46	Prograf	2249	2273	-24	-1
47	Zytiga	2237	1698	539	32
48	Soliris	2234	1551	683	44
49	Botox/Neuromodulator	2231	1982	249	13
50	Lovenox	2183	2188	-5	0

More Patent Issues

Lipitor, once the world's biggest selling drug – peaking at annual sales of more than $9 billion and with lifetime sales of more than $131 billion – is expected to generate about $3 billion in sales in 2015." Lipitor ***still*** remains the highest grossing drug of all time. Of note, Lipitor's U.S. patent expired in 2011.

Patent cliff Issues:

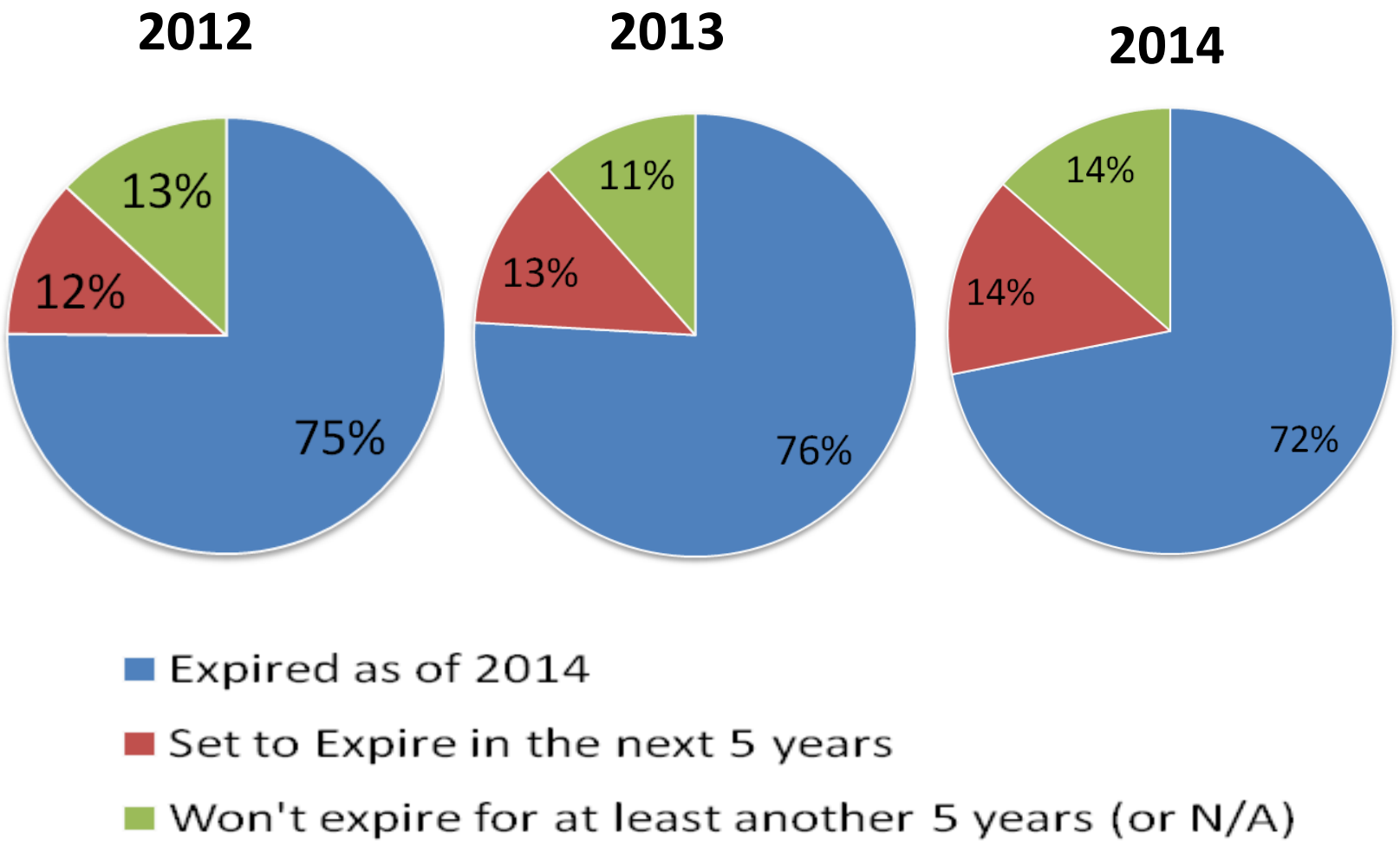
Three top Pfizer drugs are expired:

Lyrica, which expired in 2013.

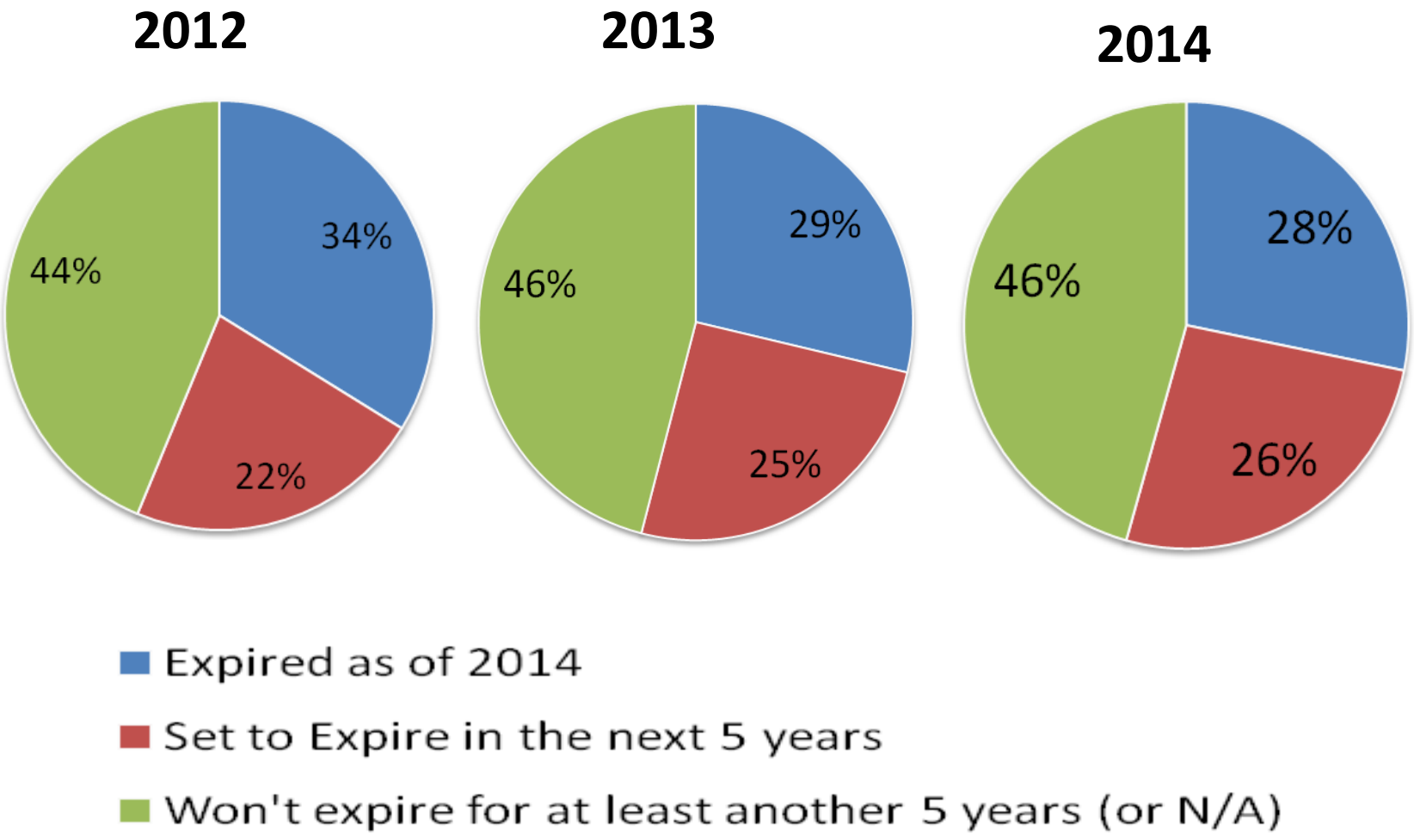
Celebrex, which expired in 2014.

Detrol, which expired in 2012.

Patent Status, Pfizer Drug Revenue Sources



Patent Status, Merck Drug Revenue Sources



Conclusion:

1. Pfizer has greater exposure to patent cliff.

2. One of Pfizer's major cancer drugs relies on Merck's cancer drug Keytruda (a mix of the two). Pfizer will likely have to share the profits.

MERCK ONCOLOGY

Conclusion:

1. **Meck's pipeline is more focused on drugs that meet <u>emerging</u> AND <u>critical</u> needs – like cancer, HIV, Ebola, and Hep C.**

2. **Innovation in Merck pipeline is <u>stronger.</u>**

3. **<u>LESS</u> patent cliff risk.**

Implications of R&D and Acquisition Accounting

Corinne Palmer

R&D Expense

- Recorded on the income statement
- Made up of expenses from:
  - Internal R&D Division
  - Separate operating segments
  - Impairment Charges (In process research and development)
- Up front and Milestone Payments
  - Partnerships
  - Licensing Agreements

R&D through M&A

Acquisition Price-
$3.9 billion

Record IPR&D Asset of **$3.2 billion** a Balance Sheet item (Indefinite life intangible asset, **subject to impairment**)

Once drug is approved, becomes definite life asset, amortized accordingly

Asset is reclassified to an individual product or product rights (folded into intangible)

R&D Expense- $7.2 billion

In Process R&D- **$4.3 billion**

IPR&D Impairment- $49 million

R&D Expense- $8.4 billion

In Process R&D- **$387 million**

IPR&D Impairment- $190 million

Why such a big difference?

R&D Expense

- $7.2 billion
- Merck Research Laboratories- Main R&D division
- $3.7 incurred directly by Merck Research Labs
- $2.8 billion- costs incurred by divisions that support R&D
    - Includes depreciation, production and G&A activities, and licensing activity

- $8.4 billion
- Pfizer Worldwide R&D- different research units- $4.5 billion
- R&D Transferred to 3 segments when proof of concept achieved
- Global Innovative Pharmaceutical- $1.6 billion
- Global vaccines, oncology, and consumer healthcare- $925 million
- Global established Pharmaceutical - $657 million
- Up front and milestone payments- $1.4 billion

In Process Research and Development

"Pipeline programs measured at fair value and capitalized in connection with mergers and acquisitions." -Pfizer 10K

Merck- $4.3 billion

Pfizer- $387 million

Merck IPR&D	
MK-3862 (14)	$3.2 billion
Bridion (13)	$200 million

Pfizer IPR&D	
InnoPharma (14)	$212 million
Next Wave (12)	$45 million

IPR&D Impairment

- Recorded as part of R&D expense
- Occurs when drugs do not reach profitability or approval
- Usually full write offs of IPR&D assets

MERCK Total= $528 million

Total= $810 million

Merck	2012	2013	2014
IPR&D Gross Carrying Balance	2,393	1,856	4,345
IPR&D Impairment	200	279	49
IPR&D Impairment Charge as a % of IPR&D Carrying Balance	8.4%	15.0%	1.1%
Pfizer			
IPR&D Gross Carrying Balance	688	1,856	387
IPR&D Impairment	393	227	190
IPR&D Impairment Charge as a % of IPR&D Carrying Balance	57.1%	12.2%	49.1%

In Conclusion…

- Merck has a more stable and consistent R&D Expense
- Merck has demonstrated greater success in acquisitions of IPR&D.
  - Quality of drugs in IPR&D
  - Acquiring drugs that stuck with Merck's mission
  - Lower IPR&D impairment costs


REGULATORY
COMPLIANCE

- Common types violations in big pharma
  - Off-Label promotion
    - The FDA approves only specific uses for drugs, any other use may not be marketed
    - Doctors have discretion to prescribe other uses for meds but companies cannot “educate” or try to sell the other uses to doctors
  - Kickbacks
    - For decades big pharmaceutical companies have been paying the doctors who prescribe their medicine the most
    - Companies create elaborate and hard to trace payment methods that make kickbacks very hard to track
      - For example: Speaking engagements
    - Highly illegal and very dangerous for the general public, we don’t want to be prescribed medicine we don’t need!
  - Bribery
    - The FCPA was created to lengthen the reach of the United States government to try to tackle bribery
    - It is against FCPA regulations to bribe any foreign official
    - Pervasive and hard to catch

- 2009 - $2.3 Billion dollar settlement for violations relate to Off-Label Promotion
  - » *"the largest health care fraud settlement in the history of the Department of Justice" - United States Department of Justice*
  - » Pervasive sales and marketing scheme to try to get doctors to promote 13 different drugs for off label uses.
  - » Sales teams were incentivized to use such sales schemes
  - » Largest health care fraud settlement in history of US DOJ
- 2011- $14.5 Million dollar settlement for Off-Label Promotion
- 2012 - $45 Million to SEC and $15 Million to DOJ for FCPA Violations for bribery
  - » Violations spanned across 8 countries

- 2011- $950 million For Off-Label Promotion
  - Pervasive and organization wide violations
  - Used “tutorial program“ which was really just a way to promote Off-Label
- 2015 - $5.9 Million Civil violations related to Off-Label Promotion
  - Off-Label promotion by firm that was acquired by Merck, violations occurred before Merck’s acquisition
- 2015 – No fine or settlement stemming from DOJ probe

VS

MERCK

Pfizer		Merck	
Violation	Settlement & Fines	Violation	Settlement & Fines
2009 – FCA violations related to off-label promotion	$2.3 billion	2011 – FCA violations related to off-label promotion	$950 million
2011 – FCA violations related to off-label promotion	$14.5 million	2015 – civil violations related to off-label promotion	$5.9 million
2012 – FCPA violations (SEC complaint)	$45 million	2010 – 2014 DOJ FCPA probe	No fines/settlement
2012 – FCPA violation (DOJ complaint)	$15 million		
Total (approx.)	$2,374,500,000		$955,900,000

Merck's Advanced Analytics

- In 2010, Merck started using advanced analytics in their internal audit efforts
- These efforts have been expanding in the past 5 years
- Even though we can not be totally sure if the advanced analytics are the reason that they have not seen a pattern of FCA/FCPA violations, we can safely assume that it is playing some part

Summing up

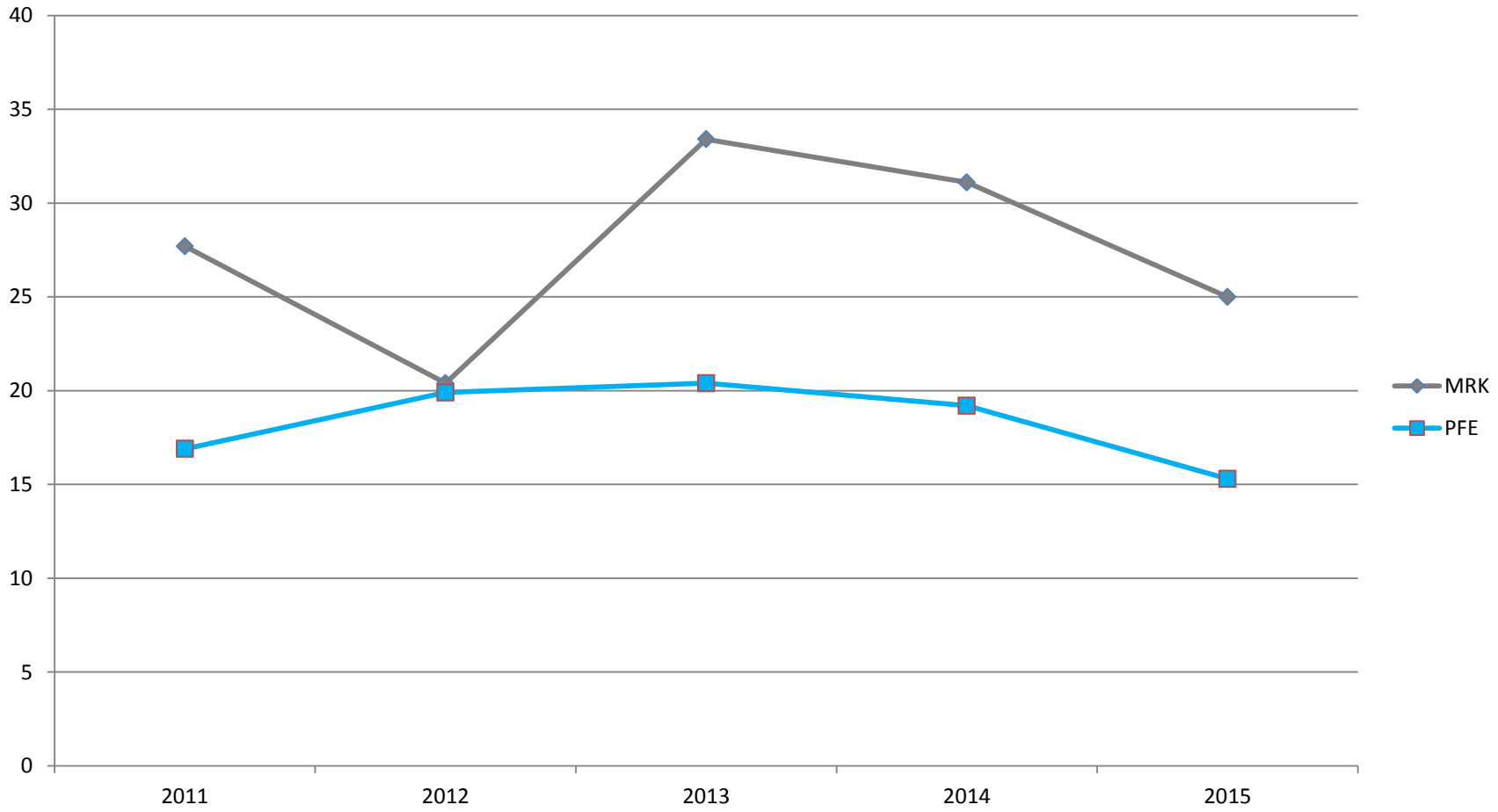
- Pfizer and Merck both have a history of violations
- Pfizer has shown more of a pattern of violations compared to Merck
- Merck's utilization of advanced analytics are promising
- Based on regulatory compliance considerations, we would feel that an investment in Pfizer poses a large risk
- An investment is Merck poses some compliance risk, but that is somewhat mitigated by technological advances in auditing practices and lack of a pattern of violations

FINAL EVALUATION: MERCK vs. PFIZER

- Merck's Development of Keytruda
  - An oncology drug that stimulates the body to use its own processes to battle cancer
- Patent Cliff risks
  - Drugs that contribute 40% - 50% of Merck's annual revenue (2012 – 2014) will not lose patent exclusivity for at least 5 years.
  - Drugs that contribute 70% of Pfizer's annual revenue have already lost patent exclusivity.
- R&D Expense
  - Merck spends less, acquisition focused on key expansion areas, eg, cancer, Hepatitis C, drug-resistant bacteria

http://www.fool.com/investing/general/2015/02/07/5-things-merck-co-incs-management-wants-you-to-kno.aspx

Comparison of Merck and Pfizer's P/E Ratio



Market Data on Free Cash Flows & Dividend

	PFE			MRK		
	FCF ($ billion)	Dividends	Div. As a % of FCF	FCF ($ billion)	Dividends	Div. As a % of FCF
3/15 Q1	$13.2	$6.7	50%	$6.5	$5.1	80%
3/14 Q1	$15.0	$6.5	43%	$10.4	$5.2	51%
3/13 Q1	$15.3	$6.7	44%	$8.2	$5.1	62%
3/12 Q1	$16.5	$6.2	34%	$9.8	$4.8	49%

Merck has generated fewer free cash flows than Pfizer but its dividends, on average, represent a greater percentage of FCF

Final Investment Decision

https://en.wikipedia.org/wiki/File:Merck_Logo.svg

“. . . IN THE EYE OF THE BRIBE HOLDER”

Data Analytics and a Real Life Pharma Mystery

Health | Wed Jun 17, 2015 6:10pm EDT

Related

Merck to pay $5.9 million for misleading marketing of pink eye drug: U.S

NEW YORK | BY NATE RAYMOND

Merck & Co Inc has agreed to pay $5.9 million to resolve claims that a former unit fraudulently promoted a drug used to treat pink eye for unapproved purposes, U.S. authorities announced on Wednesday.

Manhattan U.S. Attorney Preet Bharara said Inspire Pharmaceuticals, which Merck acquired in 2011 and later sold, promoted its drug AzaSite to healthcare providers for uses the Food and Drug Administration had not approved as safe and effective.

While the FDA had approved AzaSite for treating bacterial conjunctivitis, or pink eye, Inspire sought more revenue by marketing the drug for the non-approved treatment of

INSPIRE

June 2009

OUR BUSINESS

Inspire is a biopharmaceutical company focused on researching, developing and commercializing prescription pharmaceutical products for ophthalmic and pulmonary diseases. We intend to build and commercialize a sustainable pipeline of innovative new products based on our technical and scientific expertise.

OUR COMMERCIAL PRODUCTS

Inspire employs a U.S. sales force for the promotion of *AzaSite*® for bacterial conjunctivitis and *Elestat*® for allergic conjunctivitis. Inspire licensed *AzaSite* from InSite Vision Incorporated. *Elestat* is co-promoted under an agreement with Allergan, Inc.

OUR INVESTMENT HIGHLIGHTS

- Biopharmaceutical company with R&D and commercial capabilities in two therapeutic areas: ophthalmology and pulmonology
- Innovative, late-stage pipeline with multiple product candidates
- Growing revenue stream from promotion of *AzaSite*®, co-promotion of *Elestat*® and royalties on *Restasis*®

AzaSite®

AzaSite (azithromycin ophthalmic solution) 1% delivers high and sustained concentrations in ocular tissue[1,2] while delivering broad spectrum coverage against the most common ocular pathogens.[3] Additionally, the active ingredient in *AzaSite* is azithromycin, which has anti-inflammatory activity.*[,4,5,6] Full prescribing information available at

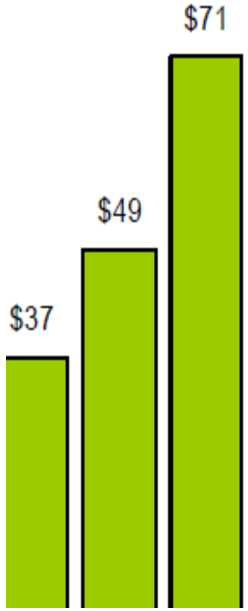
AzaSite®

AzaSite (azithromycin ophthalmic solution) 1% delivers high and sustained concentrations in ocular tissue[1,2] while delivering broad spectrum coverage against the most common ocular pathogens.[3] Additionally, the active ingredient in *AzaSite* is azithromycin, which has anti-inflammatory activity.*[,4,5,6] Full prescribing information available at www.azasite.com.

?

activity at both the H_1 and H_2 receptors. Full prescribing information available at www.elestat.com.

RECENT NEWS



Inspire Announces Presentations at European Cystic Fibrosis Society Annual Meeting

Inspire Announces Presentations at American Thoracic Society Annual Meeting

Inspire Reports First Quarter 2009 Financial Results

Inspire Announces Poster Presentations at the 2009 Association for Research an

* **The anti-inflammatory activity of topically administered *AzaSite* has not been clinically established.**

[1] Torkildsen G, O'Brien TP. *Clinical Therapeutics*. 2009; 31 (1):1-10.
[2] Data on file, Inspire Pharmaceuticals, Inc., Study Report 041-103.
[3] Data on file, Inspire Pharmaceuticals, Inc., NDA Clinical Summary.
[4] Jacot JL, Jacot TA, Sheppard JD Jr, Lattanzio FA Jr, Williams PB, Brubaker K. Evaluation of MMP 2/9 modulation by azithromycin and DuraSite on human corneal epithelial cells and bovine corneal endothelial cells *in vitro*. Poster presented at: 2008 Association for

* **The anti-inflammatory activity of topically administered *AzaSite* has not been clinically established.**

requirement of [the Federal Food, Drug, and Cosmetic] Act and FDA implementing regulations."

B. Inspire Targeted Doctors Likely To Write Prescriptions for Blepharitis

41. Inspire recognized early on that pediatricians treated the most cases of bacterial conjunctivitis, followed by primary care doctors, and described pediatricians as "the most

[redacted]

C. Inspire Trained Its Sales Force on the Purported Anti-Inflammatory Effects of AzaSite and Encouraged Its Sales Force to Focus on Blepharitis

44. Inspire emphasized to its sales force the benefits of treating blepharitis with

[redacted]

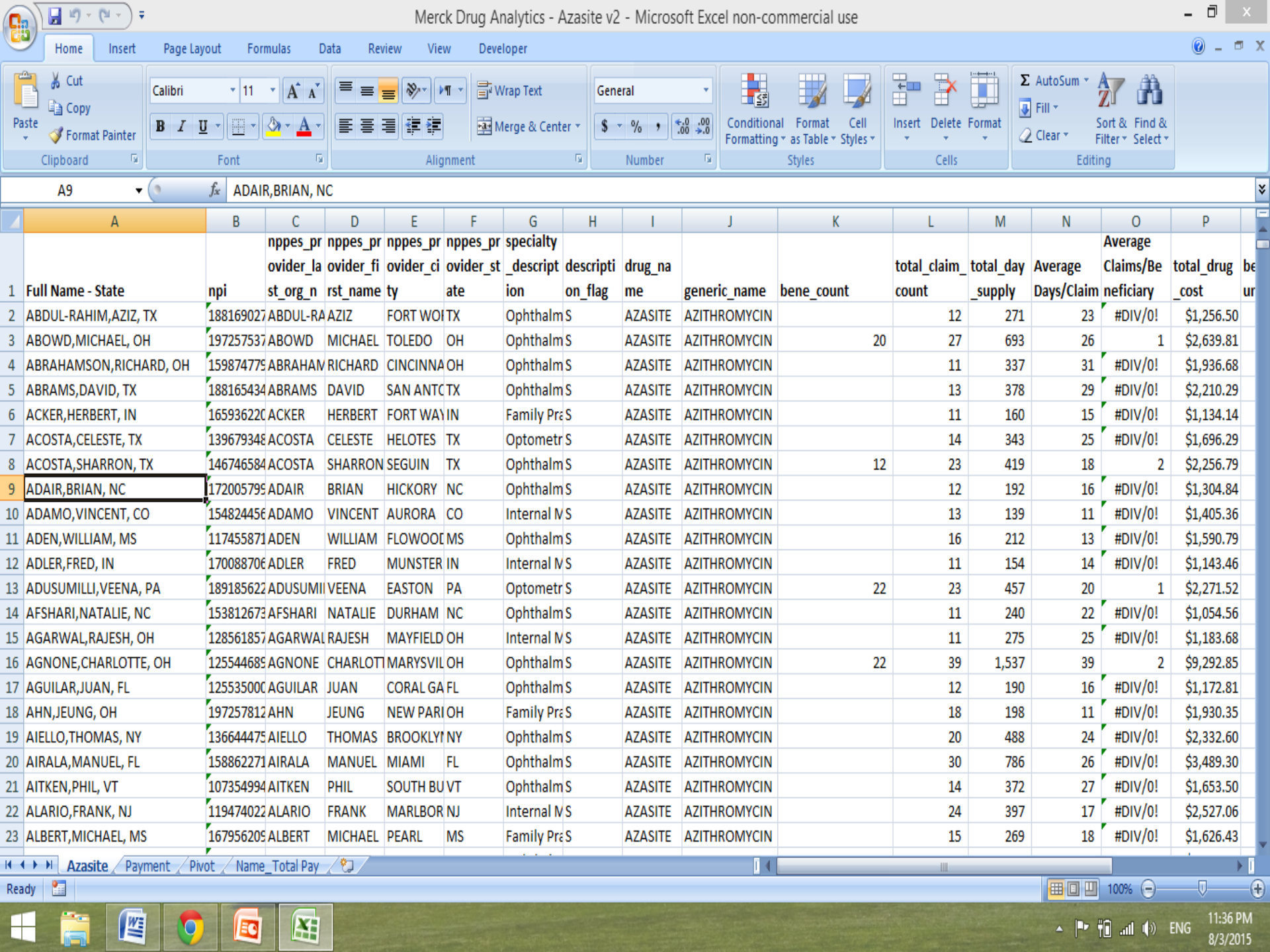
E. Inspire Adopted a Speakers Program to Promote AzaSite as a Treatment for Blepharitis

53. Inspire had a nationwide speaker program that employed eye doctors to make

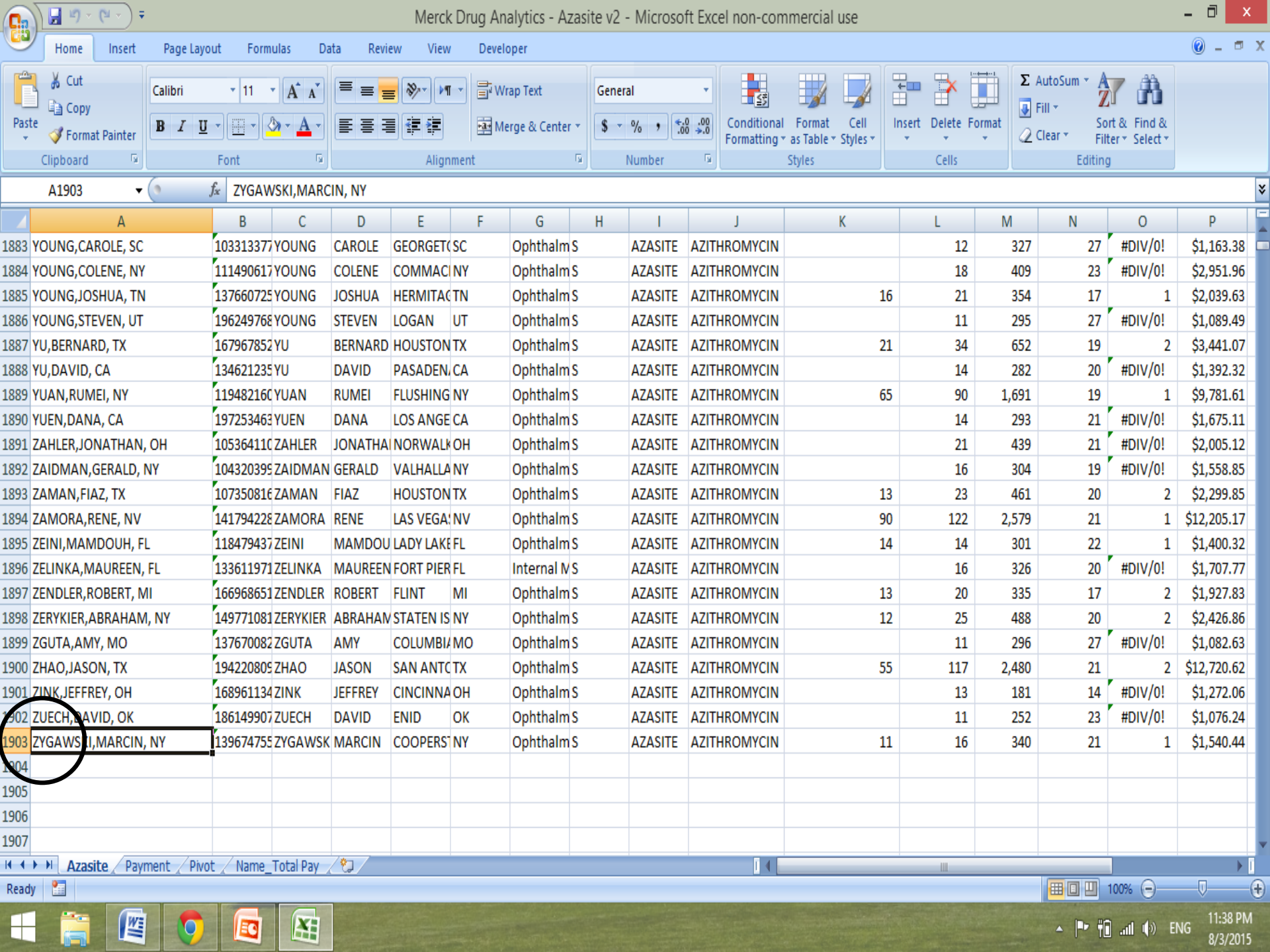
The Sunshine Act

MERCK

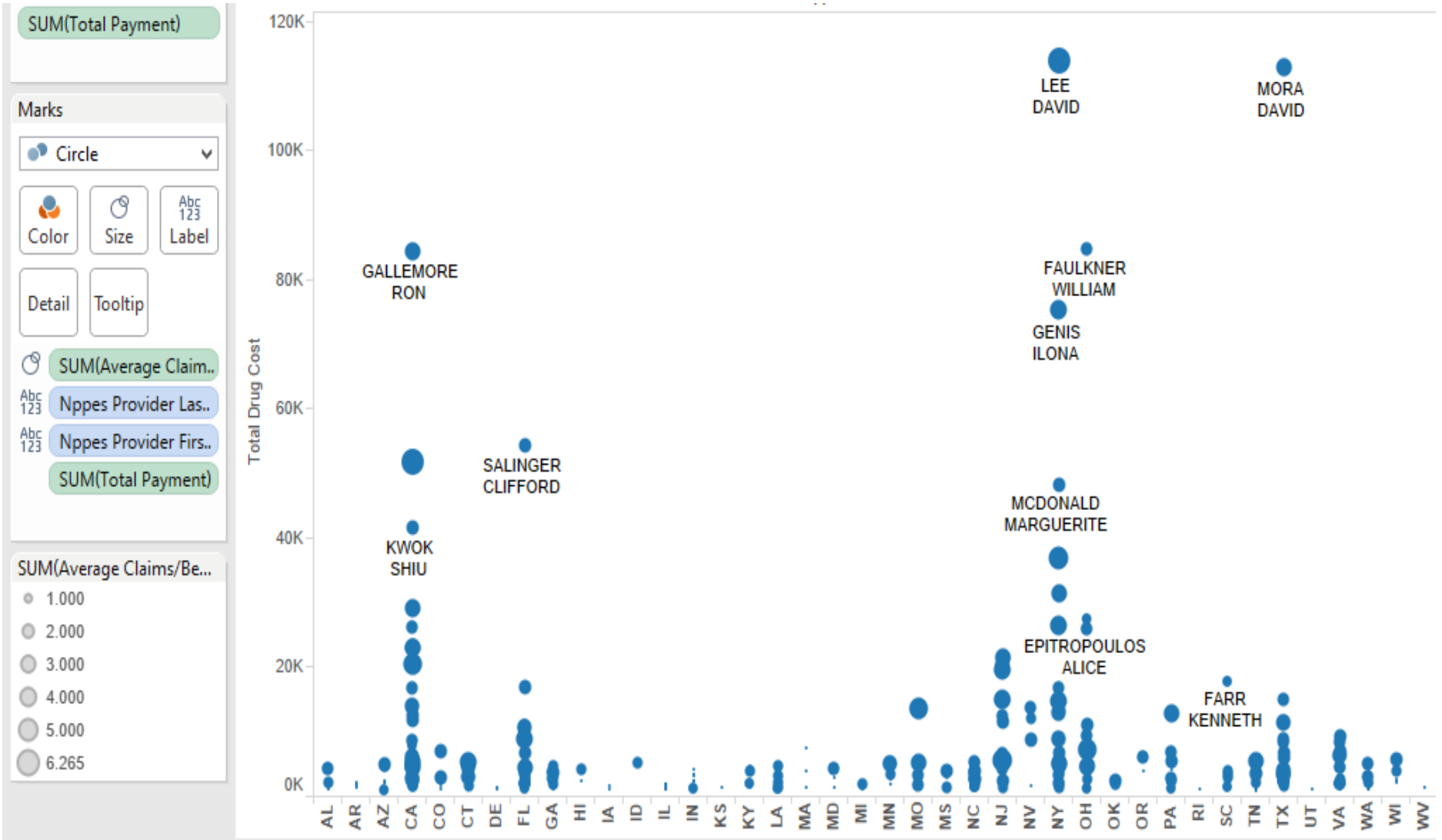
+ableau®



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	
1	Full Name - State	npi	nppes_provider_last_org_n	nppes_provider_first_name	nppes_provider_city	nppes_provider_state	specialty_description	description_flag	drug_name	generic_name	bene_count	total_claim_count	total_day_supply	Average Days/Claim	Average Claims/Beneficiary	total_drug_cost	be ur
2	ABDUL-RAHIM,AZIZ, TX	188169027	ABDUL-RA	AZIZ	FORT WOI	TX	Ophthalm	S	AZASITE	AZITHROMYCIN		12	271	23	#DIV/0!	$1,256.50	
3	ABOWD,MICHAEL, OH	197257537	ABOWD	MICHAEL	TOLEDO	OH	Ophthalm	S	AZASITE	AZITHROMYCIN	20	27	693	26	1	$2,639.81	
4	ABRAHAMSON,RICHARD, OH	159874779	ABRAHAM	RICHARD	CINCINNA	OH	Ophthalm	S	AZASITE	AZITHROMYCIN		11	337	31	#DIV/0!	$1,936.68	
5	ABRAMS,DAVID, TX	188165434	ABRAMS	DAVID	SAN ANTC	TX	Ophthalm	S	AZASITE	AZITHROMYCIN		13	378	29	#DIV/0!	$2,210.29	
6	ACKER,HERBERT, IN	165936220	ACKER	HERBERT	FORT WA\	IN	Family Pra	S	AZASITE	AZITHROMYCIN		11	160	15	#DIV/0!	$1,134.14	
7	ACOSTA,CELESTE, TX	139679348	ACOSTA	CELESTE	HELOTES	TX	Optometr	S	AZASITE	AZITHROMYCIN		14	343	25	#DIV/0!	$1,696.29	
8	ACOSTA,SHARRON, TX	146746584	ACOSTA	SHARRON	SEGUIN	TX	Ophthalm	S	AZASITE	AZITHROMYCIN	12	23	419	18	2	$2,256.79	
9	ADAIR,BRIAN, NC	172005795	ADAIR	BRIAN	HICKORY	NC	Ophthalm	S	AZASITE	AZITHROMYCIN		12	192	16	#DIV/0!	$1,304.84	
10	ADAMO,VINCENT, CO	154824456	ADAMO	VINCENT	AURORA	CO	Internal M	S	AZASITE	AZITHROMYCIN		13	139	11	#DIV/0!	$1,405.36	
11	ADEN,WILLIAM, MS	117455871	ADEN	WILLIAM	FLOWOOI	MS	Ophthalm	S	AZASITE	AZITHROMYCIN		16	212	13	#DIV/0!	$1,590.79	
12	ADLER,FRED, IN	170088706	ADLER	FRED	MUNSTER	IN	Internal M	S	AZASITE	AZITHROMYCIN		11	154	14	#DIV/0!	$1,143.46	
13	ADUSUMILLI,VEENA, PA	189185622	ADUSUMII	VEENA	EASTON	PA	Optometr	S	AZASITE	AZITHROMYCIN	22	23	457	20	1	$2,271.52	
14	AFSHARI,NATALIE, NC	153812673	AFSHARI	NATALIE	DURHAM	NC	Ophthalm	S	AZASITE	AZITHROMYCIN		11	240	22	#DIV/0!	$1,054.56	
15	AGARWAL,RAJESH, OH	128561857	AGARWAL	RAJESH	MAYFIELD	OH	Internal M	S	AZASITE	AZITHROMYCIN		11	275	25	#DIV/0!	$1,183.68	
16	AGNONE,CHARLOTTE, OH	125544689	AGNONE	CHARLOTT	MARYSVIL	OH	Ophthalm	S	AZASITE	AZITHROMYCIN	22	39	1,537	39	2	$9,292.85	
17	AGUILAR,JUAN, FL	125535000	AGUILAR	JUAN	CORAL GA	FL	Ophthalm	S	AZASITE	AZITHROMYCIN		12	190	16	#DIV/0!	$1,172.81	
18	AHN,JEUNG, OH	197257812	AHN	JEUNG	NEW PARI	OH	Family Pra	S	AZASITE	AZITHROMYCIN		18	198	11	#DIV/0!	$1,930.35	
19	AIELLO,THOMAS, NY	136644475	AIELLO	THOMAS	BROOKLY!	NY	Ophthalm	S	AZASITE	AZITHROMYCIN		20	488	24	#DIV/0!	$2,332.60	
20	AIRALA,MANUEL, FL	158862271	AIRALA	MANUEL	MIAMI	FL	Ophthalm	S	AZASITE	AZITHROMYCIN		30	786	26	#DIV/0!	$3,489.30	
21	AITKEN,PHIL, VT	107354994	AITKEN	PHIL	SOUTH BU	VT	Ophthalm	S	AZASITE	AZITHROMYCIN		14	372	27	#DIV/0!	$1,653.50	
22	ALARIO,FRANK, NJ	119474022	ALARIO	FRANK	MARLBOR	NJ	Internal M	S	AZASITE	AZITHROMYCIN		24	397	17	#DIV/0!	$2,527.06	
23	ALBERT,MICHAEL, MS	167956209	ALBERT	MICHAEL	PEARL	MS	Family Pra	S	AZASITE	AZITHROMYCIN		15	269	18	#DIV/0!	$1,626.43	



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1883	YOUNG,CAROLE, SC	103313377	YOUNG	CAROLE	GEORGET(	SC	Ophthalm	S	AZASITE	AZITHROMYCIN		12	327	27	#DIV/0!	$1,163.38
1884	YOUNG,COLENE, NY	111490617	YOUNG	COLENE	COMMAC	NY	Ophthalm	S	AZASITE	AZITHROMYCIN		18	409	23	#DIV/0!	$2,951.96
1885	YOUNG,JOSHUA, TN	137660725	YOUNG	JOSHUA	HERMITAC	TN	Ophthalm	S	AZASITE	AZITHROMYCIN	16	21	354	17	1	$2,039.63
1886	YOUNG,STEVEN, UT	196249768	YOUNG	STEVEN	LOGAN	UT	Ophthalm	S	AZASITE	AZITHROMYCIN		11	295	27	#DIV/0!	$1,089.49
1887	YU,BERNARD, TX	167967852	YU	BERNARD	HOUSTON	TX	Ophthalm	S	AZASITE	AZITHROMYCIN	21	34	652	19	2	$3,441.07
1888	YU,DAVID, CA	134621235	YU	DAVID	PASADEN	CA	Ophthalm	S	AZASITE	AZITHROMYCIN		14	282	20	#DIV/0!	$1,392.32
1889	YUAN,RUMEI, NY	119482160	YUAN	RUMEI	FLUSHING	NY	Ophthalm	S	AZASITE	AZITHROMYCIN	65	90	1,691	19	1	$9,781.61
1890	YUEN,DANA, CA	197253463	YUEN	DANA	LOS ANGE	CA	Ophthalm	S	AZASITE	AZITHROMYCIN		14	293	21	#DIV/0!	$1,675.11
1891	ZAHLER,JONATHAN, OH	105364110	ZAHLER	JONATHA	NORWALK	OH	Ophthalm	S	AZASITE	AZITHROMYCIN		21	439	21	#DIV/0!	$2,005.12
1892	ZAIDMAN,GERALD, NY	104320395	ZAIDMAN	GERALD	VALHALLA	NY	Ophthalm	S	AZASITE	AZITHROMYCIN		16	304	19	#DIV/0!	$1,558.85
1893	ZAMAN,FIAZ, TX	107350816	ZAMAN	FIAZ	HOUSTON	TX	Ophthalm	S	AZASITE	AZITHROMYCIN	13	23	461	20	2	$2,299.85
1894	ZAMORA,RENE, NV	141794228	ZAMORA	RENE	LAS VEGA	NV	Ophthalm	S	AZASITE	AZITHROMYCIN	90	122	2,579	21	1	$12,205.17
1895	ZEINI,MAMDOUH, FL	118479437	ZEINI	MAMDOU	LADY LAKE	FL	Ophthalm	S	AZASITE	AZITHROMYCIN	14	14	301	22	1	$1,400.32
1896	ZELINKA,MAUREEN, FL	133611971	ZELINKA	MAUREEN	FORT PIER	FL	Internal M	S	AZASITE	AZITHROMYCIN		16	326	20	#DIV/0!	$1,707.77
1897	ZENDLER,ROBERT, MI	166968651	ZENDLER	ROBERT	FLINT	MI	Ophthalm	S	AZASITE	AZITHROMYCIN	13	20	335	17	2	$1,927.83
1898	ZERYKIER,ABRAHAM, NY	149771081	ZERYKIER	ABRAHAM	STATEN IS	NY	Ophthalm	S	AZASITE	AZITHROMYCIN	12	25	488	20	2	$2,426.86
1899	ZGUTA,AMY, MO	137670082	ZGUTA	AMY	COLUMBIA	MO	Ophthalm	S	AZASITE	AZITHROMYCIN		11	296	27	#DIV/0!	$1,082.63
1900	ZHAO,JASON, TX	194220805	ZHAO	JASON	SAN ANTC	TX	Ophthalm	S	AZASITE	AZITHROMYCIN	55	117	2,480	21	2	$12,720.62
1901	ZINK,JEFFREY, OH	168961134	ZINK	JEFFREY	CINCINNA	OH	Ophthalm	S	AZASITE	AZITHROMYCIN		13	181	14	#DIV/0!	$1,272.06
1902	ZUECH,DAVID, OK	186149907	ZUECH	DAVID	ENID	OK	Ophthalm	S	AZASITE	AZITHROMYCIN		11	252	23	#DIV/0!	$1,076.24
1903	ZYGAWSKI,MARCIN, NY	139674755	ZYGAWSK	MARCIN	COOPERS	NY	Ophthalm	S	AZASITE	AZITHROMYCIN	11	16	340	21	1	$1,540.44
1904																
1905																
1906																
1907																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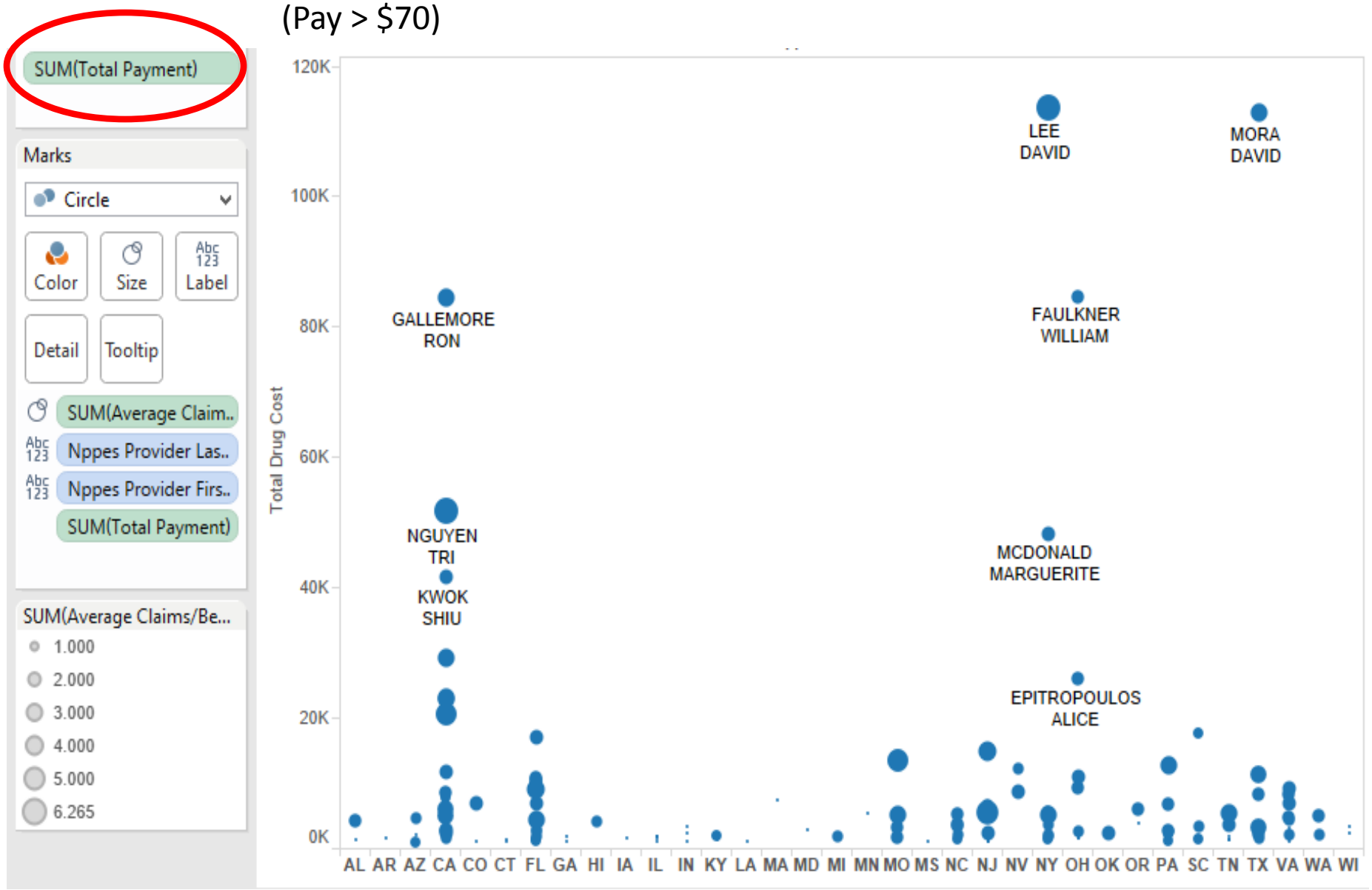
Nppes Provider Firs..
SUM(Total Payment)
SUM(Average Claims/Be...
1.000
2.000
3.000
4.000
5.000
6.265
Total Drug Cost
120K
100K
80K
60K
40K
20K
0K
LEE DAVID
MORA DAVID
GALLEMORE RON
FAULKNER WILLIAM
GENIS ILONA
SALINGER CLIFFORD
MCDONALD MARGUERITE
KWOK SHIU
EPITROPOULOS ALICE
FARR KENNETH
AL AR AZ CA CO CT DE FL GA HI IA ID IL IN KS KY LA MA MD MI MN MO MS NC NJ NV NY OH OK OR PA RI SC TN TX UT VA WA WI WV

(Pay > $70)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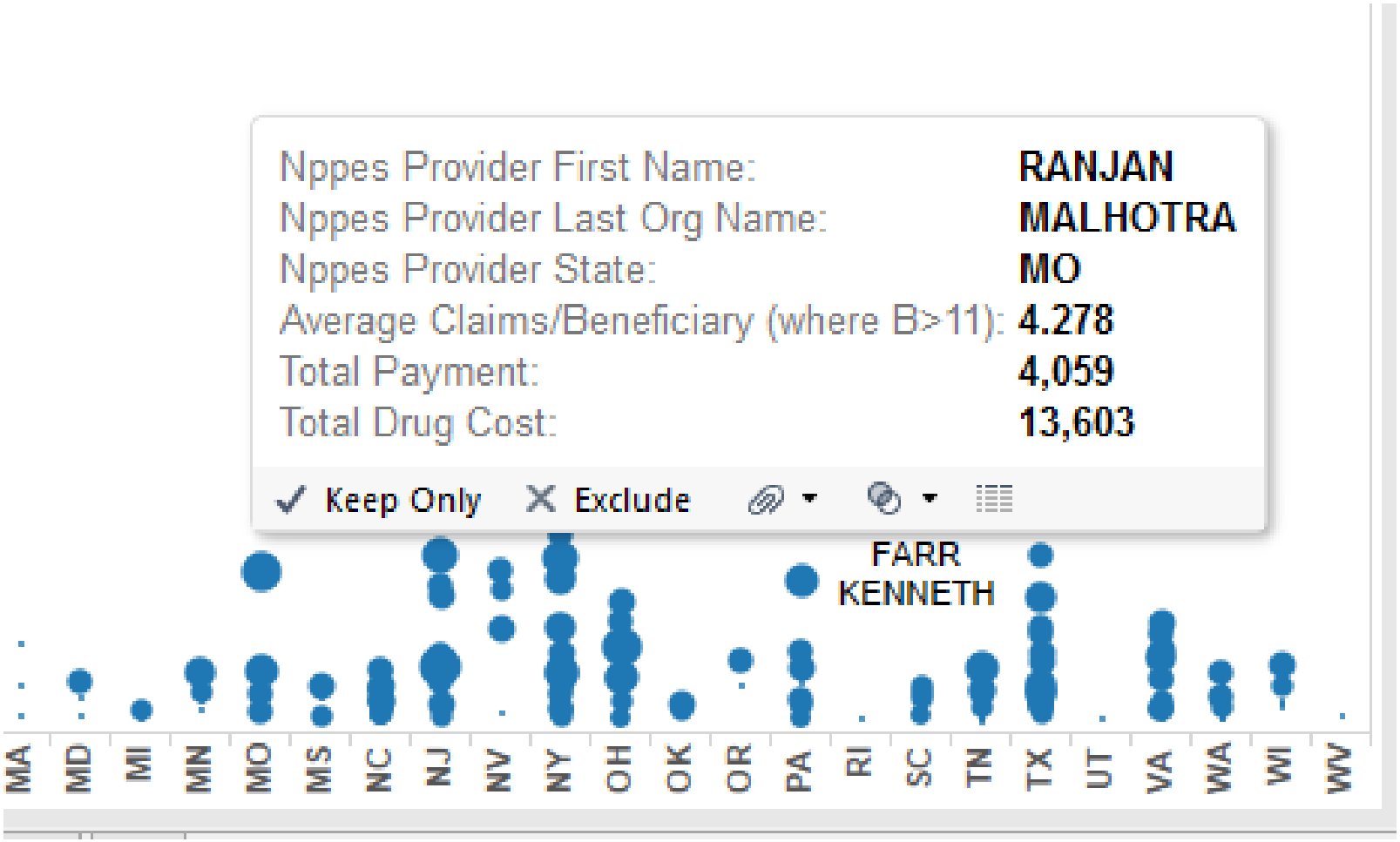
Total Drug Cost
LEE DAVID
MORA DAVID
GALLEMORE RON
FAULKNER WILLIAM
NGUYEN TRI
KWOK SHIU
MCDONALD MARGUERITE
EPITROPOULOS ALICE
AL AR AZ CA CO CT FL GA HI IA IL IN KY LA MA MD MI MN MO MS NC NJ NV NY OH OK OR PA SC TN TX VA WA WI


Nppes Provider First Name: RANJAN
Nppes Provider Last Org Name: MALHOTRA
Nppes Provider State: MO
Average Claims/Beneficiary (where B>11): 4.278
Total Payment: 4,059
Total Drug Cost: 13,603
Keep Only
Exclude
FARR
KENNETH
MA
MD
MI
MN
MO
MS
NC
NJ
NV
NY
OH
OK
OR
PA
RI
SC
TN
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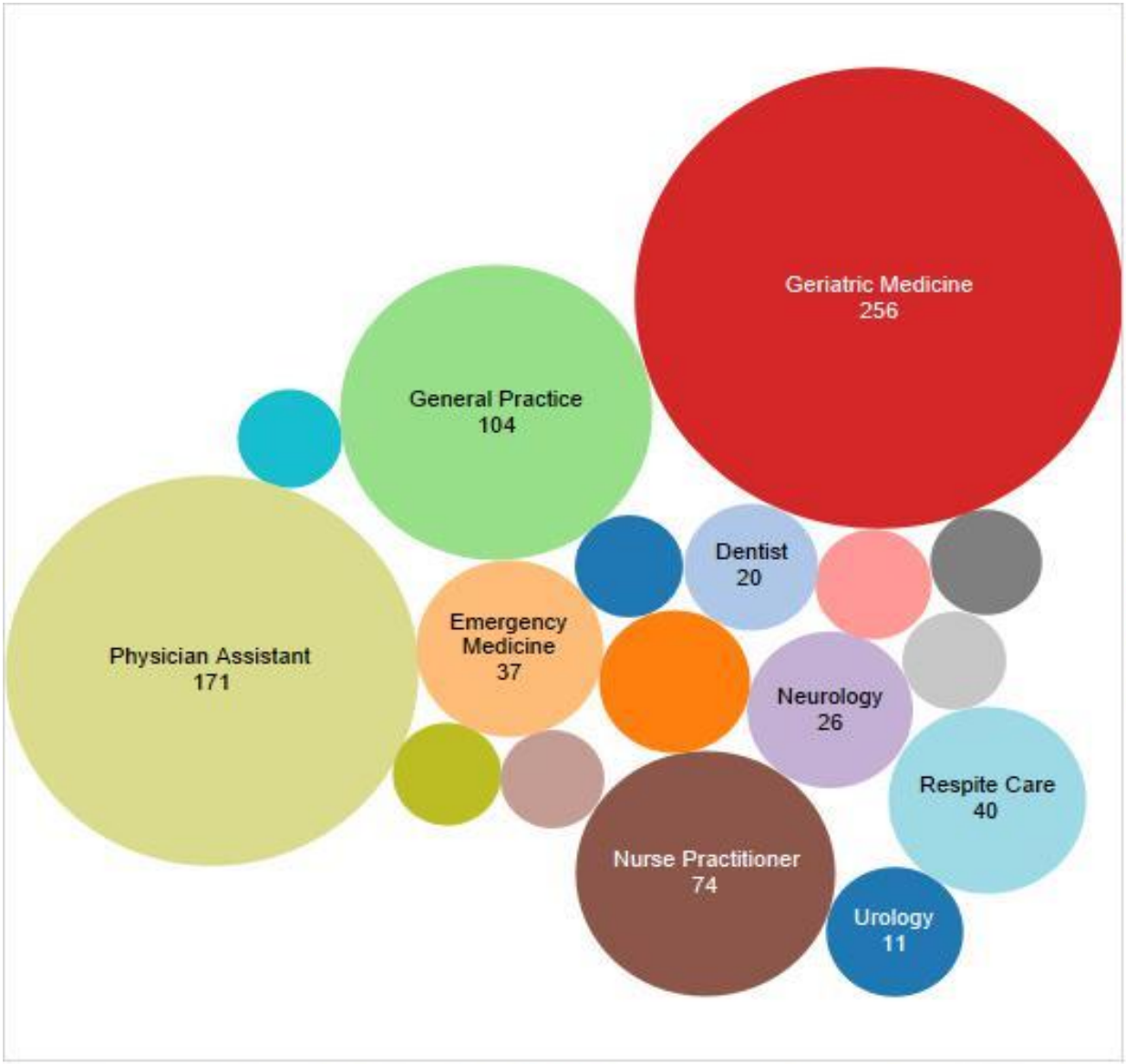
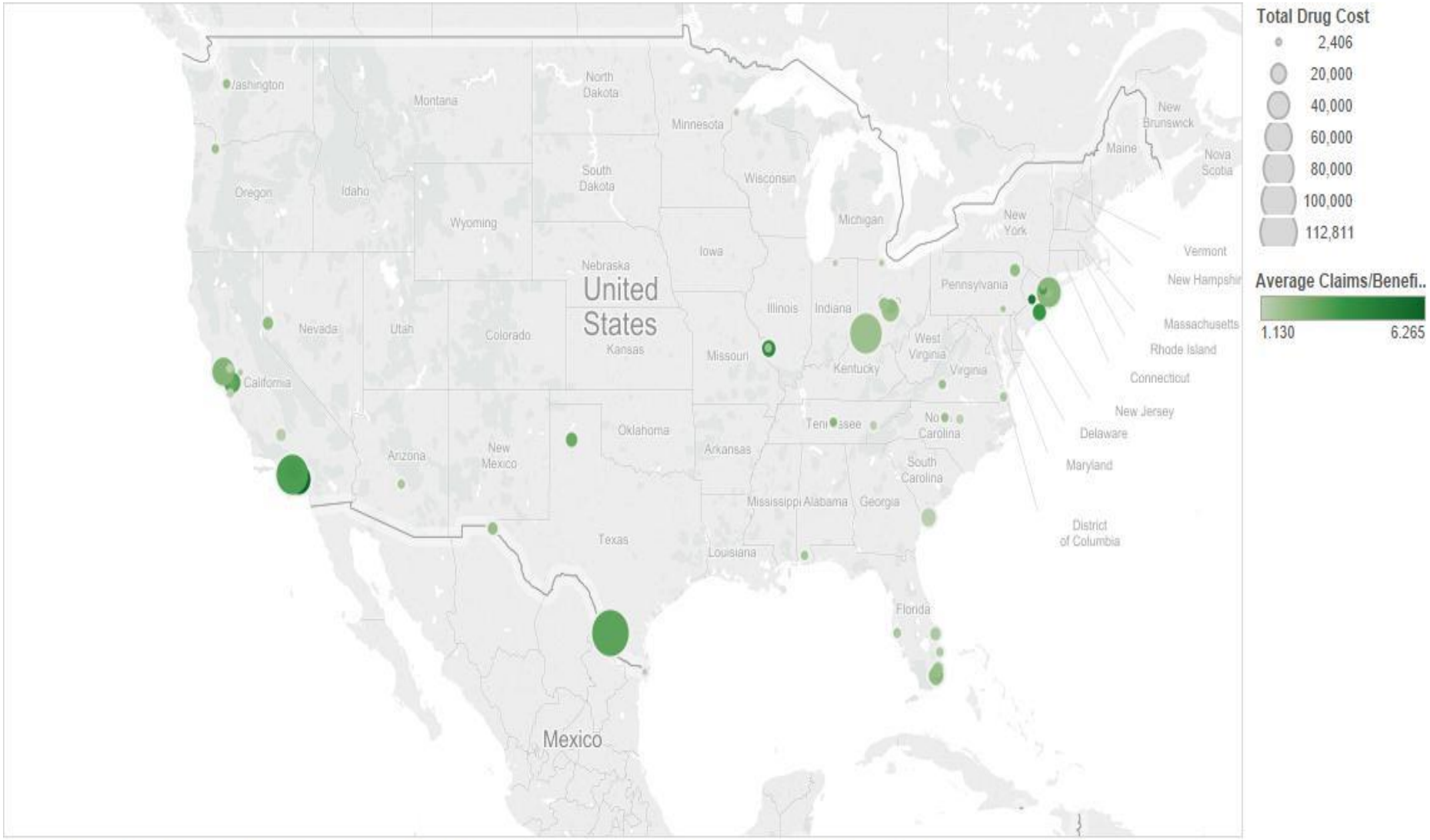
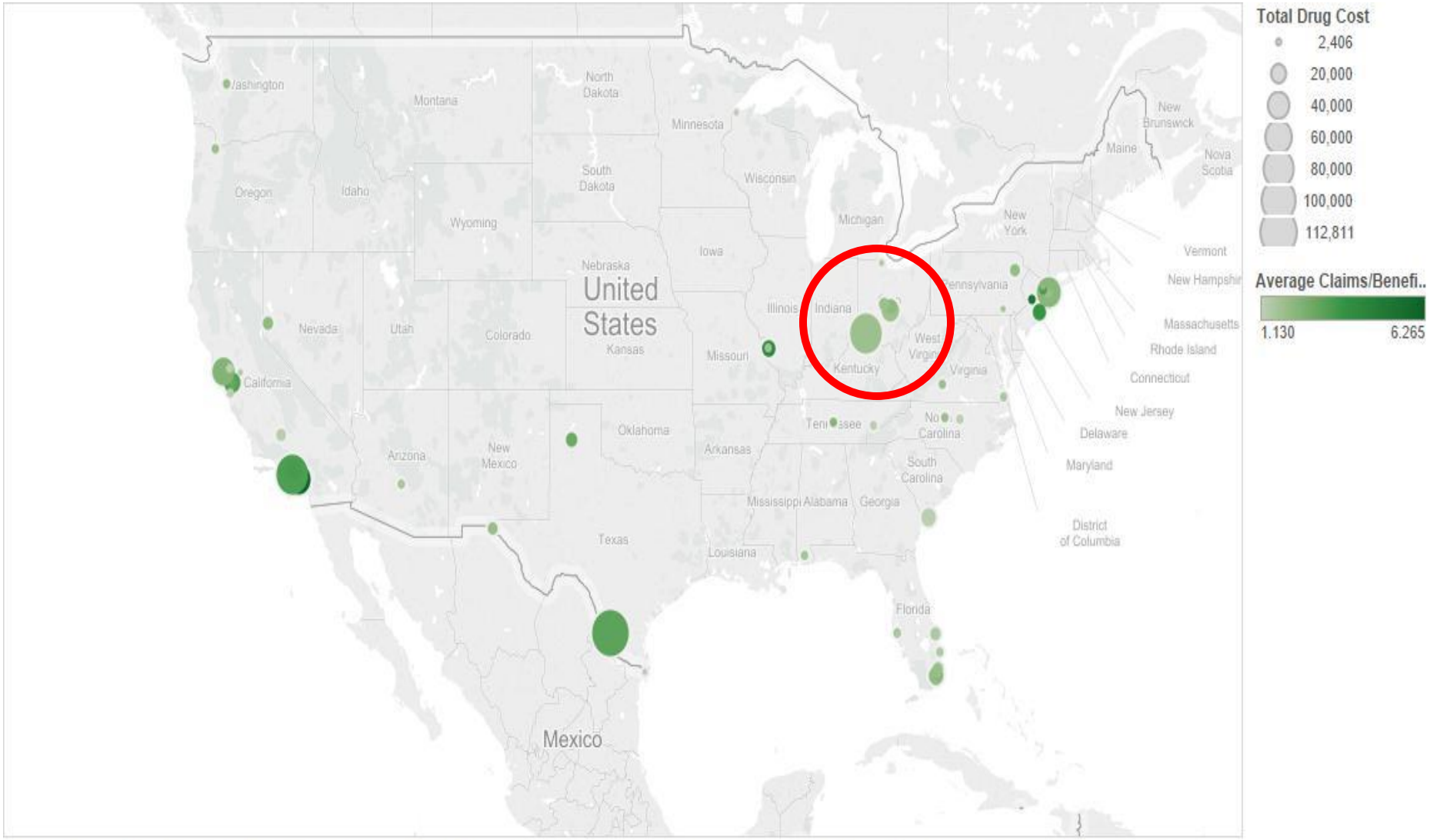


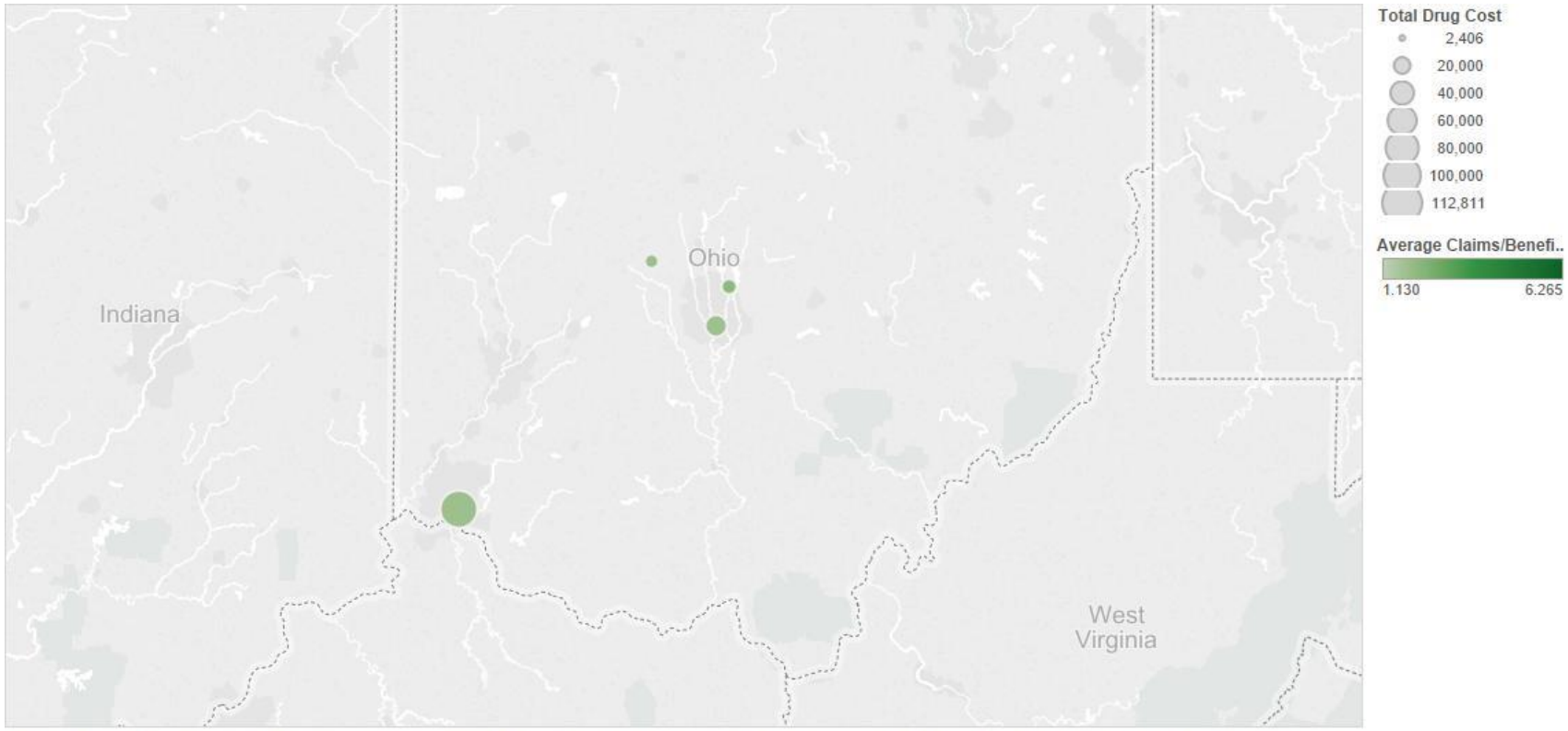
Specialty Description and sum of Total Claim Count. Color shows details about Specialty Description. Size shows sum of Total Drug Cost. The marks are labeled by Specialty Description and sum of Total Claim Count. The data is filtered on sum of Bene Count, which keeps all values. The view is filtered on Specialty Description, which excludes Family Practice, Internal Medicine, Ophthalmology and Optometry.



Map based on Longitude (generated) and Latitude (generated). Color shows sum of Average Claims/Beneficiary (where B>11). Size shows sum of Total Drug Cost. Details are shown for various dimensions. The data is filtered on sum of Total Claim Count, which ranges from 25 to 1,082. The view is filtered on sum of Total Payment, which ranges from 70 to 10,267.



Map based on Longitude (generated) and Latitude (generated). Color shows sum of Average Claims/Beneficiary (where B>11). Size shows sum of Total Drug Cost. Details are shown for various dimensions. The data is filtered on sum of Total Claim Count, which ranges from 25 to 1,082. The view is filtered on sum of Total Payment, which ranges from 70 to 10,267.



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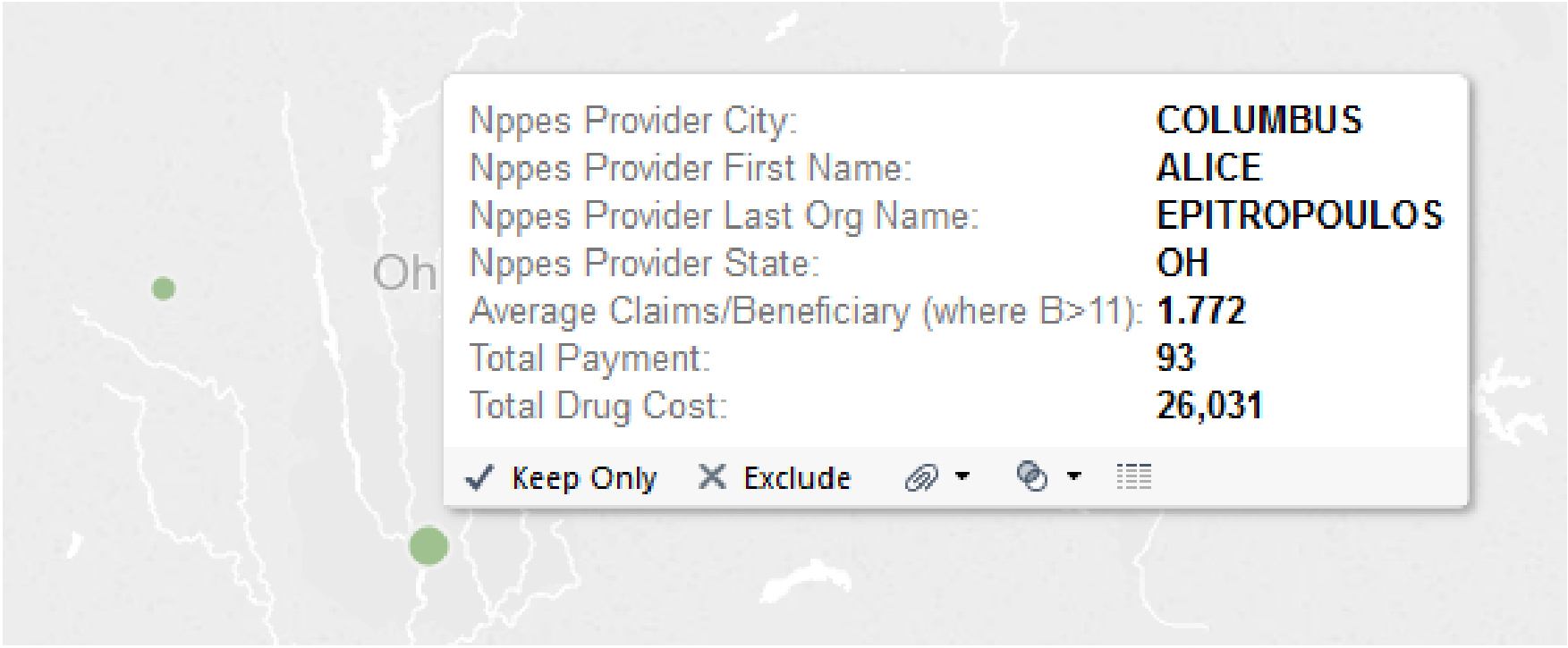
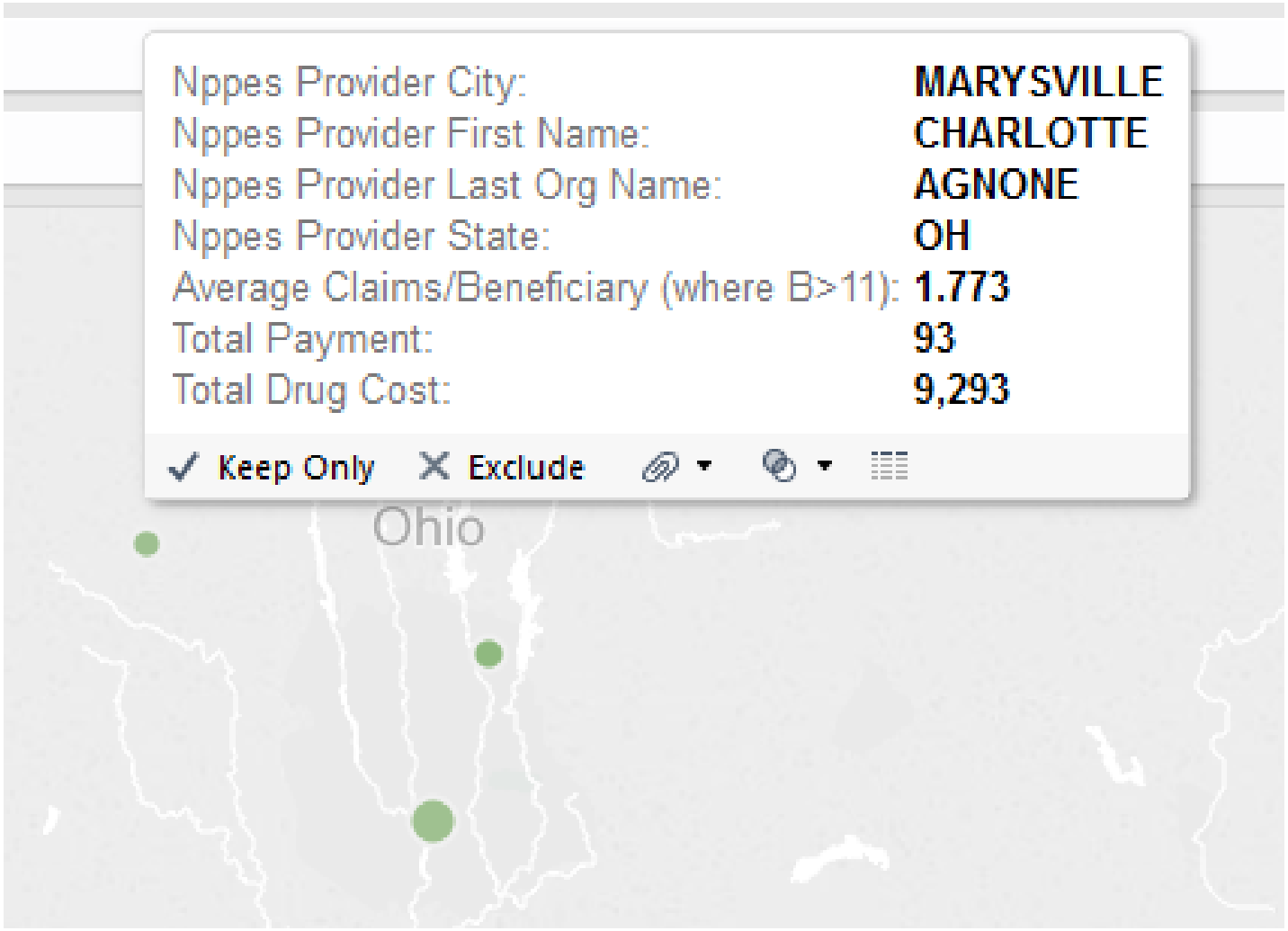
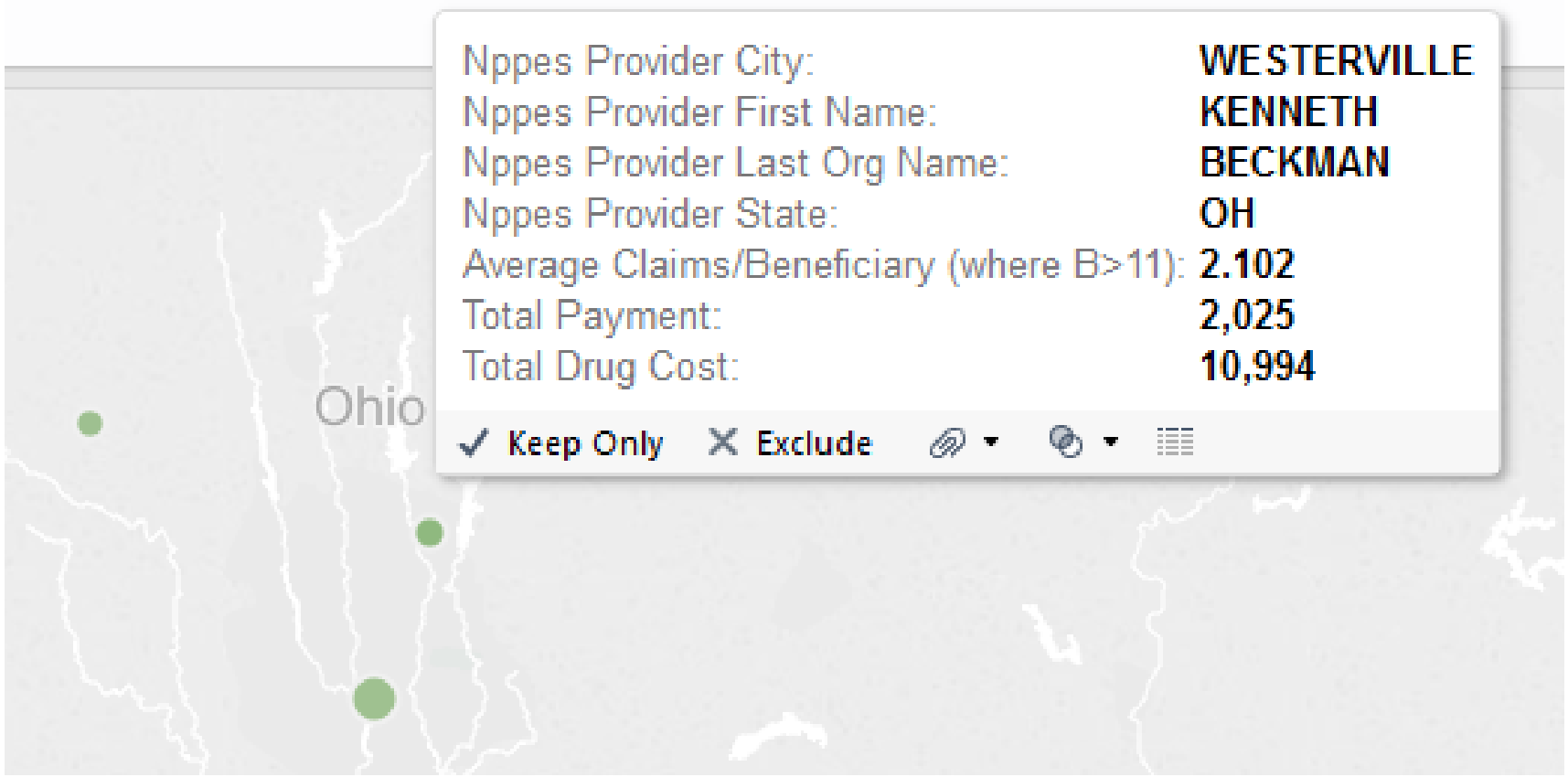

Oh
Nppes Provider City: COLUMBUS
Nppes Provider First Name: ALICE
Nppes Provider Last Org Name: EPITROPOULOS
Nppes Provider State: OH
Average Claims/Beneficiary (where B>11): 1.772
Total Payment: 93
Total Drug Cost: 26,031
Keep Only
Exclude


Nppes Provider City: MARYSVILLE
Nppes Provider First Name: CHARLOTTE
Nppes Provider Last Org Name: AGNONE
Nppes Provider State: OH
Average Claims/Beneficiary (where B>11): 1.773
Total Payment: 93
Total Drug Cost: 9,293
Keep Only
Exclude
Ohio


Nppes Provider City: WESTERVILLE
Nppes Provider First Name: KENNETH
Nppes Provider Last Org Name: BECKMAN
Nppes Provider State: OH
Average Claims/Beneficiary (where B>11): 2.102
Total Payment: 2,025
Total Drug Cost: 10,994
Keep Only
Exclude
Ohio

eye.osu.edu/directory/communityfaculty/

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THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Havener Eye Institute
Department of Ophthalmology & Visual Science

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Community Faculty

Clinical Professors

Susan C. Benes, MD John A. Burns, MD Kenneth V. Cahill, MD

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John A. Burns, MD
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Robert J. Derick, MD
Jack Dingle, MD
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Richard E. Simmons, MD
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Roger H. Sherman, MD

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Charlotte Agnone, MD
J. Geoffrey Allen, MD
N. Douglas Baker, MD
Kenneth Beckman, MD
Robert P. Bennett, MD
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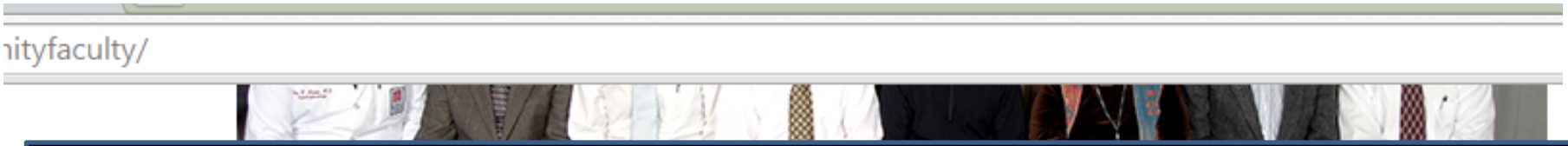

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