UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 6, 2012

Cadence Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-33103**	**41-2142317**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12481 High Bluff Drive, Suite 200
San Diego, California 92130
(Address of principal executive offices, including zip code)

(858) 436-1400
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

Cadence Pharmaceuticals, Inc. ("Cadence") hosted an Analyst and Investor Day on December 6, 2012. A copy of the slides used during the event is attached as Exhibit 99.1 to this Current Report on Form 8-K, and Theodore R. Schroeder, President and Chief Executive Officer of Cadence, and other executive officers expect to use selections from these slides at various upcoming meetings.

In accordance with General Instruction B.2. of Form 8-K, the information under Items 7.01 and 9.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, except as expressly set forth by specific reference to Items 7.01 and 9.01 to this Current Report on Form 8-K in such filing.

By filing this information, Cadence makes no admission as to the materiality of any information in this report. The information contained in this report and the exhibit hereto is intended to be considered in the context of Cadence's filings with the Securities and Exchange Commission and other public announcements that Cadence makes, by press release or otherwise, from time to time. Cadence undertakes no duty or obligation to publicly update or revise the information contained in this report or the exhibit hereto, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases, through its website or through other public disclosure.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Analyst and Investor Day Presentation, dated December 6, 2012

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CADENCE PHARMACEUTICALS, INC.

By: /s/ William R. LaRue
William R. LaRue
Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary

Date: December 6, 2012

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
99.1	Analyst and Investor Day Presentation, dated December 6, 2012

Exhibit 99.1

Cadence Pharmaceuticals Analyst and Investor Day

Millennium Broadway Hotel
New York City

December 6, 2012

Improving the lives of hospitalized patients

Caution on forward-looking statements

This presentation includes forward-looking statements, which are based on our current beliefs and expectations. Such statements include, without limitation, statements regarding: the anticipated U.S. market opportunity for OFIRMEV; our financial estimates and projections; our expectations regarding growth in customer base, market base, order rates and market penetration, and their ability to drive revenue growth for OFIRMEV; physician projections regarding OFIRMEV utilization in surgical inpatients and the average number of doses to be administered to patients; statements regarding the prospects for approval by the FTC and DOJ of our settlement with Perrigo Company, and for ultimately receiving any payments under that settlement from Perrigo; our confidence in the strength of the patents covering OFIRMEV and ability to prevail in the ongoing intellectual property litigation against Exela PharmaSci and its affiliates; the sustainability of our core business; the sufficiency of our capital resources to fund our operations; and our ability to execute our strategies for acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Our actual future results may differ materially from our current expectations due to the risks and uncertainties inherent in our business. In addition, past results and trends may not be indicative or a guarantee of future results or trends. These risks include, but are not limited to: our dependence on the successful commercialization of OFIRMEV, which is our only product; our ability to achieve broad market acceptance and generate revenues from sales of OFIRMEV; our dependence on our contract manufacturers and our ability to ensure an adequate and continued supply of OFIRMEV to meet market demand; our ability to successfully enforce our marketing exclusivities and intellectual property rights, and to defend the patents covering OFIRMEV, including our current patent litigation; the potential that we may be required to continue patent litigation for substantial lengths of time, file additional lawsuits to defend our patent rights from challenges by Exela or other companies that may submit ANDAs for generic versions of OFIRMEV, and the substantial costs associated with such lawsuits; potential product liability exposure; the risk that we may not be able to raise sufficient capital when needed, or at all; and other risks detailed under “Risk Factors” and elsewhere in our Annual Report on Form 10-K for the period ended December 31, 2011, and our other filings made with the Securities and Exchange Commission from time to time.

All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and we undertake no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

Agenda

- **Introductory Remarks**
  Theodore R. Schroeder, President & CEO
  Cadence Pharmaceuticals
- **OFIRMEV: Driving Sustainable Growth**
  Scott A. Byrd, Senior Vice President, Chief Commercial Officer
  Cadence Pharmaceuticals
- **Clinical Experience with OFIRMEV**
  David Cziperle, M.D.
  Clinical Assistant Professor of Thoracic and Cardiovascular Surgery at Loyola University

Q&A

- **Multi-modal Pain Management: Potential to Improve the Cost and Quality of Care**
  Robert Ang, M.D., Vice President, Medical Affairs
  Cadence Pharmaceuticals
- **Pain Management; A Hospital Pharmacist's Perspective**
  John Marshall, PharmD, BCPS
  Clinical Pharmacy Coordinator-Critical Care, Beth Israel Deaconess Medical Center

Q&A Panel

- **Closing Remarks**
  Theodore R. Schroeder, President & CEO

OFIRMEV® product overview

OFIRMEV® (acetaminophen) injection

A non-NSAID, non-opioid IV antipyretic / analgesic agent

Approved by FDA on November 2, 2010

Approved for:

- Mild to moderate pain
- Moderate to severe pain with adjunctive opioid analgesics
- Fever
- Approved for use in adults and children 2 years of age and older

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OFIRMEV® important safety information

OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation.

Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment.

Do not exceed the maximum recommended daily dose of acetaminophen. Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death.

OFIRMEV should only be administered as a 15 minute intravenous infusion.

Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy.

The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients.

The antipyretic effects of OFIRMEV may mask fever in patients treated for post-surgical pain.

To report SUSPECTED ADVERSE REACTIONS, contact Cadence Pharmaceuticals Inc. at 1-877-MIS-CADX (1-877-647-2239) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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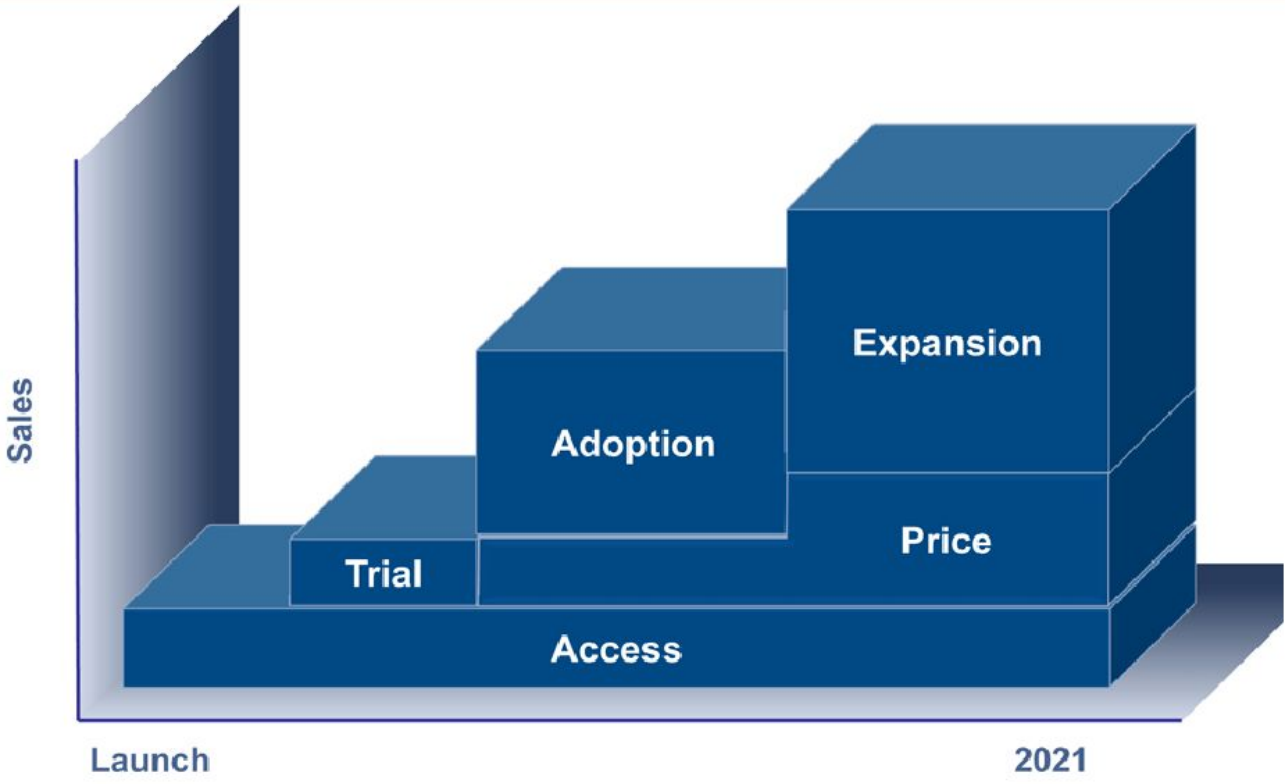
OFIRMEV:
Driving Sustainable Growth

Scott A. Byrd
Senior Vice President,
Chief Commercial Officer
Cadence Pharmaceuticals

Launch, Growth, Expansion: building blocks



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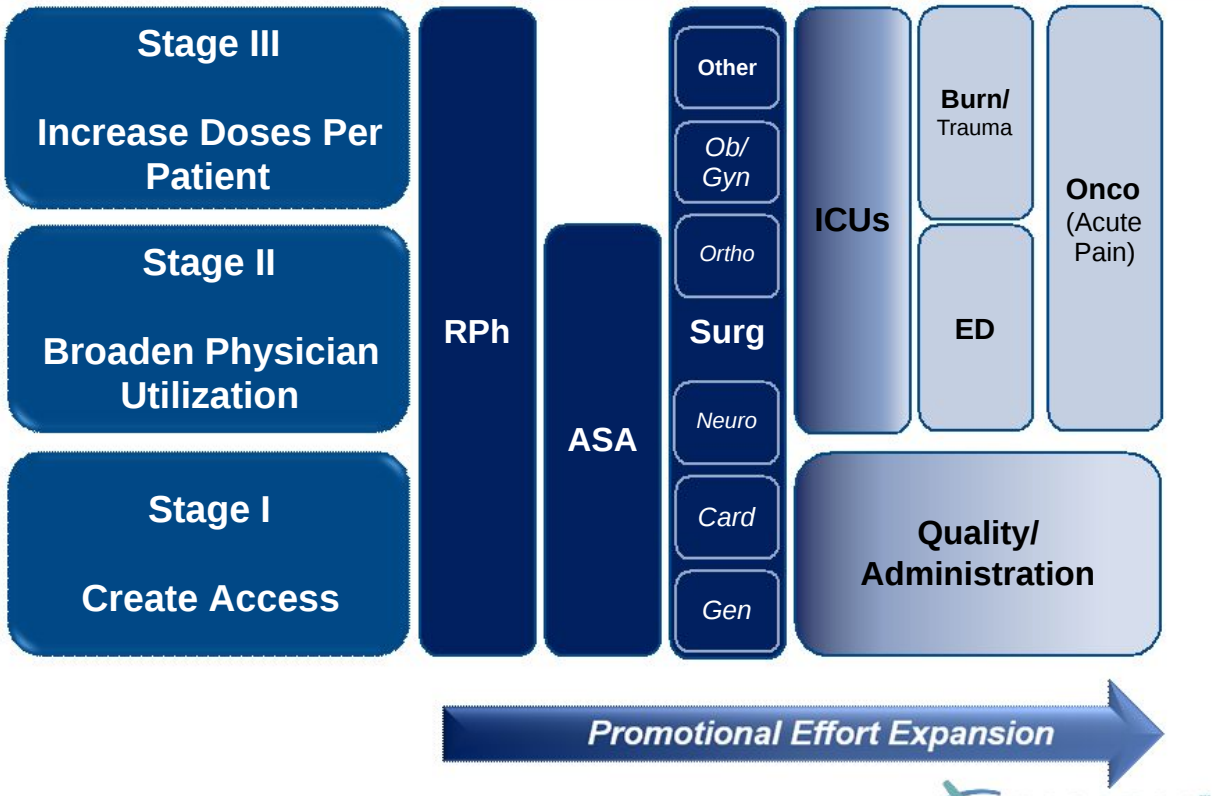
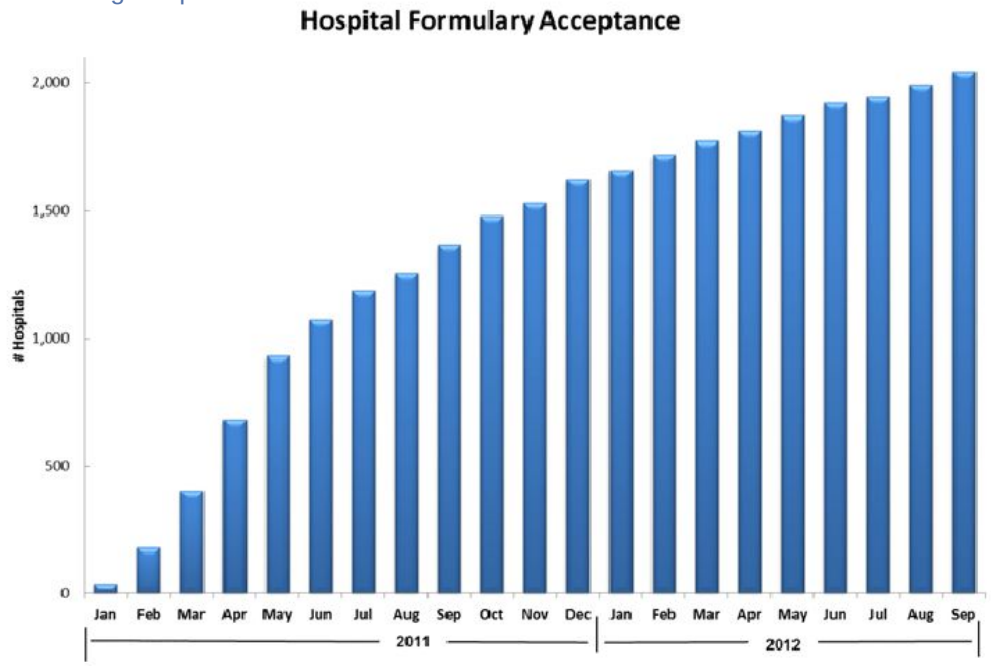
Launch, Growth, Expansion: promotional effort



Launch Performance: rapid formulary penetration

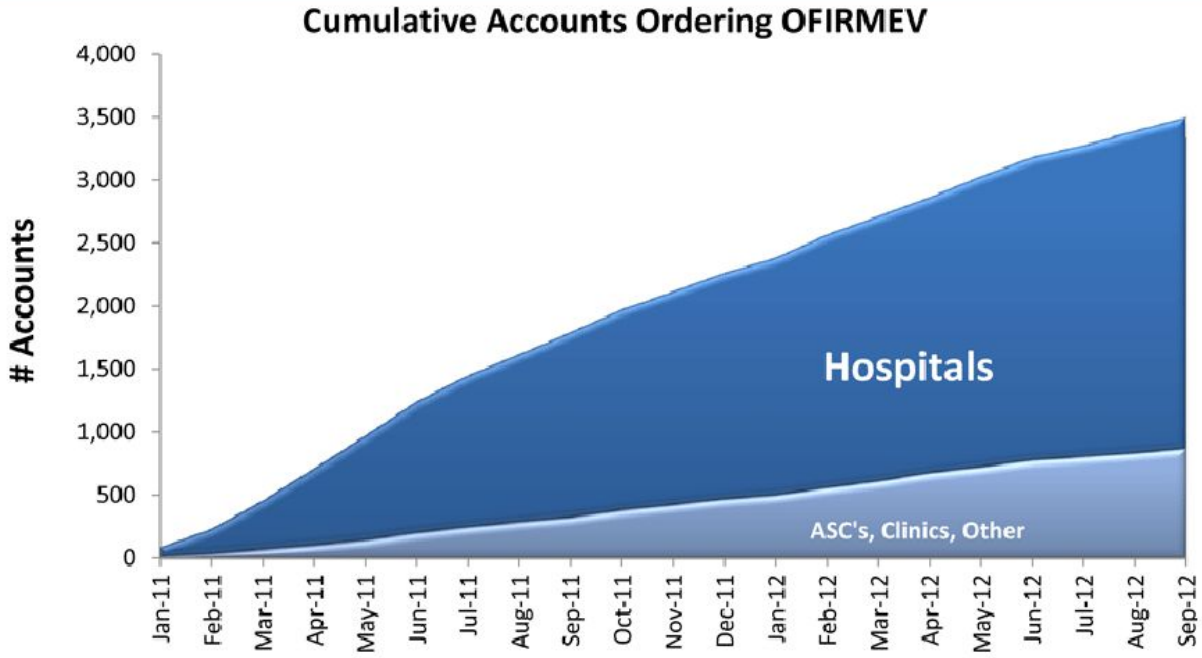
Hospitals continue to add OFIRMEV to formulary

- Formulary adoption exceeded company projections
- Over 400 hospitals added OFIRMEV in 2012, for a total of over 2,000 formulary approvals through Sep 2012



Source: Cadence Internal Data

Launch Performance:
significant growth in new customers



Significant and continuous growth in new customers

- **10% growth in unique accounts ordering OFIRMEV in Q3 vs. Q2**
- **Growth driven by hospital adoption**

Source: Source Healthcare Analytics, Source®PHAST Institution, Oct 23, 2012.

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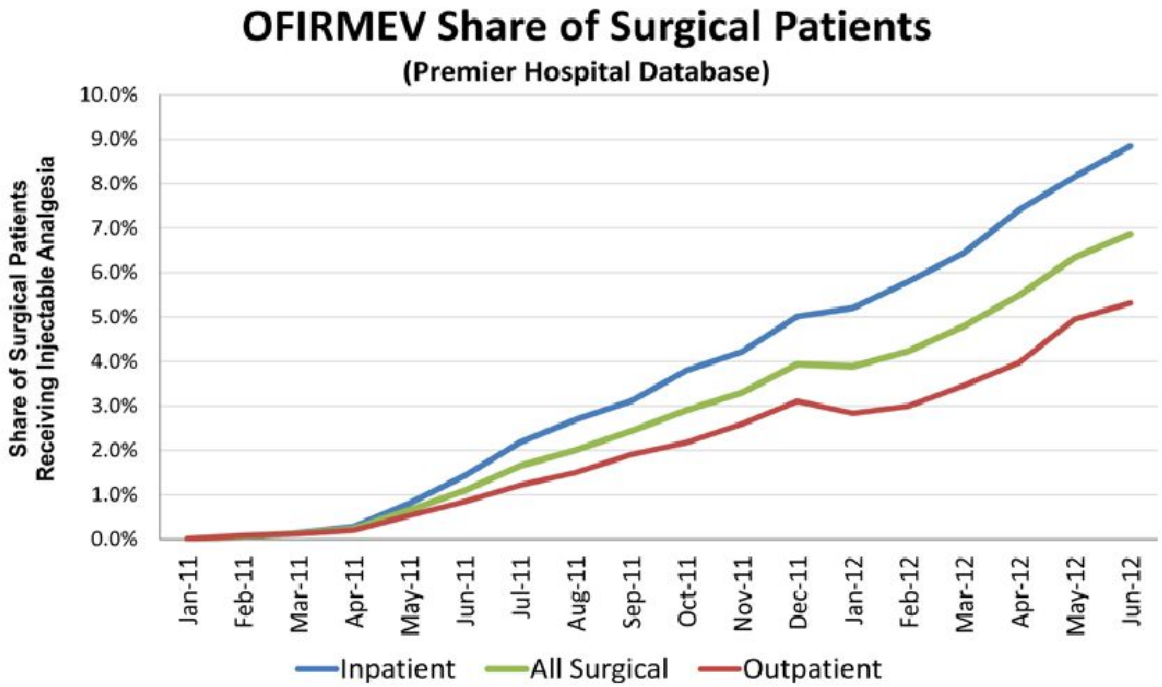
Launch Performance:
rapid penetration of perioperative pain management



Source:
Premier Hospital Database, report provided by Premier Research Services Nov. 9, 2012
Analysis of patient discharge data
Sample includes over 400 hospitals representing approximately 4.5M surgical patient discharges/year

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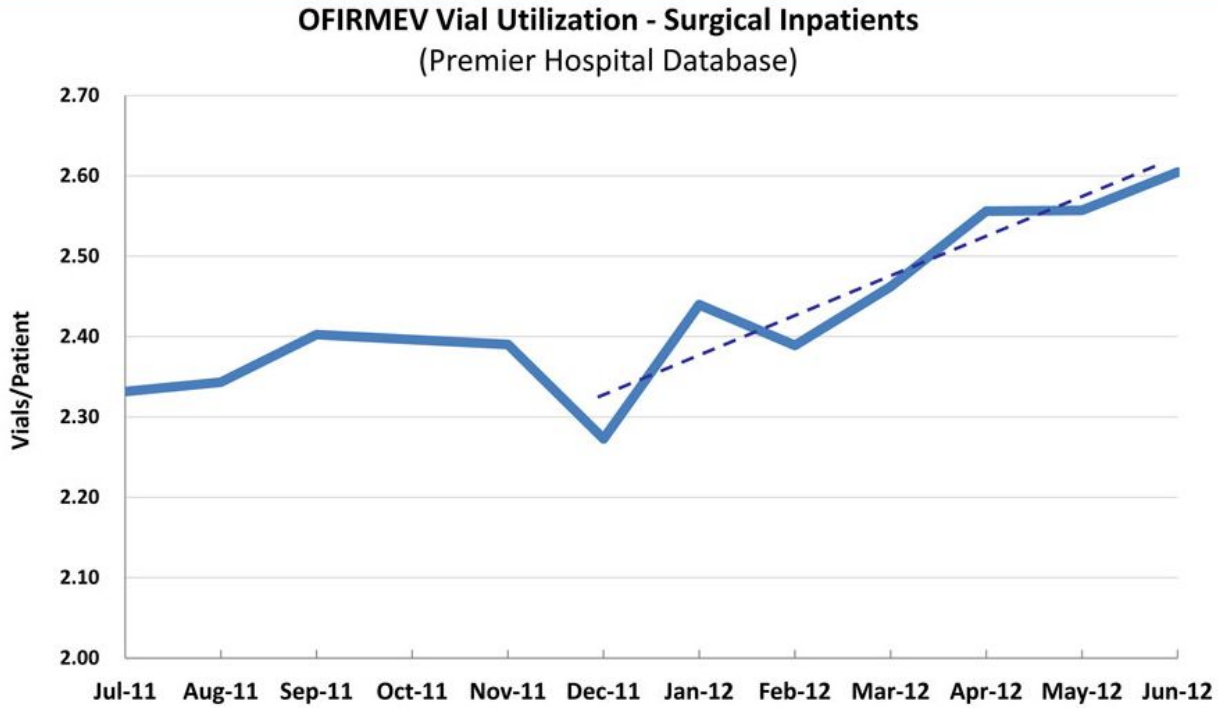
Launch Performance:
increasing utilization per patient



Source:
Premier Hospital Database, report provided by Premier Research Services Nov. 9, 2012
Analysis of patient discharge data
Sample includes over 400 hospitals representing approximately 4.5M surgical patient discharges/year

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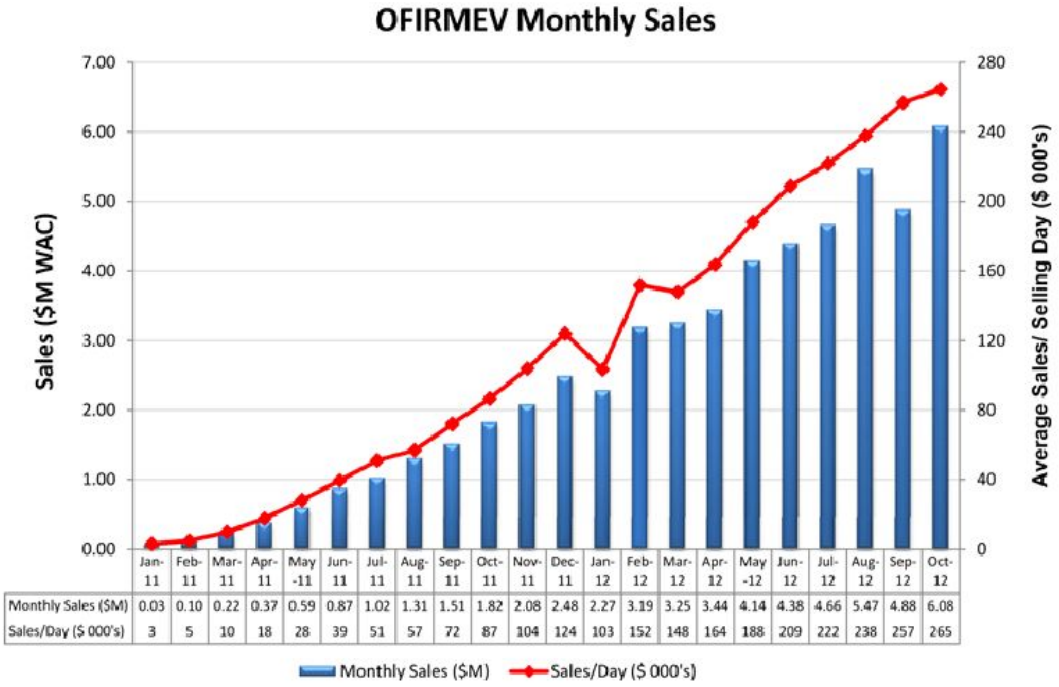
Launch Performance:
significant sales growth through Oct 2012

OFIRMEV sales continue to accelerate

- Annualized October '12 sales ≈ $73M



	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12	Feb-12	Mar-12	Apr-12	May-12	Jun-12	Jul-12	Aug-12	Sep-12	Oct-12
Monthly Sales ($M)	0.03	0.10	0.22	0.37	0.59	0.87	1.02	1.31	1.51	1.82	2.08	2.48	2.27	3.19	3.25	3.44	4.14	4.38	4.66	5.47	4.88	6.08
Sales/Day ($ 000's)	3	5	10	18	28	39	51	57	72	87	104	124	103	152	148	164	188	209	222	238	257	265

Source: Source Healthcare Analytics, Source® PHAST Institution, Nov 21, 2012.

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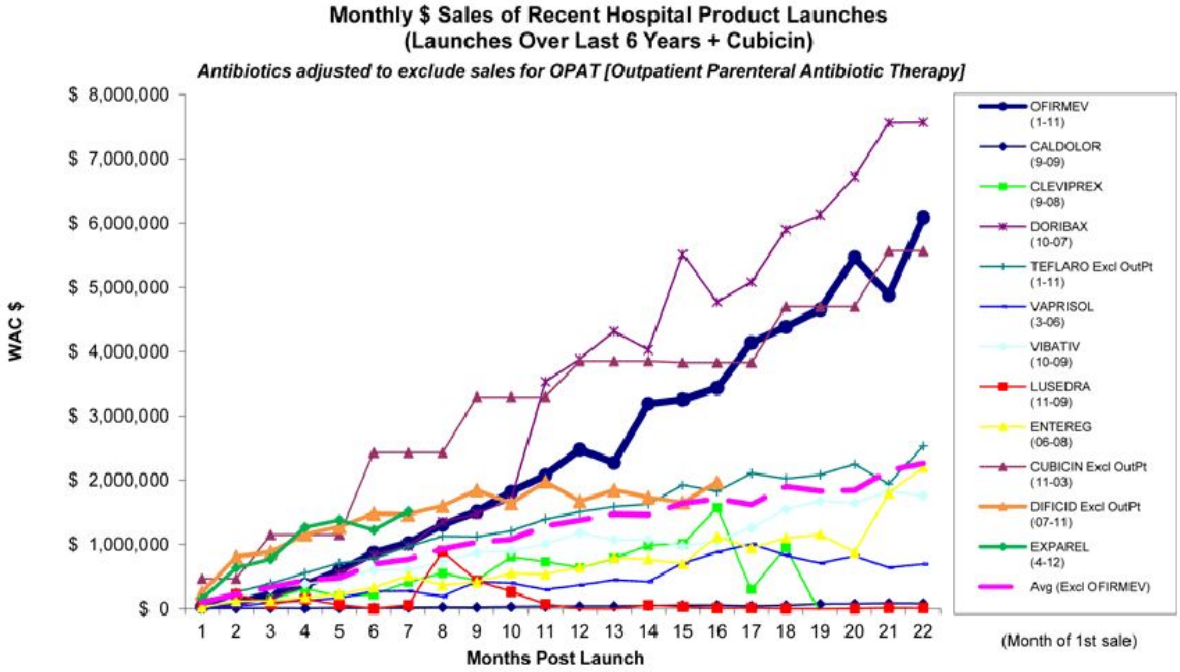
Launch Performance:
top-tier revenue growth during first 2 years of launch

OFIRMEV hospital sales growth compares favorably vs. recent hospital launches despite significantly lower price.



Source: Source Healthcare Analytics, Source® PHAST Institution. Cubist Pharmaceuticals, Inc. Form 10-Q reports. Based on Cadence comparison to other selected product launches in hospital market over period Mar 2006 – Oct 2012. OPAT utilization from Cubist Corporate Presentation, Cubist.IP.9.06.

** Cubicin monthly sales are averaged within each quarter

Launch Performance:
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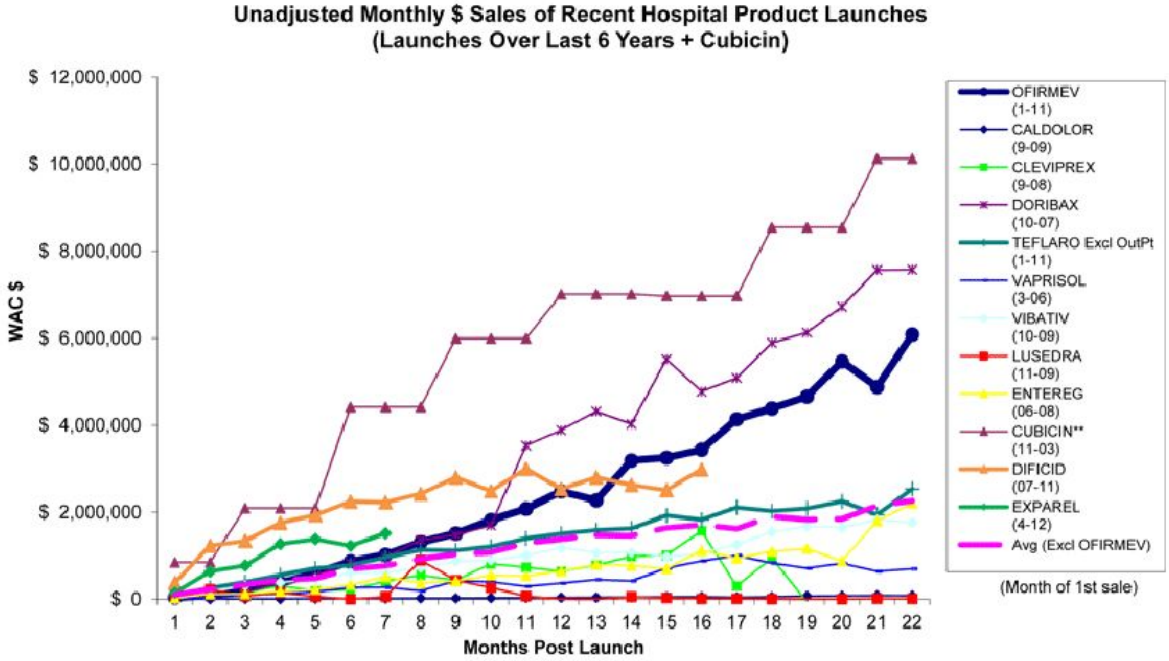

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Achieving Sustainable Growth: market dynamics

- **Headwinds**
  - Hospital silo management
  - Hospital budget pressures
- **Tailwinds**
  - CMS and Joint Commission focus on quality of pain management
    - Value Based Purchasing Program, HCAHPS
    - Joint Commission Sentinel Event Alert “Safe Use of Opioids”
  - Positive physician and nurse experience with OFIRMEV
    - 98% of physicians surveyed reported that OFIRMEV’s efficacy met or exceeded their expectations*
    - 2 of 3 indicate they are very likely to recommend to colleagues*
  - Growing base of positive local data (clinical and economic)

*Awareness, Trial, Usage (ATU) study conducted by GfK Healthcare, May 2012 (n=180 surgeons and anesthesiologists)

Achieving Sustainable Growth: commercial strategy

- **Broaden and deepen post-op pain utilization**
  - Increase penetration of surgeon user base
  - Continue to improve ease of use (stocking at point of care, standing orders, etc.)
  - Increase initiatives with front line caregivers– nurses and physician assistants
- **Expand into non-operative acute pain management**
  - Non-operative acute pain management estimated to represent 30-40% of IV analgesic use
  - Non-operative applications currently account for only about 10% of OFIRMEV use
- **Demonstrate that multi-modal pain management may be a key solution to the economic and quality squeeze being experienced by hospitals**

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Long Term Growth Opportunity: three key drivers

Significant and sustainable future growth

Long Term Opportunity: ketorolac as a case study

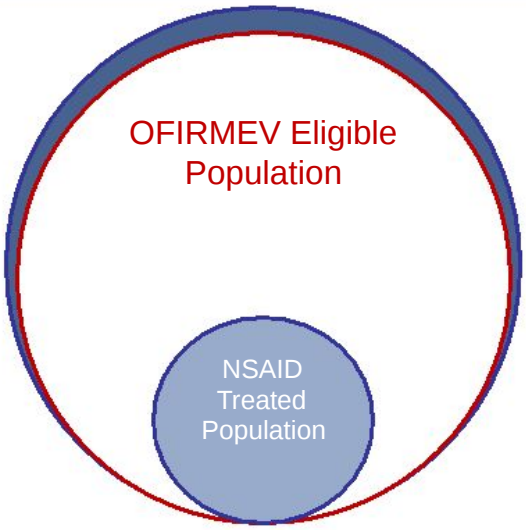
Benchmarking potential future use of OFIRMEV against ketorolac utilization

Limitations of NSAIDs

Contraindications/ Boxed Warnings:

- High Risk of Bleeding
- Prophylactic analgesic prior to major surgery
- Advanced renal impairment
- Active or history of peptic ulcers or GI bleeding
- Nursing mothers & labor/delivery
- Patients receiving aspirin or NSAIDs

Perioperative Pain Population



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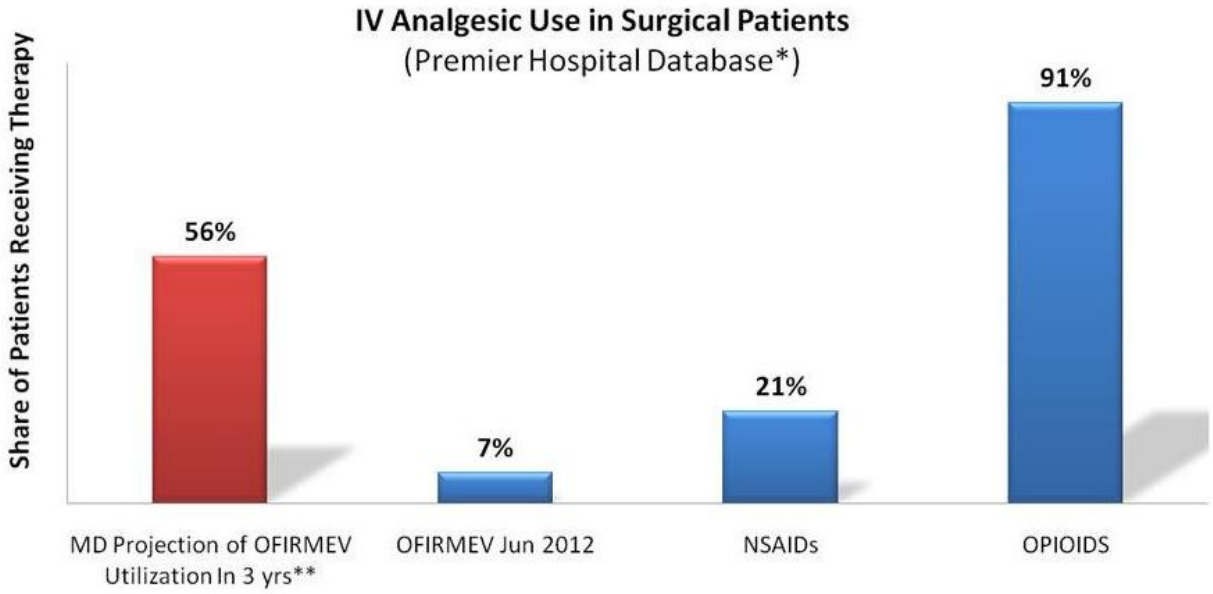
Long Term Opportunity: share of patients

Physicians project OFIRMEV to be much more broadly utilized than NSAIDs



Sources:
* Premier Hospital Database, report provided by Premier Research Services Nov 9, 2012
**Awareness, Trial, Usage (ATU) study conducted by GfK Healthcare, May 2012 (n=180 surgeons and anesthesiologists)
Question: Thinking ahead to 3 years from now, what proportion of your surgical procedures do you expect to include the use of OFIRMEV?

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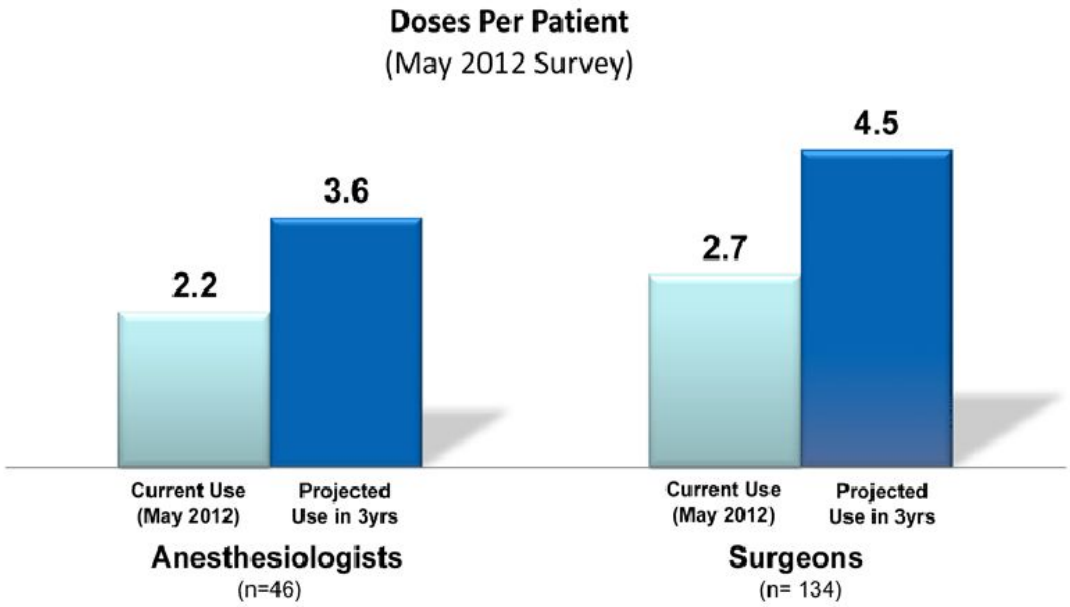
Long Term Opportunity: doses per patient

Physicians project significant increases in doses per patient



Source: Awareness, Trial, Usage Study conducted by GfK Healthcare, May 2012
Question 1: When you use OFIRMEV, how many vials are you using per one typical surgical procedure?
Question 2: How many vials of OFIRMEV do you expect to use per one typical surgical procedure 3 years from now?

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Long Term Growth Opportunity: three key drivers

Significant and sustainable future growth

David J. Cziperle, M.D., FACS

- American Board of Surgery
- American Board of Thoracic Surgery

- 31 Thoracic and Cardiovascular Surgeons
- 3 Vascular Surgeons
- 3500 annual Cardiac Procedures
- 4000 annual Thoracic/Vascular Procedures

- 22 Hospitals
- 21 Community Based Hospitals
- 1 University Based Hospital
- Practice Area Encompasses 3 States and a 250 Mile Geographic Radius
- Multiple Healthcare Systems

Late 2010

- I was contacted by a senior pharmaceutical representative regarding a new product “Intravenous Acetaminophen”
- Initial contact was approximately 5 minutes
- Subsequent contact was approximately 90 minutes

My Initial Response

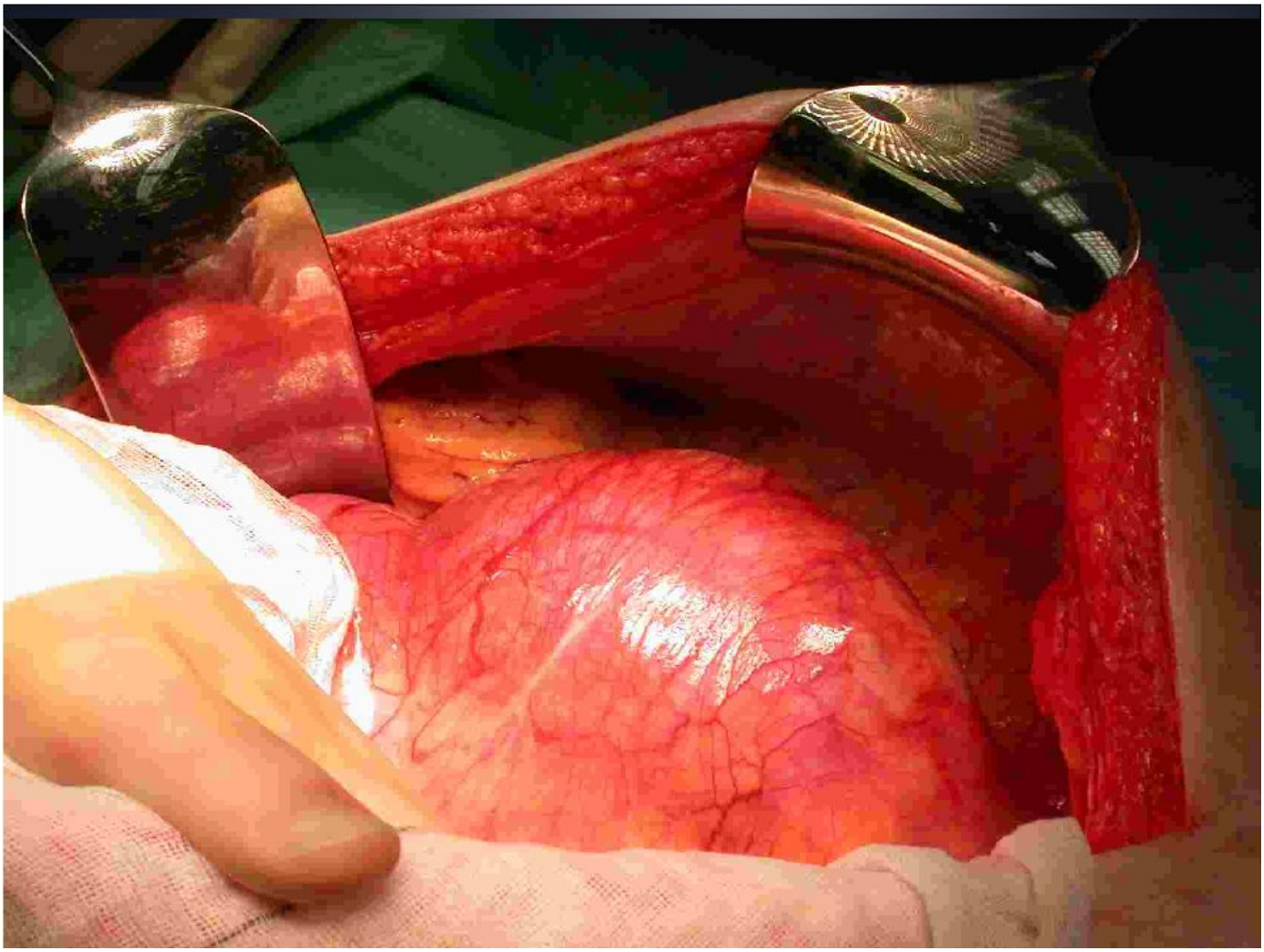
- What's the big deal….acetaminophen has been around since the 1950s?
- Why hasn't an intravenous product been available?
- Does it really work?
- Is it safe?
- Why should I use it instead of the traditional oral and rectal acetaminophen products?
- How much does it cost?

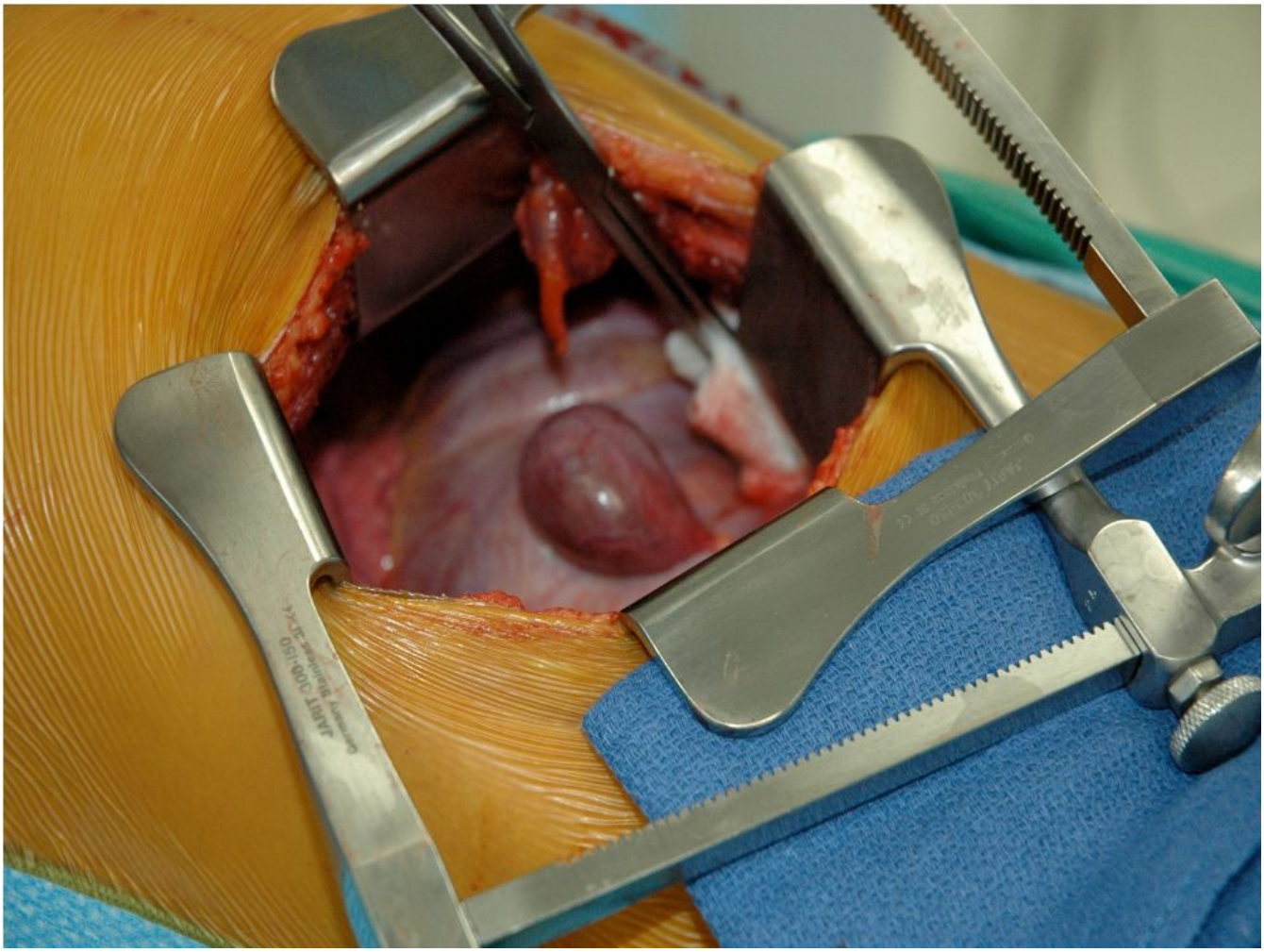
What I Subsequently Learned

- OFIRMEV is the only drug of its kind. A new class of Non-Opioid, Non-NSAID intravenous analgesic. Approved for use in adults and children greater than 2 years of age. Also utilized to treat fever.
- Used in Europe as PERFALGAN since 2002
- Over 400 million doses utilized in 60 countries prior to US approval
- A well established safety profile
- Traditional utilization of oral and rectal acetaminophen has substandard and unpredictable absorption that translates into an ineffective patient treatment response
- Cost approximately $10.80 per dose

Early 2011

- November 2010 presentation to Cadence Pharmaceutical management team regarding daily clinical practice of a Thoracic and Cardiovascular Surgeon
- Opened a dialogue about potential OFIRMEV utilization in patients undergoing Thoracic and Cardiovascular Surgical Procedures





Traditional Analgesic Experience

- Pain ….The Fifth Vital Sign
- Patients who experience severe pain have a prolonged recovery time and an increased risk of complications
- Utilize narcotics/opioids for pain treatment
- Narcotic related side effects are to be expected

Traditional Pain Treatment Paradigm

- Mild Pain……Administer Narcotics/Opioids
- Moderate Pain…….Administer More Narcotics/Opioids
- Severe Pain……Administer increasing doses of Narcotics/OpioidsConsider sustained release products/Epidural/PCA

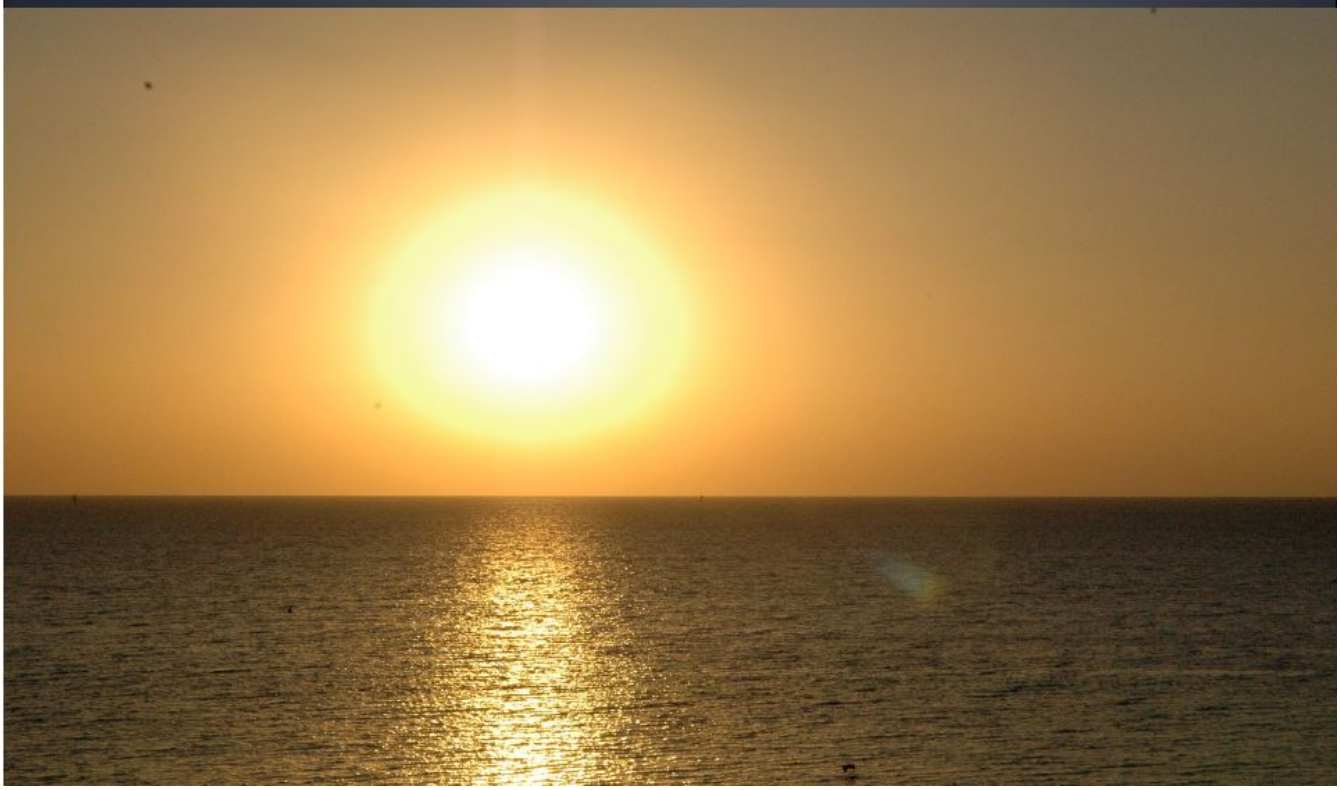
2004 ASA Task Force

- Recommended a multi-modality pain management strategy
- Slow to gain traction as Traditional Pain Management Paradigm was well entrenched
- Surgeons continued to rely on narcotics/opioids as the foundation of pain management
- Surgeons began to embrace pain pumps/local nerve blocks/NSAIDs
- Surgeons primarily focused on live patient discharges with little emphasis on patient satisfaction

2012 Pain Treatment Paradigm

- Mild Pain……Administer Non-Narcotic/Non-Opioid (OFIRMEV)
- Moderate Pain…….Administer Non-Narcotic/Non-Opioid (OFIRMEV) Consider other Non-Narcotic/Non-Opioid agents and techniques
- Severe Pain……Administer Narcotic/Opioids as an adjunct to a foundation of Non-Narcotic/Non-Opioids (OFIRMEV)

OFIRMEV…A New Product



Before Utilizing the First Dose

- Physician exposure to the OFIRMEV clinical studies. Outstanding improvement in patient satisfaction scores coupled with decreased narcotic consumption in multiple studies across multiple surgical specialties
- Well Established Safety Profile
- World-Wide Experience
- Low Cost Per Dose
- Obtaining Hospital Formulary Approval

Hospital Formulary Process

- A Formal Process
- Can be complicated with many potential pitfalls
- Potential Restrictions to Utilization….Surgeons/Anesthesiologists/NPO status/Not Automatic Renewal
- Committee Members……Physicians/Pharmacists/Administrators
- IF YOU CANNOT PASS THE FORMULARY PROCESS…..THE PRODUCT IS DOOMED!!!!!

Post-Formulary Approval
The Initial Physician Experience

- Is OFIRMEV Effective?
- Ease of Administration
- Positive Patient Feedback
- Positive Nursing Feedback
- Any Adverse Effects?

Post-Formulary Approval Initial Pharmacy Experience

- Is there Physician interest in OFIRMEV?
- Is OFIRMEV being utilized responsibly?
- Impact of OFIRMEV on Pharmacy budget
- Ordering/Storage/Distribution Issues
- Is OFIRMEV placed at point of use or is it hidden in the basement?
- Institution Trial Impact Studies….Does OFIRMEV meet expectations?

Navigating Through Pharmacy Issues

- Physician-Patient care relationship is paramount
- Physicians must use OFIRMEV responsibly
- Physician as educator of Pharmacists/Administrators/Nursing Staff/Medical Staff
- Persistence

December 2012
OFIRMEV Personal Experience

- Approaching 18-24 months of clinical experience
- Utilized in every patient unless contraindicated
- Initial dose administered in the operating room
- Duration of Use 24-48 hours (4-8 doses per patient)
- Part of Standing Orders
- No adverse effects noted to date
- Good Patient Satisfaction Scores

December 2012
OFIRMEV Personal Experience

- Many patients no longer receive narcotics/opioids
- Selected patients bypass the PACU
- Generally, Decreased Length of Stay
- Overall Decreased use of Pain Pumps/Epidurals/PCAs
- EMR/CPOE Best Practice Guidelines
- OFIRMEV has been added to Orthopedic/Bariatric/General Surgery/Plastic Surgery/Neurosurgery/Thoracic and Cardiovascular standing order sets. Exceptional outcome across 250 mile practice radius across multi-specialties

CABG Procedure Case Study Patient G: Perioperative Analgesic Protocol

MEDICATION	IntraOp	PostOp Day 0	PostOp Day 1	PostOp Day 2	PostOp Day 3
OFIRMEV® (acetaminophen) injection	1 g	Two doses 1 g q6h	One dose 1 g q6h		
IV propofol	110 mg				
IV fentanyl	250 µg				
IV ketorolac		Two doses 15 mg q6h	Two doses 15 mg q6h		
IV morphine bolus		Three doses 4 mg prn	One dose 4 mg, one dose 2 mg prn		
PO hydrocodone/ acetaminophen			One tablet 5/325 mg	Two tablets 5/325 mg	Two tablets 5/325 mg

Do not exceed the maximum total daily dose of acetaminophen of 4 g

CABG Procedure Case Study Patient G: Outcomes

- **Pain Assessment***
  - POD 0: 3/10 pain at 22:00 after meds given
  - POD 1: 10/10 pain at 1:15 before meds given; 4/10 pain after meds given
  - POD 2 - 3: Pain assessment not reported
- **Opioid Consumption (PostOp)**
  - POD 0: Total of 12 mg of morphine IV consumed, no oral narcotics administered
  - POD 1: Total of 6 mg of morphine IV consumed
  - POD 1 - 3: Total of 5 tablets of PO hydrocodone/acetaminophen
- **Patient Satisfaction**
  - "Excellent" rating for pain control on a 4-point categorical scale

* Based on 10-point numeric rating scale (NRS)

Note: Clinical trials for OFIRMEV have shown an attendant decrease in opioid consumption, the clinical benefit of which was not evaluated or demonstrated.

CABG Procedure Case Study Patient G: Observations

- POD 0: Patient admitted to ICU for monitoring (patient bypassed PACU)
- POD 0: Patient extubated at 16:50 (5 hr and 22 min postoperatively)
- POD 1: Chest tubes, Foley catheter, invasive monitoring lines removed
- POD 1: Patient ambulating and discharged to the floor (telemetry unit)
- POD 2: Increased physical activity
- POD 3: Discharged home

Please see full Prescribing Information for complete safety information

The Future…Beyond 2012

- Impact of August 2012 Joint Commission Sentinel Event Alert Regarding Safe Use of Opioids in Hospitals
- HCAHPS…….Hospital Consumer Assessment of Healthcare Providers and Systems
- Affordable Care Act of 2010……..Hospital Reimbursements Based on HCAHPS Scores
- Physician Reimbursement Based on “Report Cards”

NEXT STEPS

- Physician Education regarding multimodal pain management strategy and utilization of OFIRMEV to decrease narcotic/opioid consumption
- Hospital CEO/CFO/administration education regarding Budget Impact Model utilizing multimodal pain managementto achieve narcotic/opioid reduction and reduce adverse effects
- The Joint Commission/HCAHPS/Affordable Care Act are here to stay

NEXT STEPS

- Hospital CEO/CFO acceptance of increased Pharmacy costs due to OFIRMEV utilization in order to achieve potential cost reduction benefit to the institution from better patient satisfaction scores and decreased narcotic/opioid utilization
- Incorporation of OFIRMEV in best practice pattern subset standing physician orders in EMR/CPOE systems
- Achieving any of the above “Next Steps” should lead to an increase in OFIRMEV utilization

Multimodal Pain Management: Potential to Improve the Cost and Quality of Care

Dr. Robert Ang, MD MBA
Vice President, Medical Affairs
Cadence Pharmaceuticals

Opioids: frequent adverse events

Type of Opioid-Related Adverse Event	Incidence Following:	
	PCA Opioids	IM or IV Bolus Opioids
Gastrointestinal	37.1%	28.2%
Central nervous system	33.9%	75.9%
Pruritus	14.7%	13.9%
Urinary retention	16.4%	4.1%
Respiratory depression	1.8%	2.4%

Source: Oderda G. Pharmacotherapy 2012;32(9 Suppl):6-11

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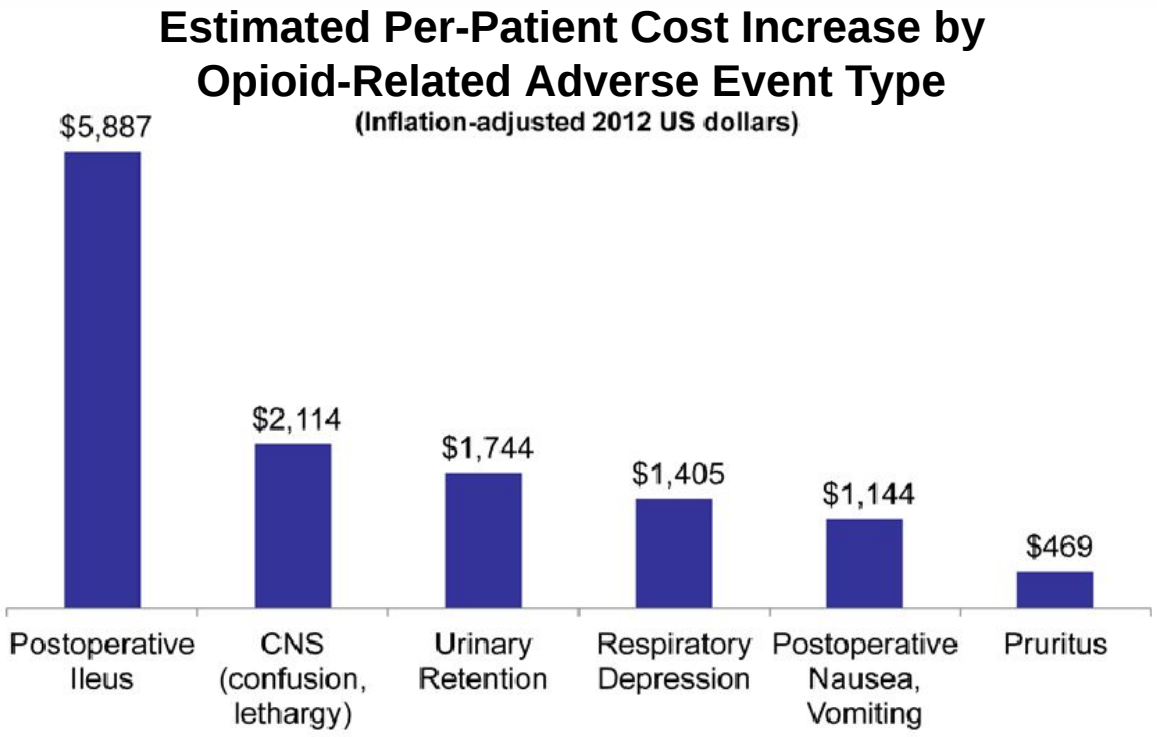
Opioids: considerable costs of related adverse events



Ileus data from Simons R, et al. Reg Anesth Pain Med 2009; PS3:17; all other data from Oderda GM, et al. J Pain Symptom Manage 2003 Mar;25(3):276-83. Inflation adjustment uses cost increases for inpatient hospital services.

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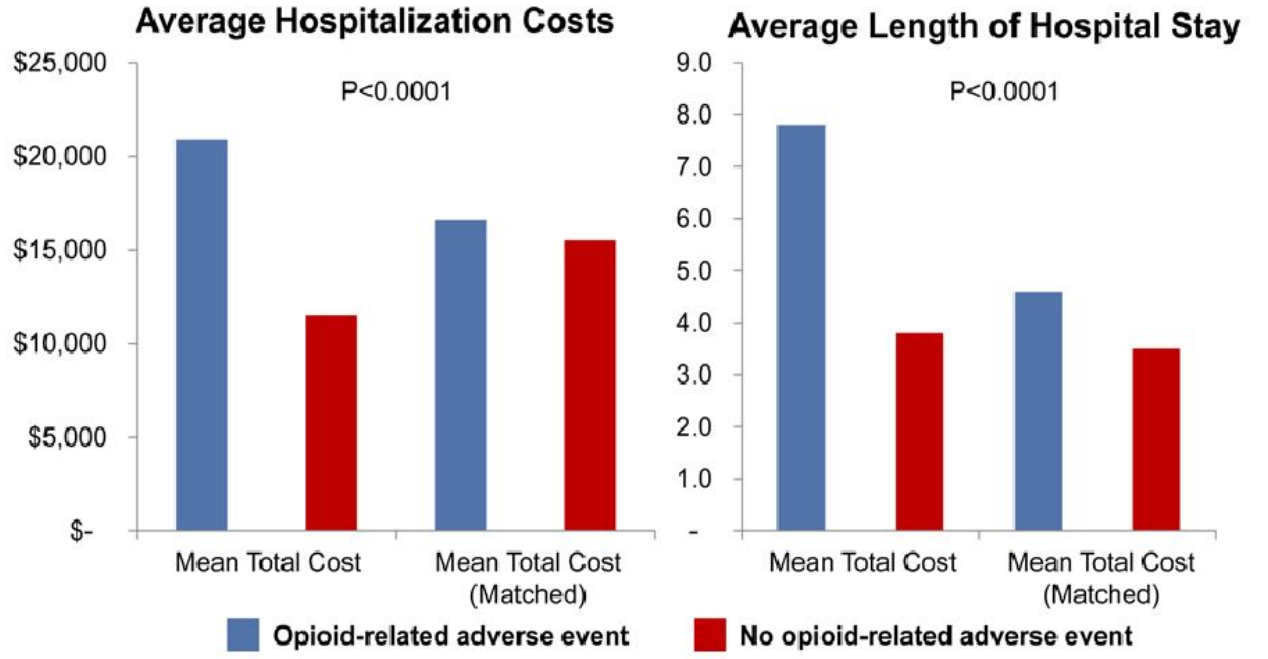
Avoidance of Opioid-Related Adverse Events May Reduce Hospital Costs

Retrospective analysis of >180,000 surgical inpatients utilizing the Premier Research Database, patients undergoing open/lap colectomy, lap cholecystectomy, hysterectomy and total hip replacement



Case matching used +/-3 years of age, gender and APR severity of illness
Oderda GM, et al. Poster presented at 2011 Midyear Clinical Meeting of ASHP, New Orleans

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The Joint Commission Sentinel Event Alert

- **What is a Sentinel Event?**
  - Definition: an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof
  - Sentinel Event Alerts issued to compel immediate investigation and response
- **New Alert: "*Safe use of opioids in hospitals*"**
  - Recommendations for pain management in order to avoid opioid overdose
  - Provide numerous actions that can be taken to avoid opioid-related adverse events
  - **Endorses the use of non-opioids as a first line approach to minimize opioid consumption**

The Joint Commission
Sentinel Event Alert

A complimentary publication of The Joint Commission

Issue 49, August 8, 2012

Safe use of opioids in hospitals

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

Accredited organizations should consider information in an Alert when designing or redesigning relevant processes and consider implementing relevant suggestions contained in the Alert or reasonable alternatives.

Please route this issue to appropriate staff within your organization. *Sentinel Event Alert* may only be reproduced in its entirety and credited to The Joint Commission. To receive by e-mail, or to view past issues, visit www.jointcommission.org

While opioid use is generally safe for most patients, opioid analgesics may be associated with adverse effects,[1,2,3] the most serious effect being respiratory depression, which is generally preceded by sedation.[4,5,6] Other common adverse effects associated with opioid therapy include dizziness, nausea, vomiting, constipation, sedation, delirium, hallucinations, falls, hypotension, and aspiration pneumonia.[6,7] Adverse events can occur with the use of any opioid; among these are fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and sufentanil. While there are numerous problems associated with opioid use, including underprescribing, overprescribing, tolerance, dependence, and drug abuse, this Alert will focus on the safe use of opioids that are prescribed and administered within the inpatient hospital setting. The Joint Commission recognizes that the emergency department presents unique challenges that should also be addressed by the hospital, but may not be directly addressed in this Alert. This Alert will provide a number of actions that can be taken to avoid the unintended consequences of opioid use among hospital inpatients.

Opioid analgesics rank among the drugs most frequently associated with adverse drug events. The literature provides numerous studies of the adverse events associated with opioids. One study found that most adverse drug events were due to drug-drug interactions, most commonly involving opioids, benzodiazepines, or cardiac medications.[8] In addition, a British study of 3,695 inpatient adverse drug reactions found that 16 percent were attributable to opioids, making opioids one of the most frequently implicated drugs in adverse reactions.[9] The incidence of respiratory depression among post-operative patients is reported to average about 0.5 percent. Some of the causes for adverse events associated with opioid use are:

- Lack of knowledge about potency differences among opioids.
- Improper prescribing and administration of multiple opioids and routes of [illegible]

Source: The Joint Commission Sentinel Event Alert. Safe use of opioids in hospitals. Issue 49; August 8, 2012.

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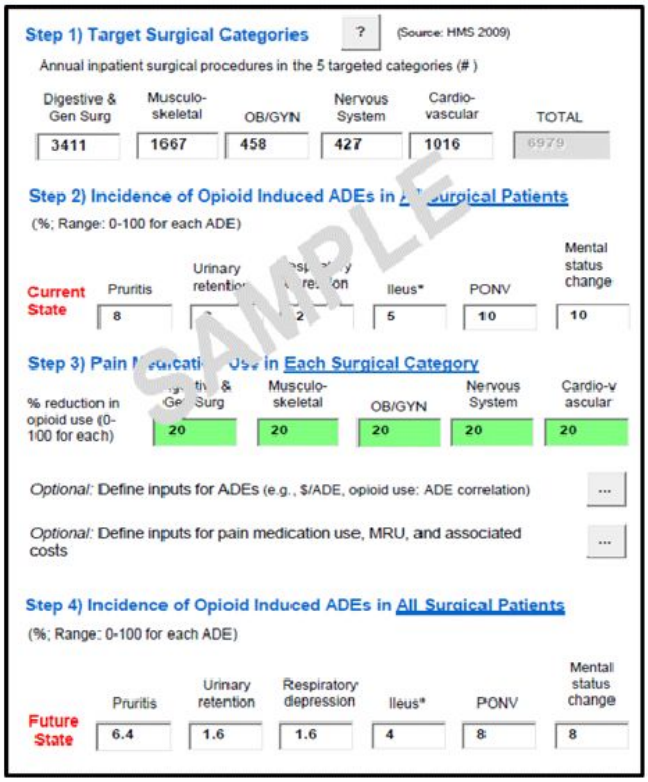
Inpatient Budget Impact Model

Use:

Proprietary, unbranded disease-state awareness tool for population-based decision makers only

Data Inputs:

- Prepopulated (though customizable):
  - o surgical procedure volume;
  - o opioid-related adverse event incidence rates (e.g. PONV, ileus, respiratory depression); and
  - o adverse event incidence costs.
- Facility's goal for % opioid reduction
- Relationship between opioid reduction and adverse event incidence reduction



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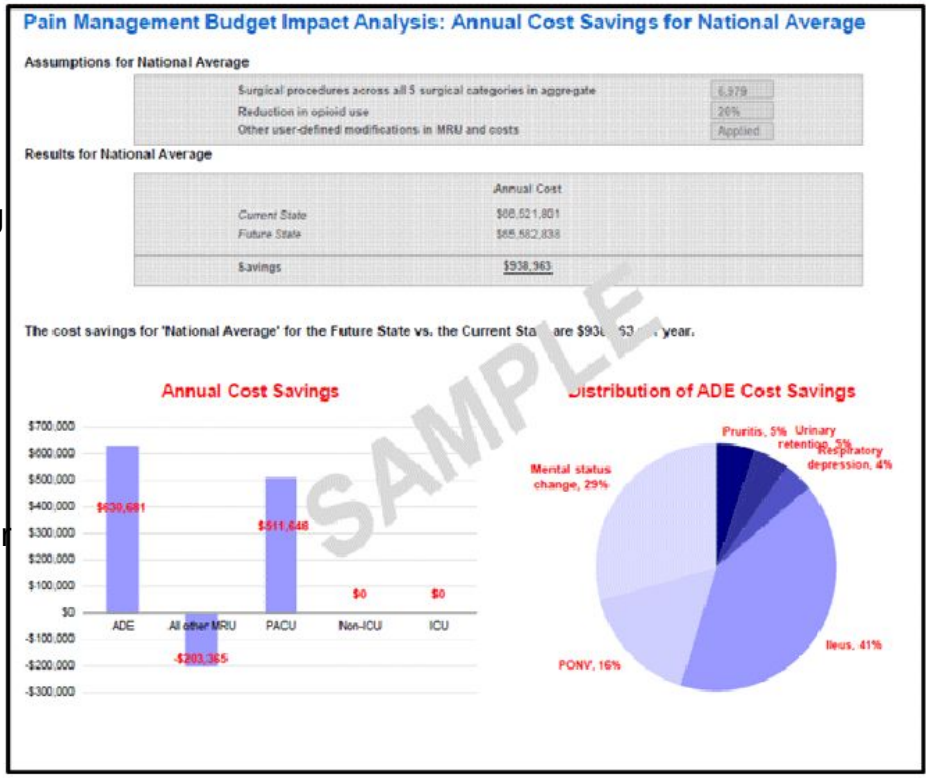
Inpatient Budget Impact Model: Outputs

Model Outputs:

The model illustrates the estimated budget impact in several ways, providing users with both high-level and department-specific summaries.

Potential overall savings are displayed as:
- annual cost savings,
- cost savings per stay, or
- cost savings per procedure.



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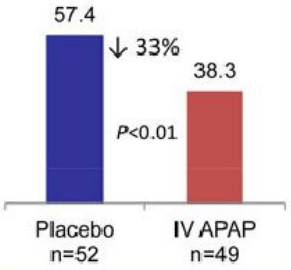
IV Acetaminophen and Opioid Consumption

Total Hip & Knee Replacement[1]

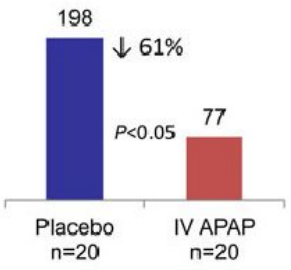
(Morphine over 24 h, mg)



- Randomized, double-blind study conducted at 7 US sites
- Patients randomized the morning after total hip or knee replacement surgery
- IV APAP 1000 mg or placebo given Q6h

Major Abdominal Surgery[2]

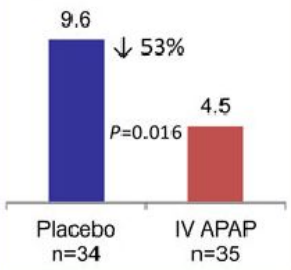
(Meperidine, mg)



- Randomized, double-blind study conducted at a single site in Turkey
- Patients undergoing major abdominal or pelvic surgery
- In the ICU, patients randomized to IV APAP 1000 mg or placebo given Q6h

Total Hip Replacement[3]

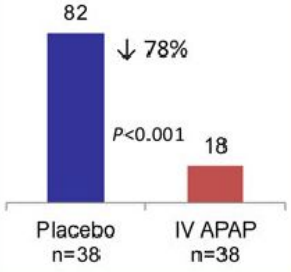
(Morphine equivalents 0-6 h, mg)



- Randomized, double-blind study conducted at 11 US sites
- Patients randomized the morning after total hip replacement surgery
- IV APAP 1000 mg or placebo given as a single dose

Adult Tonsillectomy[4]

(Meperidine doses per group)



- Randomized, double-blind study conducted in Egypt
- Patients randomized following induction
- IV APAP 1000 mg or placebo given Q6h

Note: Opioid consumption reduction is highly dependent on clinical trial design, and the clinical consequence of any amount of opioid consumption reduction may not have been evaluated or demonstrated in a given trial.

Sources: 1. Sinatra et al., Anesthesiology 2005; 102(4): 822-831; 2. Memis et al., J Critical Care 2010;25(3):458-462; 3. Data on file, Cadence Pharmaceuticals, Inc.; 4. Atef et al., Eur Arch Otorhinolaryngol 2008; 265(3): 351-3555.

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IV Acetaminophen – A Hospital Pharmacy Perspective

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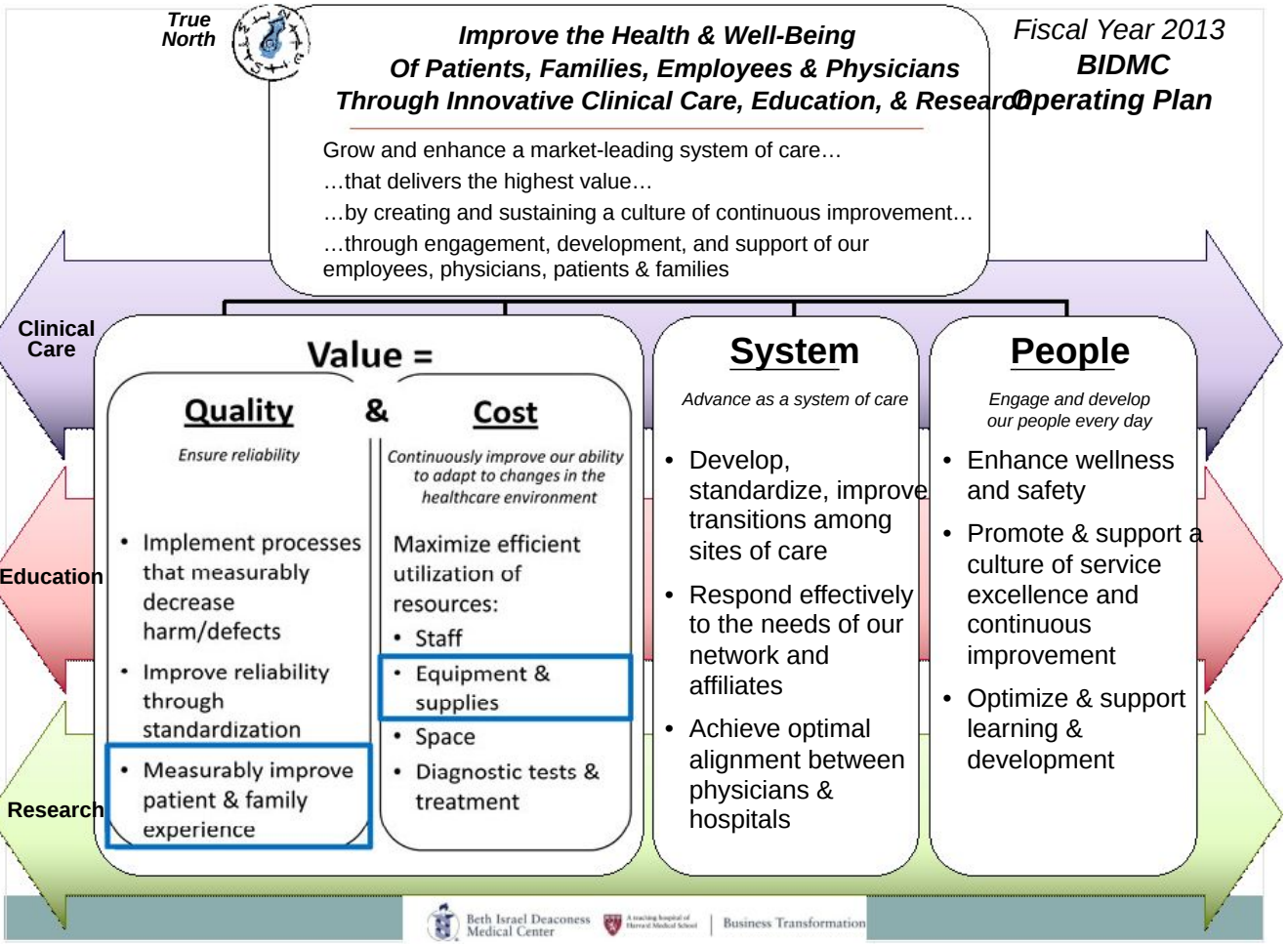
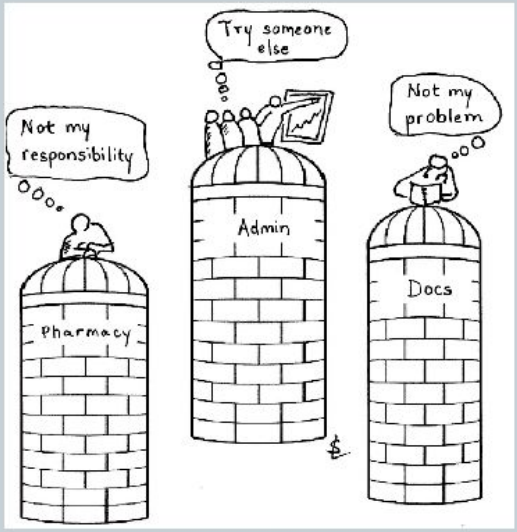

True North
Improve the Health & Well-Being
Of Patients, Families, Employees & Physicians
Through Innovative Clinical Care, Education, & Research
Fiscal Year 2013
BIDMC
Operating Plan
Grow and enhance a market-leading system of care…
…that delivers the highest value…
…by creating and sustaining a culture of continuous improvement…
…through engagement, development, and support of our employees, physicians, patients & families
Clinical Care
Education
Research
Value =
Quality
Ensure reliability
• Implement processes that measurably decrease harm/defects
• Improve reliability through standardization
• Measurably improve patient & family experience
&
Cost
Continuously improve our ability to adapt to changes in the healthcare environment
Maximize efficient utilization of resources:
• Staff
• Equipment & supplies
• Space
• Diagnostic tests & treatment
System
Advance as a system of care
• Develop, standardize, improve transitions among sites of care
• Respond effectively to the needs of our network and affiliates
• Achieve optimal alignment between physicians & hospitals
People
Engage and develop our people every day
• Enhance wellness and safety
• Promote & support a culture of service excellence and continuous improvement
• Optimize & support learning & development
Beth Israel Deaconess Medical Center
Business Transformation

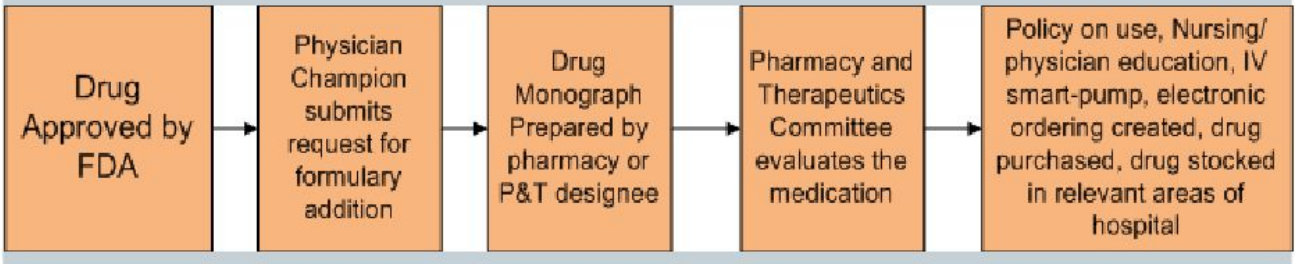
For new drugs, it can be easy for pharmacy decision makers to think like this…



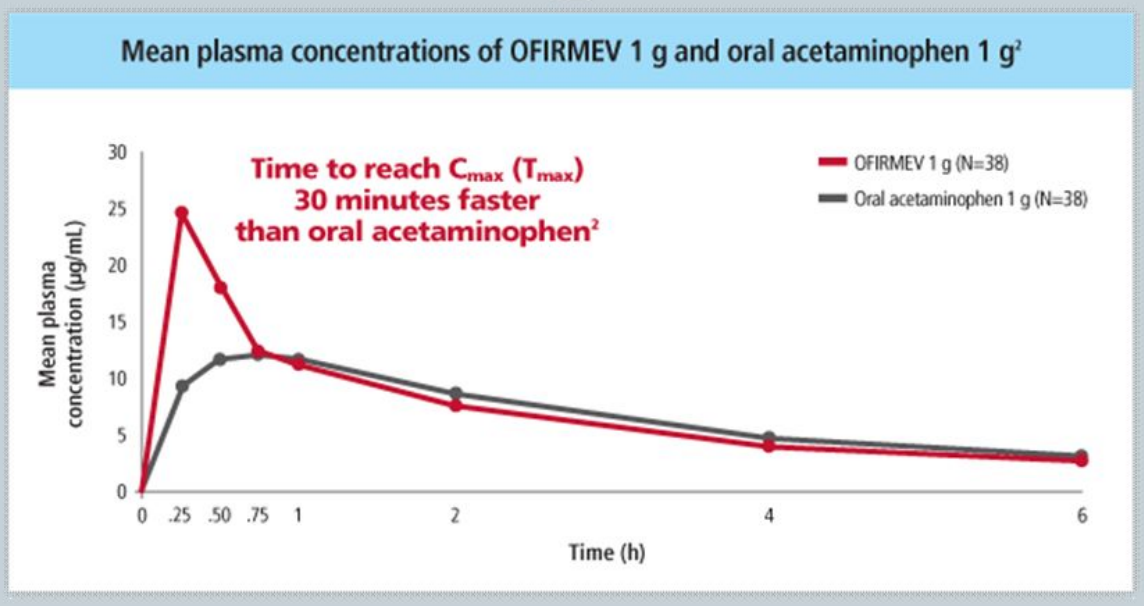
What makes BIDMC different?

BIDMC Pharmacy	Silo Mentality
• Thinks: “Am I improving patient care?” • “The best care is always the cheapest care”	• Thinks: “Am I improving drug use?” • “I need to keep my drug budget as small as possible”

The anatomy of a drug's approval and subsequent use at a hospital



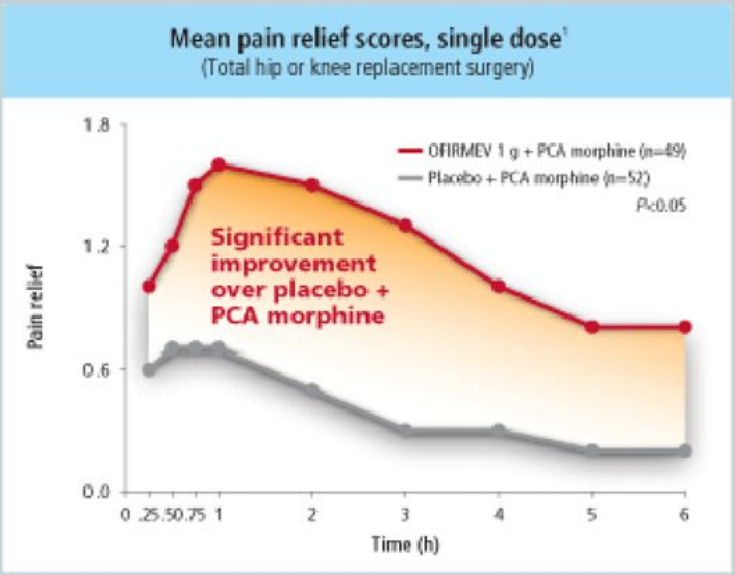
Pharmacokinetics



Reaches 70% higher concentration (Cmax) than oral acetaminophen in first 15 minutes, but overall AUC after 1 dose was the same.

Product information Cadence Pharmaceuticals, ofirmev.com

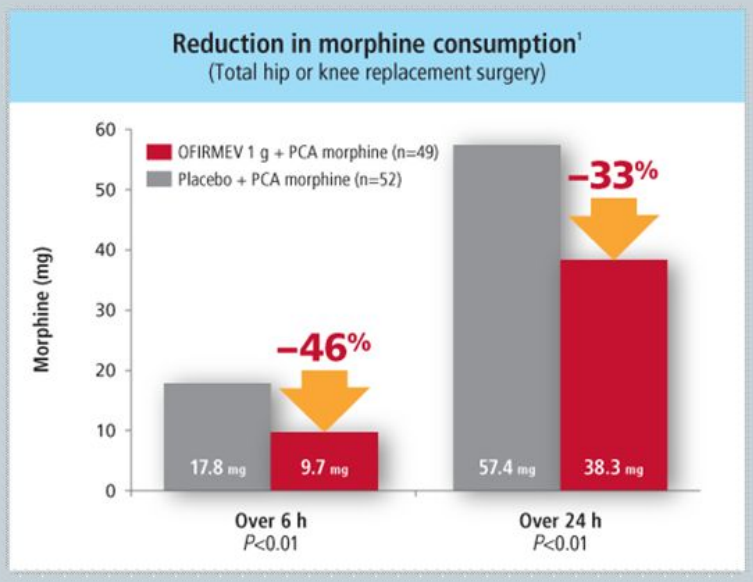
Better pain control



Better pain relief with IV acetaminophen compared to placebo (under standard of care)

Sinatra et al. Anesthesiology. 2005;102:822-831.

Opioid Reduction Effect



Less opioids required when IV acetaminophen is used compared to placebo (under standard of care)

Sinatra et al. Anesthesiology. 2005;102:822-831.

Opioid reduction

- This is an extremely attractive possibility with IV acetaminophen
  - Sentinel Event Alert (Joint Commission)
  - Goal to reduce opioid side effects
    - Post operative nausea/vomiting
    - Postoperative ileus
    - Delirium/Over-sedation

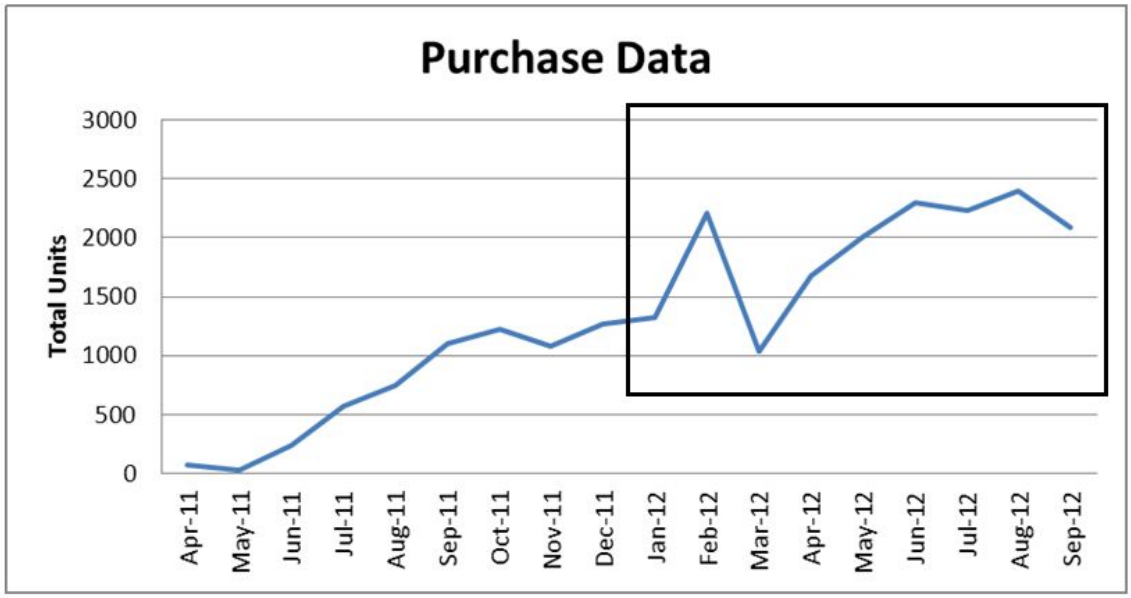
Why did BIDMC add OFIRMEV to formulary?

- IV acetaminophen was brought forth by critical care physicians
- There remains an unmet need in optimizing pain control in the hospital setting
- The American Society of Anesthesiologists recommends a multi-modal approach to pain management
- It was thought that being able to utilize IV acetaminophen would also reinvigorate the use of PO acetaminophen as an analgesic

IV acetaminophen approval

- IV acetaminophen was approved for use in patients who are unable to tolerate oral routes of acetaminophen
- No formal (IT) restrictions were placed on the ordering or duration of therapy

FY 2012 purchases



Overall use – PACU vs. Inpatient

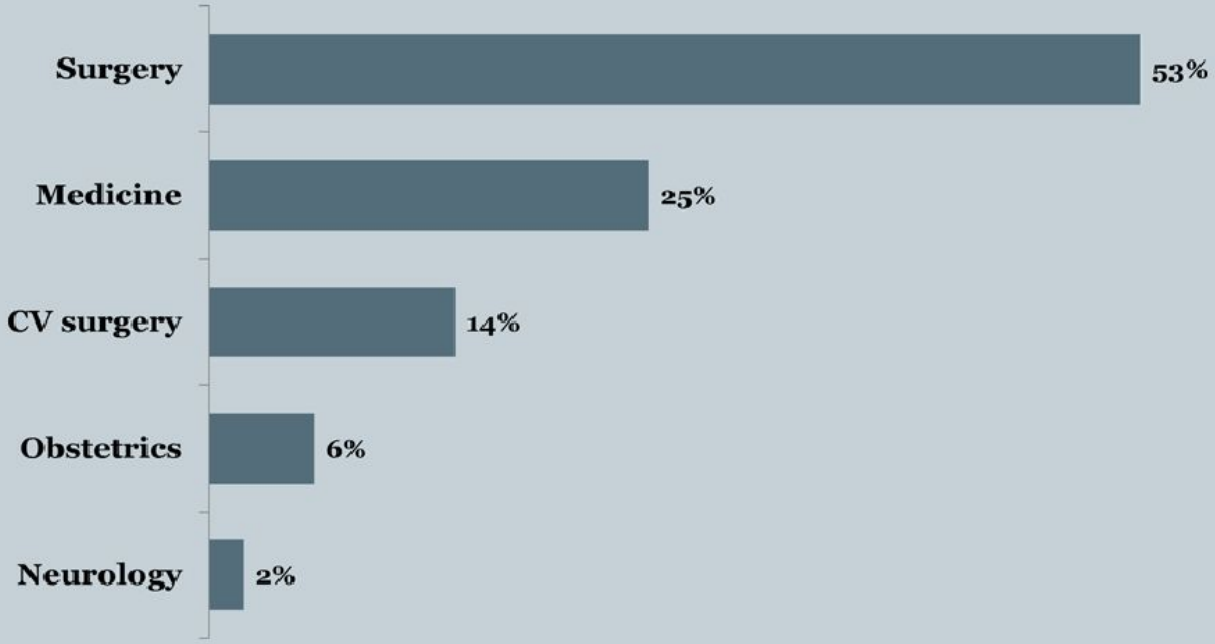
- 48% of utilization is for patients admitted to the general ward/ICU
- 52% of utilization is in the Post Anesthesia Care Unit (PACU)

Inpatient use

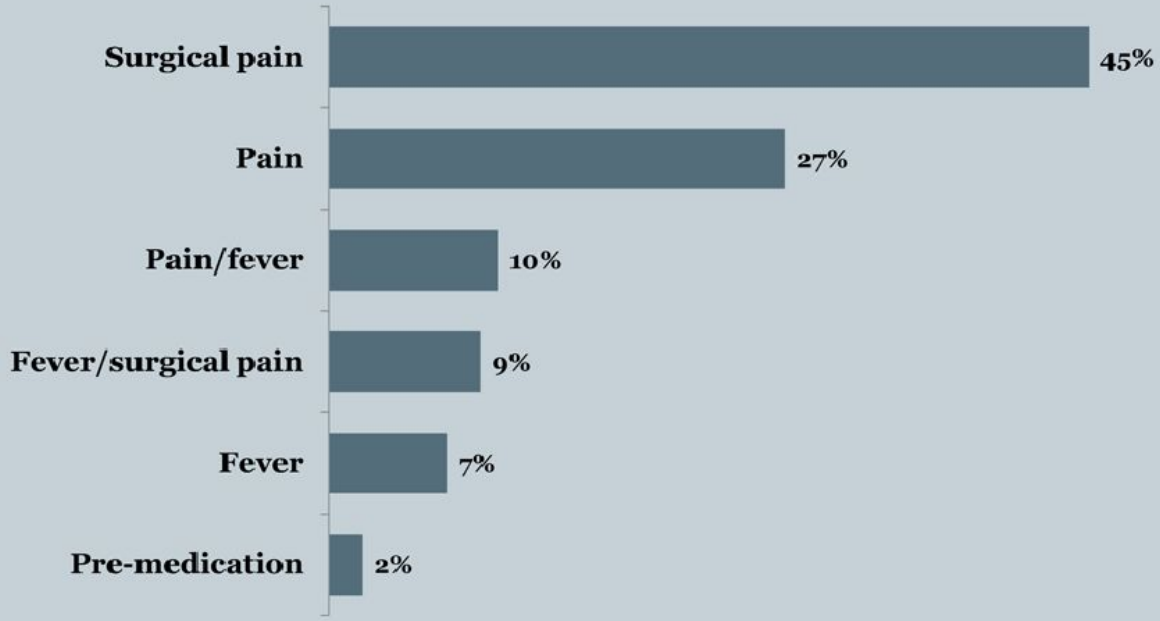
Inpatient use - analgesia

- Average age of patients: 60
- Average number of doses per patient: 6
- 84% also receiving opioids
  - Utilization as a multi-modal agent
- 24% also receiving NSAIDs (ibuprofen, ketorolac)

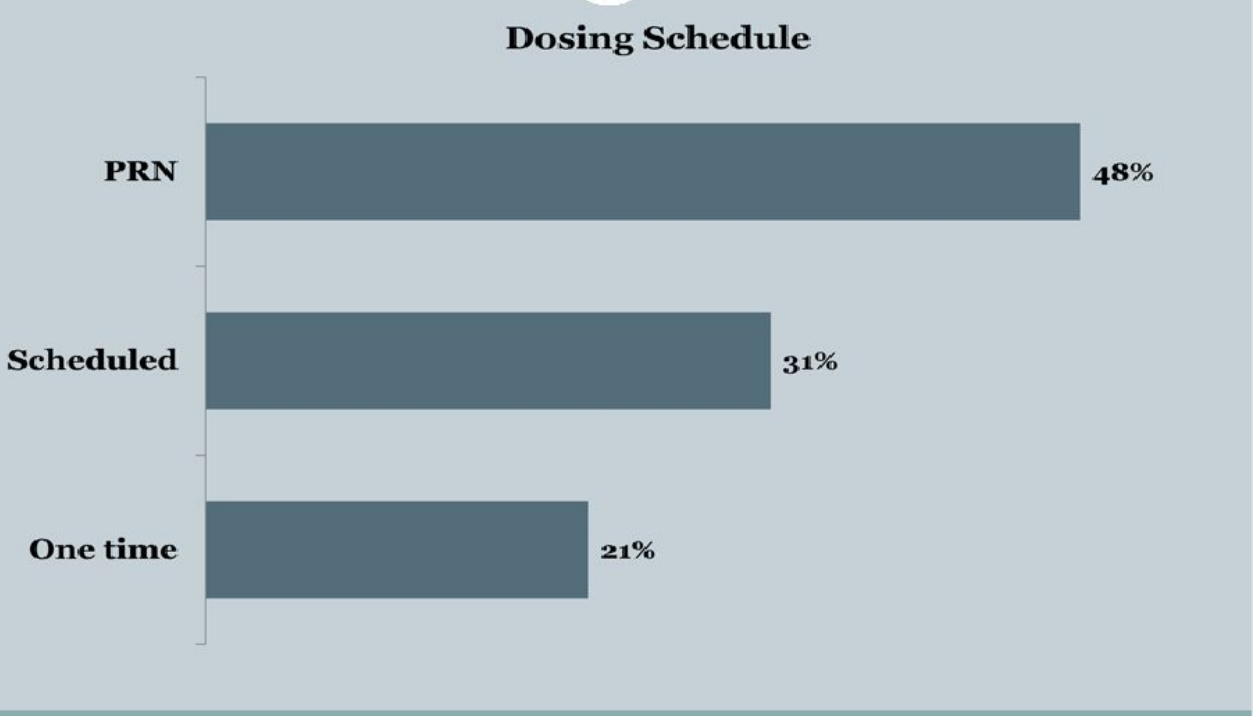
Most common settings for inpatient use



Most common indications for inpatient use



Inpatient use

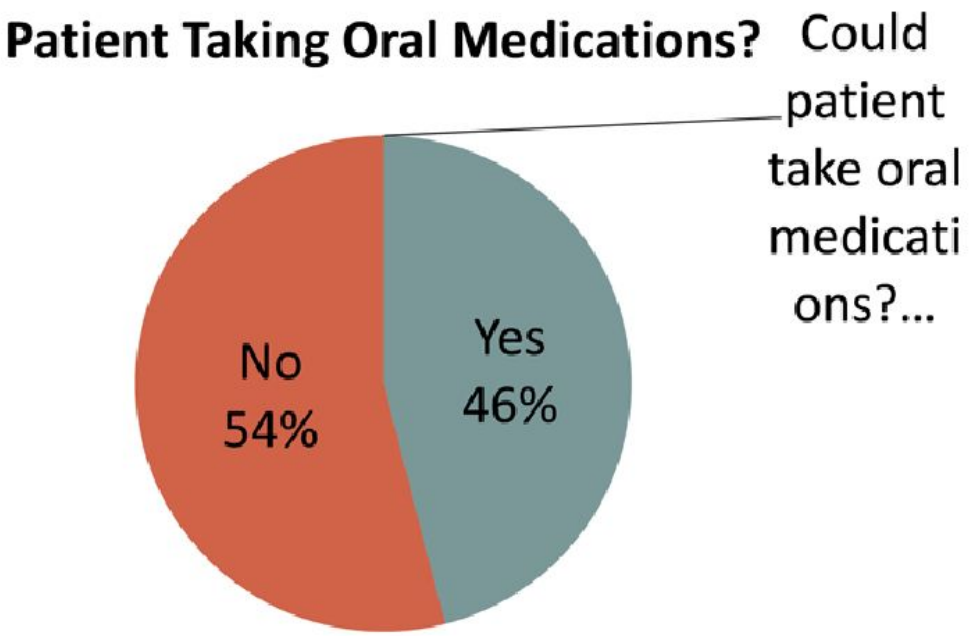


PACU Utilization

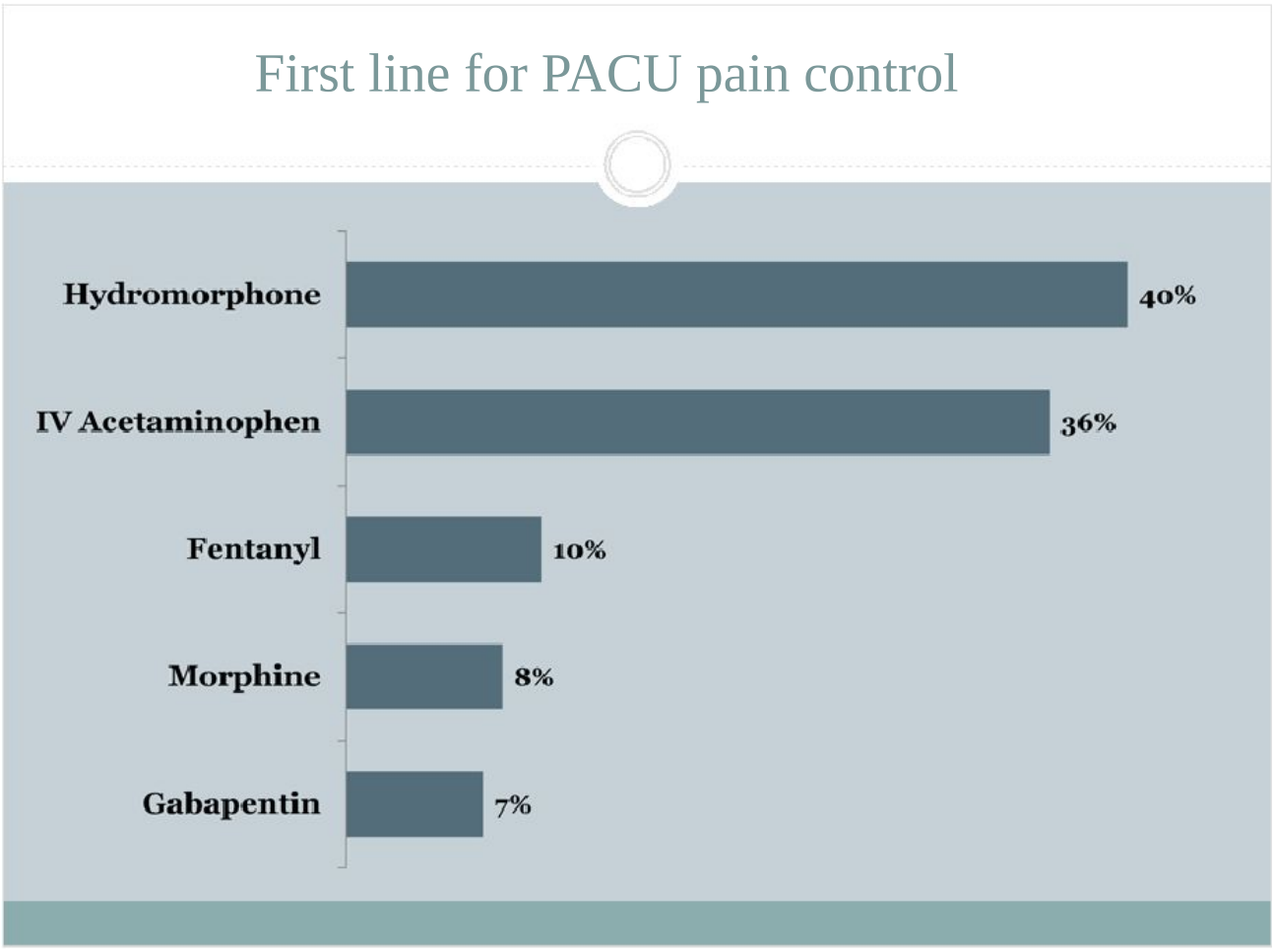
PACU

- PACU practice is highly nurse-driven
- Many orders for pain medications are written, and it is left to the nurse to determine which agents are utilized, and in what order.

PACU pain control and IV acetaminophen



First line for PACU pain control



Where IV acetaminophen fits especially well

- Patients who are at-risk for opioid-induced side effects
  - Elderly
  - Obese
  - Dementia
  - Concomitant administration of other sedatives
- Patients who have a history of experiencing opioid adverse effects
  - Post-operative nausea and vomiting
  - Opioid-induced delirium

Additional considerations potentially affecting IV acetaminophen utilization

- Improving patient satisfaction
  - Reimbursement
  - Competition
- Patient safety
  - Reducing preventable harm = Cost savings

What's next?

- Reducing needless variability in care for patients experiencing pain across the medical center
- Using evidence-based data to create better pain control algorithms
- Measuring clinical benefit from reduced opioid utilization
  - Side effects
  - Patient satisfaction

Closing Remarks

Theodore R. Schroeder
President and Chief Executive Officer
Cadence Pharmaceuticals

Par IV litigation update:
settlement with Perrigo announced Nov. 28, 2012

- **Lawsuit against Perrigo / Paddock to be dismissed with prejudice**
- **Exclusive right of first refusal granted to Perrigo to negotiate an authorized generic agreement with Cadence for the U.S.**
- **Non-exclusive right granted to Perrigo to market generic IV acetaminophen product under Perrigo's ANDA, after Dec. 6, 2020, or earlier under certain circumstances.**
  - Perrigo would purchase the product exclusively from Cadence.
  - Cadence would receive product costs plus administrative fee, and a royalty payment based on net profits from sales of the AG product
- **Other details are confidential, and the agreements are subject to FTC / DOJ review**
- **Litigation remains ongoing against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc.**

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