Disclosures

• Rich, Zach, and Steve work for Rocky Mountain Health Plans.
• We do not have any financial interest in the medications we are discussing today.
• We have no intention to malign any person, business or product.
Support Act – Pharmacy Impact

• More restrictions on opioids. This time in combination of drugs
• Started 10/1/2019
• Restricts
  – Opioids + benzodiazepines
  – Opioids + antipsychotics
Support Act – Pharmacy Impact

• Opioid + benzodiazepines
  – Required ‘hard edit’ by insurance companies
    • A ‘hard edit’ refers to a PA approval required before payment
  – ‘New starts only’ (NSO)
    • Patients who are new to therapy on one of the drugs
    • Example:
      – Patient on tramadol chronically then is prescribed alprazolam
        » Claim for alprazolam will reject for PA required since they have filled the tramadol in the past 6 months
      – Patient on clonazepam and then is prescribed oxycodone/apap
        » Claim for oxycodone/apap will deny for PA required since they have filled the clonazepam in the past 6 months
  – Does not apply to cancer or hospice patients
  – Look back is 6 months for any opioid/benzo claim
Support Act – Pharmacy Impact

• Opioids + antipsychotics
  – Required ‘soft edit’ by insurance companies
    • A ‘soft edit’ requires that an override be put in by the pharmacist before payment either in consultation with the provider or based on clinical judgement
  – ‘New starts only’ (NSO)
    • Patients who are new to therapy on one of the drugs
    • Example:
      – Patient on tramadol chronically and is now prescribed olanzapine
        » Claim for olanzapine will reject for drug utilization review (DUR) since they have filled the tramadol in the past 6 months
      – Patient on quetiapine and is now prescribed oxycodone/apap
        » Claim for oxycodone/apap will deny for DUR since they have filled the quetiapine in the past 6 months
  – Look back is 6 months for any opioid/antipsychotic claim
Question

• How familiar are you with the drug recalls involving angiotensin II receptor blockers (ARB) and histamine-2 receptor antagonists (H₂RA)?

A. I heard they were recalled
B. I don’t prescribe them
C. I’m confident answering patient questions
D. Don’t remind me
Drug Recalls

Drug Recalls

A drug recall is the most effective way to protect the public from a defective or potentially harmful product. A recall is a voluntary action taken by a company at any time to remove a defective drug product from the market.

The list below includes voluntary recalls in which public notification has been issued.

See FDA's role in drug recalls for more information.
See Recalls, Market Withdrawals, & Safety Alerts for all FDA-regulated products.
For recall notices older than 60 days, see recall and safety alerts archive.

Resources for You

- Recalls, Market Withdrawals, & Safety Alerts
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Enforcement Reports
- Drug Safety Communications
- Drug Alerts and Statements
- FDA Recall Information on Twitter

Drug Recalls - ARBs

• Since 7/2018 12 different manufacturers have recalled an angiotensin II receptor blocker (ARB) due to contamination
• List of drugs recalled include: valsartan, irbesartan, losartan
• Contamination with N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodibutylamine (NDBA).
Drug Recalls - ARBs

• What is NDMA
  – NDMA is considered a research chemical in the U.S.A.
  – Was previously used to make rocket fuel but this practice has since been stopped
  – It is unintentionally formed during various manufacturing processes
  – Primary human exposure is from
    • Smoking/chewing tobacco
    • Cured meats (particularly bacon)
    • Beer
    • Fish
    • Cheese
    • Toiletry (shampoo)
    • Cosmetics
    • Detergents
    • Pesticides
Drug Recalls - ARBs

• How can NDMA affect humans
  – Has been shown to be very harmful to the liver
    • High levels over several days or low levels over the long-term can cause serious, non-cancerous, liver disease
  – Has been shown to cause cancer in animals
    • No reports of cancer in humans
    • “reasonable to expect” that it could cause cancer in humans

## Drug Recalls - ARBs

### Interim Limits for NDMA, NDEA, and NMBA in Angiotensin II Receptor Blockers (ARBs)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Maximum Daily Dose (mg/day)</th>
<th>Acceptable Intake NDMA (ng/day)*</th>
<th>Acceptable Intake NDMA (ppm)**</th>
<th>Acceptable Intake NDEA (ng/day)*</th>
<th>Acceptable Intake NDEA (ppm)**</th>
<th>Acceptable Intake NMBA (ng/day)*</th>
<th>Acceptable Intake NMBA (ppm)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valsartan</td>
<td>320</td>
<td>96</td>
<td>0.3</td>
<td>26.5</td>
<td>0.083</td>
<td>96</td>
<td>0.3</td>
</tr>
<tr>
<td>Losartan</td>
<td>100</td>
<td>96</td>
<td>0.96</td>
<td>26.5</td>
<td>0.27</td>
<td>96</td>
<td>0.96</td>
</tr>
<tr>
<td>Irbesartan</td>
<td>300</td>
<td>96</td>
<td>0.32</td>
<td>26.5</td>
<td>0.088</td>
<td>96</td>
<td>0.32</td>
</tr>
<tr>
<td>Azilsartan</td>
<td>80</td>
<td>96</td>
<td>1.2</td>
<td>26.5</td>
<td>0.33</td>
<td>96</td>
<td>1.2</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>40</td>
<td>96</td>
<td>2.4</td>
<td>26.5</td>
<td>0.66</td>
<td>96</td>
<td>2.4</td>
</tr>
<tr>
<td>Eprosartan</td>
<td>800</td>
<td>96</td>
<td>0.12</td>
<td>26.5</td>
<td>0.033</td>
<td>96</td>
<td>0.12</td>
</tr>
<tr>
<td>Candesartan</td>
<td>32</td>
<td>96</td>
<td>3.0</td>
<td>26.5</td>
<td>0.83</td>
<td>96</td>
<td>3.0</td>
</tr>
<tr>
<td>Telmisartan</td>
<td>80</td>
<td>96</td>
<td>1.2</td>
<td>26.5</td>
<td>0.33</td>
<td>96</td>
<td>1.2</td>
</tr>
</tbody>
</table>

* The acceptable intake is a daily exposure to a compound such as NDMA, NDEA, or NMBA that approximates a 1:100,000 cancer risk after 70 years exposure

** These values are based on a drug’s maximum daily dose as reflected in the drug label
Drug Recalls - ARBs

• Clarifying the risk and scope of exposure from FDA
  – As part of our efforts to be transparent regarding impurities in ARBs, we want to make sure patients have a full understanding of how these impurities may affect them. Notably, we would like to stress that the actual risk to patients is likely much lower than our estimates, which reflect a scientific assessment of the highest possible exposure. **We initially estimated that if 8,000 people took the highest valsartan dose (320 mg) containing N-Nitrosodimethylamine (NDMA) from the recalled batches daily for four years, there may be one additional case of cancer over the lifetimes of those 8,000 people.** In reality, the vast majority of patients exposed to NDMA through ARBs received much smaller amounts of the impurity than this worst-case scenario, and, since not all ARBs are affected, it’s very likely that a patient taking an ARB for four years would not have always received one of the affected products.
Drug Recalls - ARBs

• List of resources
  – List of ARBs still on the market
    • https://www.fda.gov/drugs/drug-safety-and-availability/fdas-assessment-
      currently-marketed-arb-drug-products
  – Current general information about the recall
    • https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-
      press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-
      valsartan-losartan
  – General information including information for health care professionals
    • https://www.fda.gov/drugs/drug-safety-and-availability/recalls-
      angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-
      irbesartan
Drug Recalls - Zantac

• Recalls started 9/13/2019
• Contamination with NDMA was found to be above safety levels
• Currently limited to ranitidine capsules and OTC products but further testing has begun
  – Testing other H₂ receptor blockers (H2RA) and proton pump inhibitors (PPI)
  – High probability of more recalls coming
Drug Recalls - Zantac

• 10/24/2019
  – 2 more manufacturers of ranitidine announce recalls
  – FDA releases a statement that alternatives have not been found to be contaminated
    • Tested alternatives include
      – Pepcid (famotidine)
      – Nexium (esomeprozole)
      –Prevacid (lansoprazole)
      – Prilosec (omeprazole)
It’s a ‘Hello Sunshine’ Morning

JORNAY PM is proven to control ADHD symptoms from the time your child wakes up, and lasts throughout the day.
Question

• How much does Duexis, the fixed dose combo of famotidine and ibuprofen, cost per month?
  – A) $4
  – B) $100
  – C) $500
  – D) $3,000
  – E) $19,000
• Jornay PM (methylphenidate delayed release capsules)
  – FDA approved August 2018, became available mid-2019. Ages 6 +
  – Uses DELEXIS proprietary technology to delay GI absorption for 10 to 12 hours
  – Once released for absorption, provides extended release throughout the day
  – The idea is to provide ADHD efficacy upon waking for a less hectic household prior to school
– Uses DELEXIS proprietary technology to delay GI absorption for 10 to 12 hours
– Not to be confused with DUEXIS
  • The $3,000/month ibuprofen&famotidine tablet
– Uses DELEXIS proprietary technology to delay GI absorption for 10 to 12 hours

– [video](#)

* The DELEXIS® drug delivery system incorporates advanced microbead technology composed of 2 functional film coatings surrounding a methylphenidate core¹
How does ADHD affect your mornings?

Take the Rate My Morning Quiz, and talk to your doctor.
Mornings in your home are:

- Kinda zen
- Mild madness
- Complete chaos

Check the ADHD symptoms that can make the early morning routine tough.

(Choose all that apply)

- Listening or paying attention
- Getting organized or staying focused
- Hyperactivity or impulsivity
- Not applicable—things are mostly under control
Getting out the door in the morning

- Goes pretty smoothly—not an issue
- Sometimes happens without a hitch
- Is a struggle

Do you think mornings affect how the rest of the day goes?

- Absolutely—how I start the morning counts
- No, I can brush off what happens during the early morning routine
- Never thought about it

Get results
Having tough mornings?
Talk to your doctor

Maybe it's time to consider JORNAY PM, a medication that controls ADHD symptoms from the time of waking up. In the meantime, here are some morning tips just for you. The Doctor Discussion Guide can help you start the conversation about mornings and ADHD with your doctor.

Be a morning realist
Setting unrealistic goals can set you up for failure. Be realistic about the early morning routine and add a little more time to get things done.

Alarms aren't just for waking up
Set 'as you go' alarms to make sure you're not running overtime on each task. Remember to be practical about how long things may take.
Arithmetic Mean Plasma Methylphenidate Concentrations following a Single, Oral, 100 mg Dose of JORNAY PM (Methylphenidate Hydrochloride Extended-Release Capsule) or Methylphenidate Immediate-Release Oral Product Administered in a Crossover Manner to Healthy Adult Subjects
Jornay PM

• Dosing
  – 20mg at 8pm, titrate to maximum dose of 100mg

• Clinical Studies
  – Two Phase III studies brought Jornay PM to market
  – Multi-center, randomized, double blind, placebo controlled, n=278 over both
  – Patients aged 6-12
  – Efficacy measure: SKAMP and ADHD-rating scale, Parent Rating of Evening and Morning Behavior-Revised scale (PREMB-R AM) and the Before School Functioning Questionnaire (BSFQ)
Jornay PM

• Study 1
  – 6 week open label phase to optimize dosing
  – Followed by 1 week discontinuation phase (double blinded)
    • Patients either continued Jornay PM (n=64), or switched to placebo (n=53)
  – 1° endpoint – at 1 week, patients assessed in classroom setting over a 12 hour period using SKAMP rating scale (0= no impairment, 78=maximal impairment)
    • SKAMP – Swanson, Kotin, Agler, M-Flynn, Pelham Rating Scale (Validated instrument)
      – Measures the manifestations of ADHD using an independent observer rating of the participant's impairment in classroom observed behaviors.
      – Score is comprised of 13 items (subscales: attention with items 1-4, deportment with items 5-8, quality of work with items 9-11 and compliance with items 12-13)
Study 1, cont’d

- 2° endpoint – morning subscale of the Parent Rating of Evening and Morning Behavior-revised (PREMB-R AM)
  - 11 item validated scale, 3 AM and 8 PM
  - AM scale, 3 items, highest possible score = 9 (0= no ADHD manifestations, 9=severe)
  - Clinician-rated scale based on parent interview. In this study, the scale was filled out by the parents and reviewed by a clinician
Jornay PM

— Study 1

• Results

— 1° endpoint – SKAMP scores were statistically lower than

*Figure 2: Study 1—LS Mean SKAMP Combined Score on Day after Final Treatment, as Measured in an Analogue Classroom, N=117*
Jornay PM

• Study 1
  – Results
    • 2° endpoint – PREMB-R scores were statistically significantly lower for Jornay PM
      – 0-9 scale over 3 questions
      – Total scores: Jornay 0.9, Placebo 2.7
• Study 2
  – 3 week, multi-center, double blind, parallel group. Age 6-12 years
  – No run-in, 1° endpoint ADHD-Rating Scale IV total score
    • Scores range from 0 (no symptoms) – 54 (severe symptoms)
    • Normative scores in ADHD patients run from 18 to 29
  – 2° endpoint – Before School Functioning Questionnaire
    • Clinician rated, 20-item questionnaire using severity scale 0-3
      – Scores from 0 (no morning difficulty) – 60 (severe difficulty)
  – Results:
    • Scores on both 1° and 2° endpoints were statistically lower than placebo
### Study 1 and 2 results

#### Table 2: Summary of Primary Efficacy Results in Pediatric Patients (6 – 12 years) with ADHD (Studies 1 and 2)

<table>
<thead>
<tr>
<th>Study Number</th>
<th>Measure (Primary Endpoint)</th>
<th>Treatment Group (#ITT Subjects)</th>
<th>Mean Baseline Score (SD)</th>
<th>LS Mean (SE)</th>
<th>Placebo-subtracted Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>SKAMP CS Average</td>
<td>JORNAY PM (84)</td>
<td>NA</td>
<td>14.8 (1.17)</td>
<td>-5.9 (-9.1, -2.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Placebo (53)</td>
<td>NA</td>
<td>20.7 (1.22)</td>
<td></td>
</tr>
<tr>
<td>Study 2</td>
<td>ADHD-RS-IV</td>
<td>JORNAY PM (81)</td>
<td>43.1 (7.33)</td>
<td>24.1 (1.50)</td>
<td>-7.0 (-11.4, -2.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Placebo (80)</td>
<td>43.5 (6.84)</td>
<td>31.2 (1.60)</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- ITT: Intent-to-treat
- SE: Standard Error
- SD: Standard Deviation
- CI: Confidence Interval
- NA: Not Available
- CS: Combined Score (sum of items 1-13)
## Jornay PM – adverse events

<table>
<thead>
<tr>
<th>Body Organ System</th>
<th>Adverse Reaction</th>
<th>JORNAY PM (N=81)</th>
<th>Placebo (N=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric disorders</td>
<td>Any insomnia</td>
<td>33%</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>Initial insomnia</td>
<td>14%</td>
<td>5%</td>
</tr>
<tr>
<td></td>
<td>Middle insomnia</td>
<td>11%</td>
<td>4%</td>
</tr>
<tr>
<td></td>
<td>Terminal insomnia</td>
<td>11%</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>Insomnia, not specified</td>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>Affect lability/ Mood swings</td>
<td>6%</td>
<td>1%</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Decreased appetite</td>
<td>19%</td>
<td>4%</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td></td>
<td>Psychomotor hyperactivity</td>
<td>5%</td>
<td>1%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Blood pressure diastolic increased</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Vomiting</td>
<td>9%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>6%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Adverse events

- By way of comparison – Vyvanse (lisdextroamphetamine) adverse events

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>VYVANSE (n=233)</th>
<th>Placebo (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased Appetite</td>
<td>34%</td>
<td>3%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>13%</td>
<td>4%</td>
</tr>
<tr>
<td>Weight Decreased</td>
<td>9%</td>
<td>0%</td>
</tr>
<tr>
<td>Dry Mouth</td>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td>Palpitations</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Anorexia</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Tremor</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Adverse events

• By way of comparison – Aptensio (methylphenidate) adverse events

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Aptensio XR (n=183)</th>
<th>Placebo (n=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>10.9%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>9.8%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2.2%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain upper</td>
<td>8.2%</td>
<td>0%</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.8%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3.8%</td>
<td>0%</td>
</tr>
<tr>
<td>Metabolism and Nutritional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased Appetite</td>
<td>4.9%</td>
<td>0%</td>
</tr>
</tbody>
</table>
ADHD – long acting meds

- Daytrana (methylphenidate patch)
- Quillichew ER (methylphenidate chews)
- Quillivant XR suspension (methylphenidate susp)
- Aptensio (methylphenidate ER)
- Focalin XR (dexamethasone)
- Adzenys XR ODT (amphetamine)
- Evekeo (amphetamine)
- Dynavel XR (amphetamine)
- Concerta (methylphenidate)
- Ritalin LA (methylphenidate)
- Vyvanse (lisdextroamphetamine)
- Mydayis (amphetamine salts)
- Cotempla XR ODT (methylphenidate)
- Strattera (atomoxetine)
- Intuniv (guanfacine)
- Kapvay (clonidine)
Some ADHD drug prices

- Jornay PM $444
- Cotempla XR ODT (methylphenidate) $445
- Daytrana Patch (methylphenidate) $440
- Vyvanse (lisdextroamphetamine) $364
- Quillichew ER (methylphenidate) $400
- Ritalin LA $366
- Methylphenidate ER (generic Concerta) $130-$200
- Dexmethylphenidate ER (generic Focalin XR) $155-$200
Jornay PM

• Pros
  – Offers efficacy seemingly similar to other ADHD drugs, without the need for AM dosing. May have an advantage in pre-school morning functioning
  – Efficacy appears to persist throughout the day

• Cons
  – Another expensive brand name drug for treatment of ADHD with aggressive marketing. Several less expensive, long acting options available.
  – Insomnia incidence higher than other ADHD drugs (33%)
ADHD therapy follow up recommendations

• Adverse effects
  – Most commonly reported:
    • Insomnia (ranges from 8% to 33% depending on drug)
    • Stomachache (5% - 10%)
    • GI upset (N/V) (2% - 4%)
    • Decreased appetite (5% to 30%)
    • Headache (10%, but placebo usually around 8%)
  – Most concerning, but actual incidence low
    • Reduced growth velocity
    • Weight loss
    • Psychotic symptoms
    • Cardiac effects
ADHD therapy follow up recommendations

• Efficacy
  – Stimulants are more effective than non-stimulants
  – For elementary school aged patients, data is particularly strong for stimulants vs. non-stimulants
  – About 40% of patients respond to both methylphenidate and amphetamine, and about 40% respond to only one or the other
  – Large variability in patient response
ADHD therapy follow up recommendations

• National Institute of Mental Health (NIMH) Multimodal Therapy of ADHD study (NIMH MTA)
  — Evaluated behavioral therapy, drug therapy, and combination of the two
  — Primary results published in 1999 but follow up data continues to be published
  — Growth velocity data from this trial
    • Reduction of about 1 cm to 2 cm over 14 months, especially in children on higher or more consistent dosing (7 days per week)
      — Intensive dosed patients grew 4.25 cm average vs. 6.19 cm in patients receiving CBT alone
    — Showed improved outcomes when patients receive more frequent follow-up
ADHD therapy follow up recommendations

  - recommends children started on therapy be assessed at least monthly (preferably every 1 to 2 weeks) until optimal dose is established
  - recommends 3 to 6 month visits once child is stable, to assess learning and behavior, appetite, weight, height, and growth velocity
  - Encourages ADHD to be treated as a chronic disease following the principles of the chronic care model and medical home

- Each visit, assess for unanticipated changes in HR, BP, and for psychiatric symptoms such as aggression and altered mood.

- Stimulants may increase HR 3 – 6 BPM, and BP 2 – 4 mmHg
  - While clinically insignificant for most, a small portion (5-15%) of patients experience a clinically important increase
ADHD therapy follow up recommendations

• Weight – expectation is no weight loss over long term
  – Expect a reduction in weight *gain*
    • A reduction of about 2 kg over 3 years has been reported with most stimulants, and initial weight loss of about 2 kg may occur during first month of treatment

• Growth velocity
  – NIMH showed 1 – 2cm over 14 months
  – Reduction in growth usually tops out after 3 yrs of therapy
  – 1 to 2 cm reduction in predicted adult height does not seem to rebound after cessation of therapy
Flu mist is back
2010-2017

- Flumist- live attenuated virus
- Ineffective H1N1
- Effective against Influenza b
- Effective against HCN2
2019-2019

- Flumist changed
- New vaccine virus
- CDC
- “some data” will result in improved effectiveness against H1N1
- However, no published data on the effectiveness are available

Flu Vaccine 2019-2020

• Quadrivalent
• A/Brisbane/02/2018 (H1N1)pdm09-like virus (updated)
• A/Kansas/14/2017 (H3N2)-like virus (updated)
• B/Colorado/06/2017-like (Victoria lineage) virus
• B/Phuket/3073/2013-like (Yamagata lineage) virus
Palforzia

- Oral immunotherapy to treat peanut allergy
- Slowly increasing daily exposure to peanuts
- “calibrated quantities of ingested peanut powder”
- 20% chance of anaphylaxis
- Single year long clinical trial
Palforzia

- $4200/year
- Taken indefinitely
Palforzia

- Argued “No treatment”
- Brian Vickery allergist who did the study is employed by Aimmune
I asked him why other companies couldn’t simply sell peanut powder as a dietary supplement at a cost of a few dollars.

Well, I suppose they could,” Casale said. But he went on to explain that the real value is billing codes. When peanut flour is an FDA-approved drug, that means doctors can be reimbursed for prescribing it and overseeing its administration. The process can be covered by insurance. As it is, practitioners who offer their own versions of oral immunotherapy have to be paid out of pocket. This makes it inaccessible to many patients. So, essentially, in order to make the therapy accessible, it has to become part of the system. The system is what allows pharmaceutical companies and doctors to charge insurers thousands of dollars for peanuts.
• Real-World Experience with Peanut Oral Immunotherapy: Lessons Learned From 270 Patients

• February 2019 Volume 7, Issue 2, Pages 418–426.e4
• Aimmune Therapeutics (AIMT)
• Stock price increased by 15.4% to 25.46$
• After FDA approval
• Viaskin Peanut Patch
Question

• To find out when and how often a patient uses their albuterol, how much would you expect an albuterol inhaler with a sensor to cost?

A. $0 - $50
B. $51 - $100
C. $101 - $150
D. >$151
Meet ProAir® Digihaler™
With Companion Mobile App

ProAir® Digihaler™ is the first and only digital inhaler with built-in sensors that detect when the inhaler is used and measure inspiratory flow. This inhaler use data is then sent to the companion mobile app using Bluetooth® wireless technology so patients can review their data over time, and if desired, share it with their healthcare professionals.
ProAir Digihaler

• Same device as the ProAir respimat with built in sensor
• Indication:
  – Treatment or prevention of bronchospasm in adults and children 4 years of age and older
• Dose:
  – 2 inhalations every 4 to 6 hours. In some patients, 1 inhalation every 4 hours may be sufficient.
• Dry powder inhaler
• No priming required
• Do not use with spacers or volume holding chambers
ProAir Digihaler - Continued

• Contains a built-in electronic module which detects, records, and stores data on inhaler events for transmission to the mobile App.
  – Use of the App is not required for administration of medication to the patient.
• Sensor measure
  – When the inhaler is used
  – Inspiratory flow

• Per American Association for Respiratory Care (AARC) the recommended inspiratory flow for a dry powder inhaler (DPI) is 60 L/min
  – pMDI (e.g. albuterol sulfate – generic ProAir/Ventolin) recommended inspiratory flow rate is <30 L/min
ProAir Digihaler Discussion

• What does the information collected by the Digihaler sensor provide to clinicians?
  – When the inhaler was used
  – How often it is being used
  – Inspiratory flow rate
    • If below 30 L/min, the generic pMDI may be a better option for the patient
  – Would you make clinical decisions based on the information provided by the app?
## ProAir Digihaler - Cost

<table>
<thead>
<tr>
<th></th>
<th>ProAir Digihaler</th>
<th>Albuterol (generic ProAir)</th>
<th>Proventil</th>
<th>ProAir</th>
<th>Ventolin</th>
<th>ProAir Respimat</th>
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<tbody>
<tr>
<td><strong>Cost</strong></td>
<td>$176</td>
<td>$56.63</td>
<td>$95.68</td>
<td>$77.92</td>
<td>$88.99</td>
<td>$72.84</td>
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<tr>
<td><strong>Dosage form</strong></td>
<td>Respimat</td>
<td>HFA</td>
<td>HFA</td>
<td>HFA</td>
<td>HFA</td>
<td>Respimat</td>
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</tbody>
</table>
Did you know?

• There are OTC smart inhaler sensors
• Generally Track
  – Date/time of use
• Also provide
  – Audio/visual reminders to use
  – Apps to collect data
• Hailie sensor for Symbicort
  – $159.99
Recent Generics to the Market
Question

• When a generic is approved by the FDA, how much time does the first generic manufacturer have market exclusivity?

A. 1 year
B. 6 months
C. 3 months
D. 1 month
Advair Diskus

• Advair HFA does not have generics
• Generics include:
  – Fluticasone/salmeterol – AB rated
  – Wixela Inhub – AB rated
• Fluticasone/salmeterol is the generic for both Advair and AirDuo
  – Difference is strength
    • Fluticasone/salmeterol 100/50mcg, 250/50mcg, 500/50mcg is generic Advair Diskus
    • Fluticasone/salmeterol 55/14mcg, 113/14mcg, 252/14mcg is generic AirDuo RespiClick
Advair Diskus Continued

- Cost

<table>
<thead>
<tr>
<th>Advair Diskus</th>
<th>Fluticasone/salmeterol (generic Advair diskus)</th>
<th>Advair HFA</th>
<th>Fluticasone/salmeterol (generic Airduo)</th>
<th>Wixela Inhub</th>
<th>Symbicort</th>
<th>Breo Ellipta</th>
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<tbody>
<tr>
<td>$380 - $621</td>
<td>$231 - $389</td>
<td>$380 - $621</td>
<td>$119</td>
<td>$231 - $389</td>
<td>$364</td>
<td>$421</td>
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Lyrica

• Pregabalin is the AB rated generic
• Approved 7/19/2019
• All strengths are generic
• 16 manufacturers are already on the market
• Generic manufacturers have captured >57% market share
• Cost

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<tr>
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<th>Lyrica</th>
<th>Pregabalin</th>
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<tr>
<td></td>
<td>$562</td>
<td>$25 – 93</td>
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</table>
Uloric

- Febuxostat is the new AB rated generic
- Approved 7/1/2019
- 3 manufacturers approved
- Recent BBW added due to increased risk of heart-related death and death from all causes
- Cost

<table>
<thead>
<tr>
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<th>Febuxostat</th>
<th>Allopurinol</th>
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<tr>
<td>Uloric</td>
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<td>Allopurinol</td>
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