

FDA, Drug Safety and Anesthesia

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Drug Safety (1)

- Current state of the pharmaceutical industry
- The drug approval process
- My experiences at the FDA

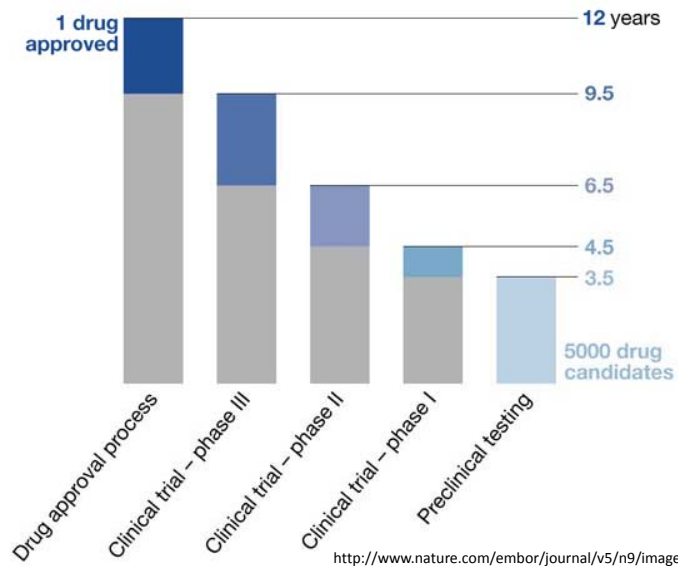
Drug Safety (2)

- Drug shortages
- Limits on pharma interactions with physicians
- Conflict-of-interest rules for academic physicians

Drug Safety (3)

- Some controversial stories:
 - Succinylcholine
 - Sevoflurane
 - Droperidol
 - Aprotinin
 - Heparin
 - Suggamadex

Drug approval process



Consolidation

THE WALL STREET JOURNAL.

WSJ.com

JANUARY 24, 2009

Pfizer Nears Giant Drug Deal

By **MATTHEW KARNITSCHNIG** and **SARAH RUBENSTEIN**

Pfizer Inc. is expected to pay between \$65 billion and \$70 billion to acquire rival Wyeth, people familiar with the matter say, as the drug maker makes a risky effort to shore itself up ahead of huge disruptions in the next few years.

Consolidation

- “Pipeline” problems
 - Losing patent protection of lipitor
- Allows Pfizer access to biologics
 - Vaccines
 - Large molecules
 - Difficult to make as generics
 - Expensive drugs

Ellis opines

- Pharma interested in two types of drugs:
 - Drugs that patients take every day for the rest of their lives
 - e.g., antihypertensives
 - Drugs for niche uses that command high prices
 - e.g., recombinant Factor VII

The New York Times

January 13, 2009

F.D.A. Eases Off-Label Drug Rules

By REUTERS

WASHINGTON (Reuters) — Health officials completed guidelines that allow pharmaceutical companies to tell doctors about unapproved uses of their medicines, a practice opposed by critics of industry marketing.

Under the guidelines, established by the [Food and Drug Administration](#), manufacturers are allowed to distribute copies of medical journal articles that describe unapproved uses. The action could help companies expand the markets for medicines and medical devices.

The move puts in place a policy that drew objections from Congressional Democrats and critics of the drug industry when it was proposed last year.

Roughly half
of drug use
is “off-label”

Off-label use and FDA fines

"Pfizer's Neurontin is a case in point. The FDA approved the drug as a supplemental medication to treat epilepsy in 1993. Pfizer took in \$2.27 billion from sales of Neurontin in 2002.

A full **94 percent -- \$2.12 billion -- of that revenue came from off-label** use, according to the prosecutors' 2004 Pfizer sentencing memo."

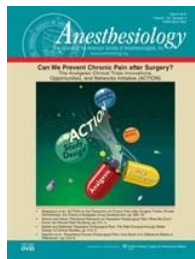
Washington Post 21 Mar 2010 <http://goo.gl/uCb9>

Off-label use and FDA fines

"...From 2001 through 2003...
Pfizer, **paid doctors more than \$5 million in cash to lure them to resorts**, where salespeople illegally pitched off-label uses for Bextra, P&U admitted."

Washington Post 21 Mar 2010 <http://goo.gl/uCb9>

Can't I read the latest
literature and prescribe
off-label for my
patients' benefit???



Updated Mar. 22, 2010

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ISSUE: MARCH 2009 | VOLUME: 35:3

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Fraud Case Rocks Anesthesiology Community

Mass. Researcher Implicated in Falsification of Data, Other Misdeeds

Adam Marcus

In what experts are calling one of the largest known cases of academic misconduct, a leading anesthesiology researcher has been accused of falsifying data and other fraud in potentially dozens of published studies.

Scott S. Reuben, MD, of Baystate Medical Center in Springfield, Mass., a pioneer in the area of multimodal analgesia, is said to have fabricated his results in at least 21, and perhaps many more, articles dating back to 1996. The confirmed articles were

...a pioneer in the area of multimodal analgesia, is said to have fabricated his results in at least 21... articles dating back to 1996.

Reuben fraud case

A cornerstone of Dr. Reuben's approach has been the use of the selective cyclooxygenase-2 inhibitor celecoxib (Celebrex) and the neuropathic pain agent pregabalin (Lyrica), both manufactured by Pfizer. Dr. Reuben has received research grants from the company and is a member of its speakers' bureau.

The company has not been accused of wrongdoing in the matter.

Reuben fraud case

"... the Reuben episode has left multimodal analgesia "in shambles concerning many of the drugs we use"—particularly celecoxib and pregabalin. "The big chunk of what people have based their protocol on is gone."

Jacques Chelly, MD, PhD, MBA, director of the Division of Regional Anesthesia and Acute Interventional Perioperative Pain at UPMC



THE PLAIN DEALER

Cleveland Clinic's Dr. Steven Nissen, shortlisted for U.S. Food and Drug Administration commissioner, talks about the agency

Tuesday, January 20, 2009

Sarah Jane Tribble

Plain Dealer Reporter

Dr. Steven Nissen rose to national prominence as a drug-industry watchdog by exposing the diabetes drug Avandia for increasing the risk of heart attack and for sounding early warnings about the painkiller Vioxx.

The NEW ENGLAND JOURNAL of MEDICINE

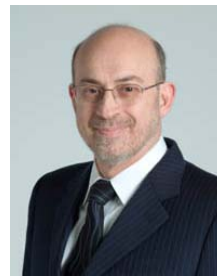
ESTABLISHED IN 1812

JUNE 14, 2007

VOL. 356 NO. 24

Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes

Steven E. Nissen, M.D., and Kathy Wolski, M.P.H.



Conclusions

- Rosiglitazone was associated with a significant increase in the risk of MI and with an increase in the risk of death from CV causes that had borderline significance.
- Our study was limited by a lack of access to original source data...
- Despite these limitations, consider the potential for serious adverse CV effects of treatment with rosiglitazone for type 2 DM.

N Engl J Med 2007;356:2457-71.

THE WALL STREET JOURNAL.

VOL. CCLIII NO. 19 SATURDAY/SUNDAY, JANUARY 24 - 25, 2009 ***** ***** \$2.00

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THE WALL STREET JOURNAL.
WSJ.com

JANUARY 14, 2009

Glaxo's Emails on Avandia Reveal Concern

By ALICIA MUNDY and JARED FAVOLE

(See Correction & Amplification below.)

When a study linking GlaxoSmithKline PLC's diabetes treatment Avandia to increased heart-attack risk was published in 2007, the pharmaceutical giant publicly responded by denouncing the researchers' conclusions. But internal emails indicate some of the company's own scientists were concerned that Glaxo's data were showing the same thing.

- The study by Dr. Nissen for NEJM was supposed to be kept under wraps until its release on May 21, but Glaxo obtained a copy on May 3 from a doctor, Steven Haffner of the University of Texas, who was reviewing it for the medical journal.

http://online.wsj.com/article/SB123190610976680477.html?mod=googlenews_wsj

- Dr. Haffner had been a Glaxo consultant on Avandia and received **\$433,000** from Glaxo between 2000 and 2007.
- He confirms giving Glaxo the study, though saying it was "a terrible mistake."

http://online.wsj.com/article/SB123190610976680477.html?mod=googlenews_wsj

Ethics?

- Sharing the article is clearly unethical
- What about \$61,000 annually???
 - What is difference is average annual compensation between academic and private practice ???

- Dr. Nissen says that when he was visited by top Glaxo scientists, including the chief medical officer, just days before publication, they tried to get him to rethink his concerns.

http://online.wsj.com/article/SB123190610976680477.html?mod=googlenews_wsj

- "They never revealed that they had obtained a copy of our manuscript and had concluded that our findings were irrefutable," he says.
- "Instead, they attacked the ...study and ... the authors and the NEJM."

http://online.wsj.com/article/SB123190610976680477.html?mod=googlenews_wsj



Academic medical centers respond

DesMoinesRegister.com

January 23, 2009

U of I to bar free drug samples, gifts

By *ERIN JORDAN*
ejordan@dmreg.com

Iowa City, Ia. — A new University of Iowa policy would prohibit physicians from giving free drug samples to patients, a long-standing practice that hospital leaders and consumer advocates say contributes to the ballooning cost of health care.

Other changes include barring U of I Health Care employees from accepting gifts and meals from private companies and requiring all doctors who do industry consulting to report who they work for and how much they are paid.



Time to vote!

- There shouldn't be limits on interactions?
- Researchers should not own stock in companies affected by their research?
- We don't care how much the pharma pays Dr. X, but the \$\$ should be public knowledge?
- Professionalism requires no such financial arrangements

The New York Review of Books

VOLUME 56, NUMBER 1 • [JANUARY 15, 2009](#)

Drug Companies & Doctors: A Story of Corruption

By [Marcia Angell](#)

Side Effects: A Prosecutor, a Whistleblower, and a Bestselling Antidepressant on Trial
by Alison Bass
Algonquin Books of Chapel Hill, 260 pp., \$24.95

Our Daily Meds: How the Pharmaceutical Companies Transformed Themselves into Slick Marketing Machines and Hooked the Nation on Prescription Drugs
by Melody Petersen
Sarah Crichton/Farrar, Straus and Giroux, 432 pp., \$26.00

Shyness: How Normal Behavior Became a Sickness
by Christopher Lane
Yale University Press, 263 pp., \$27.50; \$18.00 (paper)

How pervasive is this?

- A recent survey found that about two thirds of academic medical centers hold equity interest in companies that sponsor research within the same institution.
- A study of medical school department chairs found that two thirds received departmental income from drug companies and **three fifths received personal income.**

Campbell EG et al., "Institutional Academic-Industry Relationships," *JAMA*, October 17, 2007.

Can medical schools police this?

- "Surely you remember that SKB donated an **endowed chair** to the department and there is some reasonable likelihood that Janssen Pharmaceuticals will do so as well.
- ...In addition, Wyeth-Ayerst Pharmaceuticals has funded a **Research Career Development Award** program in the department, and I have asked both AstraZeneca and BMS to do the same.
- ...Part of the rationale for their funding our faculty in such a manner would be my service on these boards."

Former NEJM editor

- “The problems I've discussed are not limited to psychiatry, although they reach their most florid form there.
- Similar conflicts of interest and biases exist in virtually every field of medicine, **particularly those that rely heavily on drugs or devices.**”

Former NEJM editor

- **“It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines.**
- I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine.*”

“Ghostwriting” scandals

Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

THE FOOD AND DRUG
ADMINISTRATION'S OVERSIGHT
OF CLINICAL INVESTIGATORS'
FINANCIAL INFORMATION

<http://www.oig.hhs.gov/oei/reports/oei-05-07-00730.pdf>



Daniel R. Levinson
Inspector General

January 2009
OEI-05-07-00730

Drug Safety Issues in Anesthesia Practice

How does this impact
daily life?

Some controversies

- Succinylcholine
- Sevoflurane
- Droperidol
- COX2 inhibitors
- Aprotinin
- Heparin
- Suggamadex



Succinylcholine

- From 1990 to 1993, 36 cases of cardiac arrest (> 1/2 proceeding to death) were reported associated with the use of Sch.
- Most occurred in Duchenne's muscular dystrophy (occurs exclusively in males) and all but one of the children were under 8 years old.

Succinylcholine

- Nonetheless, routine use of Sch in children was banned except to emergently intubate or secure an airway.
- This provoked an uproar in the pediatric anesthesia community.

Succinylcholine

- The effects of a ban on routine use could result in increased respiratory and airway misadventures in other patients in whom succinylcholine might have been uniquely efficacious (quick on, quick off) in facilitation airway management, were its use allowed.

Succinylcholine

- Current package insert more liberal:
 - Succinylcholine in children should be reserved for emergency intubation or instances where immediate securing of the airway is necessary, e.g. **laryngospasm, difficult airway, full stomach, or for intramuscular use when a suitable vein is inaccessible.**

Rapicuronium

- Rapicuronium was felt to be a potential replacement for succinylcholine.
- It was approved August 1999.
- **Bronchospasm** was identified during Phase 3 trials as a potential problem
 - its prevalence and severity appeared even greater after it was released.
- It was withdrawn from the market in March 2001.



Sevoflurane

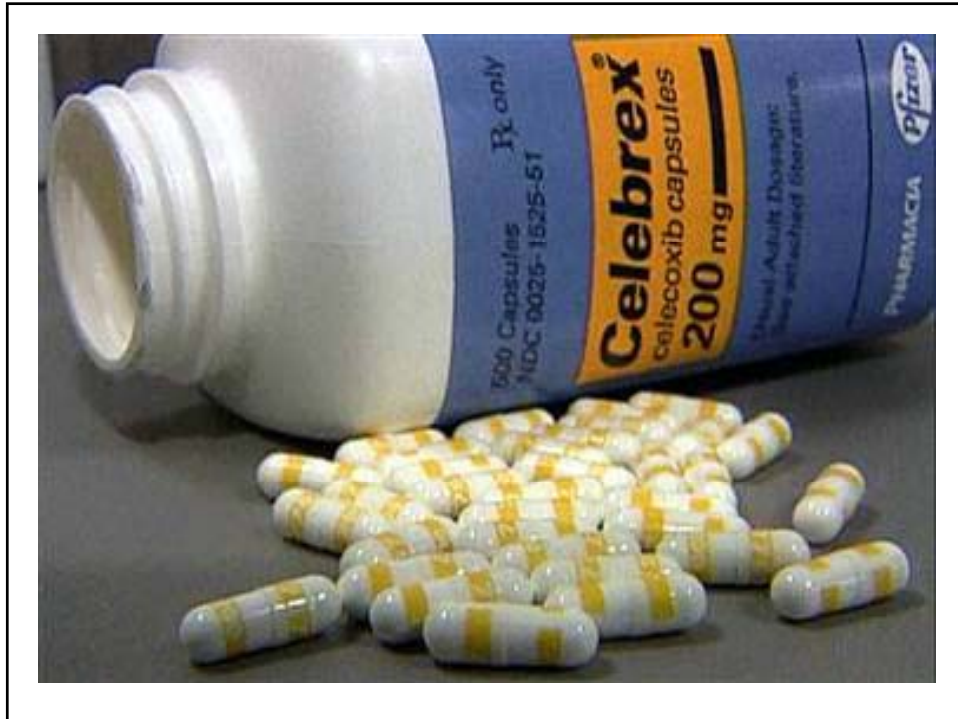
- When initially approved, there were concerns that fluoride ion and compound A production (from interaction with soda lime in CO₂ absorbents) might cause renal toxicity in humans.

Sevoflurane

- Sevoflurane was approved with a limitation on its use with low fresh gas flows; package insert now states:
 - "Although data from controlled clinical studies at low flow rates are limited, findings taken from patient and animal studies suggest that there is a potential for renal injury which is presumed due to Compound A.

Sevoflurane

- Animal and human studies demonstrate that sevoflurane administered for more than 2 MAC•hours and at fresh gas flow rates of <2 L/min may be associated with proteinuria and glycosuria."



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Sample Of Harmful Recalled Drug Cases

If you do not see a particular drug listed here or on the left, this means we have not added it to the website yet. Please contact us for information on any drug. [CLICK HERE TO CONTACT US NOW](#)

We specialize in drug cases!

OxyContin

OxyContin is a prescription painkiller used for moderate to high pain relief associated with injuries, bursitis, dislocations, fractures, neuralgia, arthritis, lower back pain, and pain associated with cancer.

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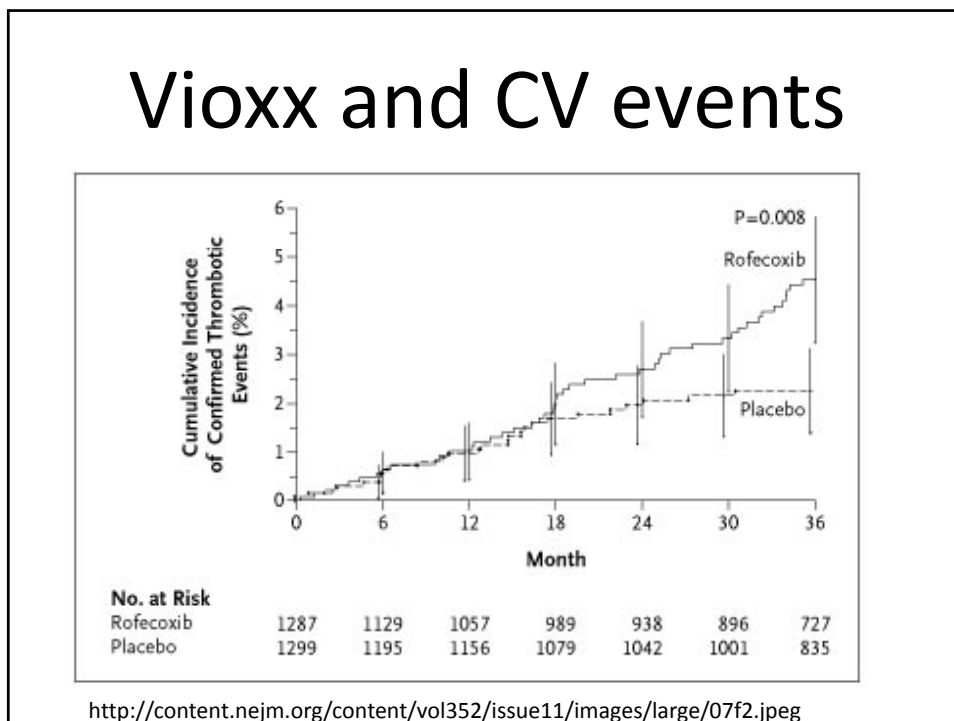
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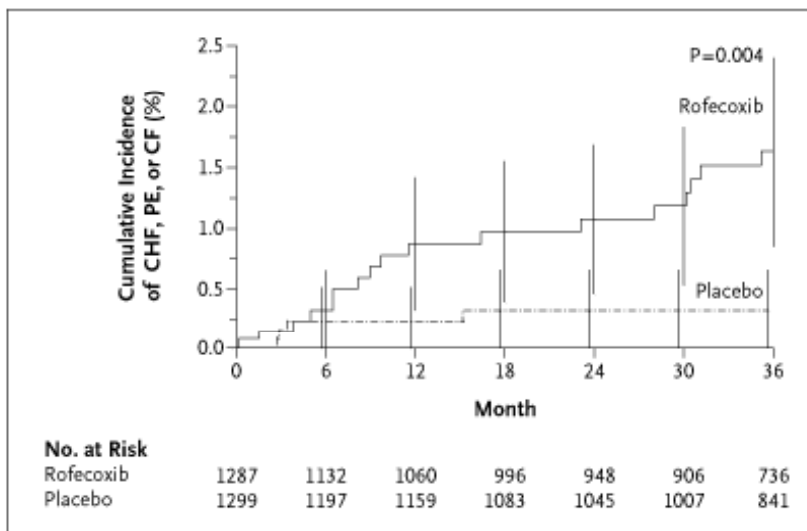
Zyprexa

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Vioxx and CV events



<http://content.nejm.org/content/vol352/issue11/images/large/07f2.jpeg>

Parecoxib and valdecoxib in CABG

	Standard care, N = 151 (%)	Current study parecoxib/valdecoxib, N = 311 (%)	P value†
Any SAE	15 (9.9)	59 (19.0)	.015
Death	0	4 (1.3)	.309
Cerebrovascular disorder	1 (0.7)	9 (2.9)	.177
Myocardial infarction	1 (0.7)	5 (1.6)	.669
Cardiac failure	2 (1.3)	3 (1.0)	.664
Abnormal renal function or increased creatinine level	0	6 (1.9)	.184
Gastrointestinal hemorrhage	0	3 (1.0)	.554
Pleural effusion	1 (0.7)	7 (2.3)	.283
Pneumonia	3 (2.0)	4 (1.3)	.688
Sternal wound infection	0	10 (3.2)†	.035
Thrombophlebitis	0	3 (1.0)	.554

J Thorac Cardiovasc Surg. 2003 Jun;125(6):1481-92.

But, wouldn't that
analgesia be nice
for a few days in a
sleep apneic?

Droperidol

Prolonged QT and Torsades de Pointes

- In 2001, the FDA issued a new “black box” warning on droperidol because of concerns of serious cardiac arrhythmias secondary to QT prolongation.
 - 273 cases reported for a 4-year period
 - 127 cases with serious adverse outcomes.
 - A possible cardiac event occurred in 74 cases.

[Journal of Clinical Anesthesia Volume 20, Issue 1](#), February 2008, Pages 35-39

Prolonged QT and Torsades de Pointes

- There were 89 deaths reported, but the dose of droperidol was ≤ 2.5 mg in only two deaths.

[Journal of Clinical Anesthesia Volume 20, Issue 1](#), February 2008, Pages 35-39

Black box warning changed practice

1 st choice antiemetic	Before black box warning	After black box warning
Droperidol	47%	5%
5-HT ₃ receptor antagonist	25%	42%
Dexamethasone	5%	16%

J Clin Anesth. 2008 Feb;20(1):35-9

■ CLINICAL INVESTIGATIONS

Anesthesiology 2007; 107:531-6

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Does Low-dose Droperidol Administration Increase the Risk of Drug-induced QT Prolongation and Torsade de Pointes in the General Surgical Population?

Gregory A. Nuttall, M.D.,* Karen M. Eckerman, C.R.N.A. M.N.A.,† Kelly A. Jacob, C.R.N.A. M.N.A.,† Erin M. Pawlaski, C.R.N.A. M.N.A.,† Susan K. Wigersma, C.R.N.A. M.N.A.,† Mary E. Shirk Marienau, C.R.N.A., M.S.,‡ William C. Oliver, M.D.,* Bradley J. Narr, M.D.,§ Michael J. Ackerman, M.D., Ph.D.¶

Pre- and post- black box warning

Before the warning

- 2,321 patients (1.66%) had QT prolongation, TdP, or death within 48 h after surgery
- **12% rec'd droperidol**

After the warning

- 2,207 patients (1.46%) had documented QT prolongation, TdP, or death within 48 h after surgery
- **0% rec'd droperidol**

Anesthesiology 2007; 107:531-6

■ CLINICAL INVESTIGATIONS

Anesthesiology 2007; 107:531-6

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“Conclusions: This indicates that the Food and Drug Administration black box warning for low dose droperidol is excessive and unnecessary.”

Anesthesiology 2007; 107:531-6

FDA response to calls for change

- "The droperidol boxed **warning applies to the approved doses** of this product as delineated in the product label...

Anesth Analg. 2008 May;106(5):1585.

FDA response to calls for change

- "...**The FDA has received no data** to support or dispute any speculation that lower, unapproved doses of droperidol might or might not be sufficiently cardiotoxic so as to merit an equal level of concern as the approved doses..."

Anesth Analg. 2008 May;106(5):1585.

FDA response to calls for change

- "...Although we are aware of the literature describing the use of lower, unapproved doses of droperidol, these **data have not been submitted to the FDA** for review."

Anesth Analg. 2008 May;106(5):1585.

Unapproved NTG



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FDA NEWS RELEASE

For Immediate Release: March 16, 2010

Media Inquiries: Thomas Gasparoli, thomas.gasparoli@fda.hhs.gov, 301-796-4737

Consumer Inquiries: 888-INFO-FDA

FDA Orders 2 Companies to Stop Marketing Unapproved Nitroglycerin Tablets

Unapproved NTG

- *“Many makers of various drugs, not only nitroglycerin tablets, have long contended that their medications did not require F.D.A. review because they were grandfathered as pre-1938 drugs.”*
- *The F.D.A., ...in recent years has been cracking down on a decades-old backlog of unapproved drugs...”*

NY Times March 26, 2010
<http://www.nytimes.com/2010/03/27/business/27nitro.html>

Typical problem

No one will pay to do
studies of old
(off-patent) drugs

Drug Shortages

FDA U.S. Food and Drug Administration Department of Health and Human Services
 CENTER FOR DRUG EVALUATION AND RESEARCH
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- [More Information on Drug Shortages, Product Recalls and Warnings \(11/20/2008\)](#)
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Scopolamine

“Scopolamine is ...being removed from the Pyxis machines. Once it is gone there will most likely be no more until the end of May. I have emphasized

- 1) we are critically dependent on scopolamine for certain types of patients
- 2) there is no good substitute,
- 3) there may be an increase in adverse events
- 4) that these events, if they occur, may have significant medical – legal consequence ...

I urged them to find alternative sources as a bridge ... I can do no more.”

David S. Smith, M.D., Ph.D.
 Department of Anesthesiology and Critical Care QI Coordinator

Drug shortages at Penn

- Vecuronium
 - Back to pancuronium
- Thiopental
- Remifentanyl
- Propofol
 - *Two faculty have observed that ketamine destabilizes the propofol emulsion of the new generic propofol*

David S. Smith, M.D., Ph.D.
Department of Anesthesiology and Critical Care QI Coordinator

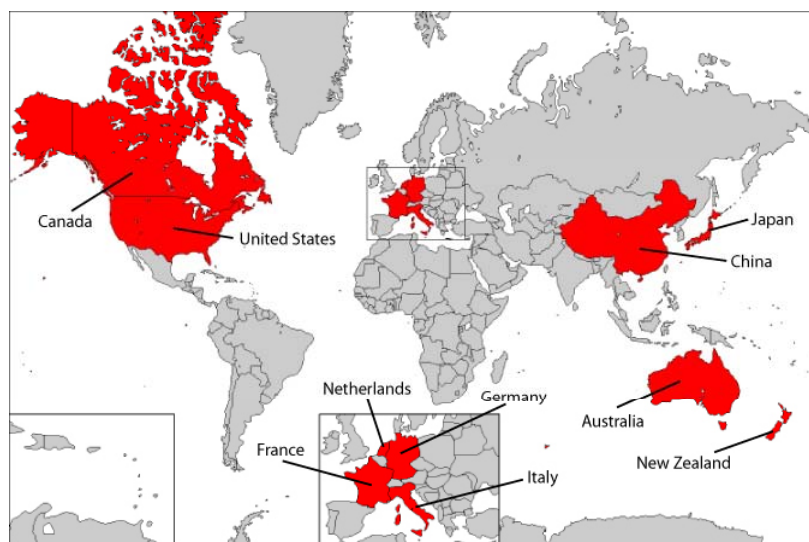


The NEW ENGLAND JOURNAL of MEDICINE

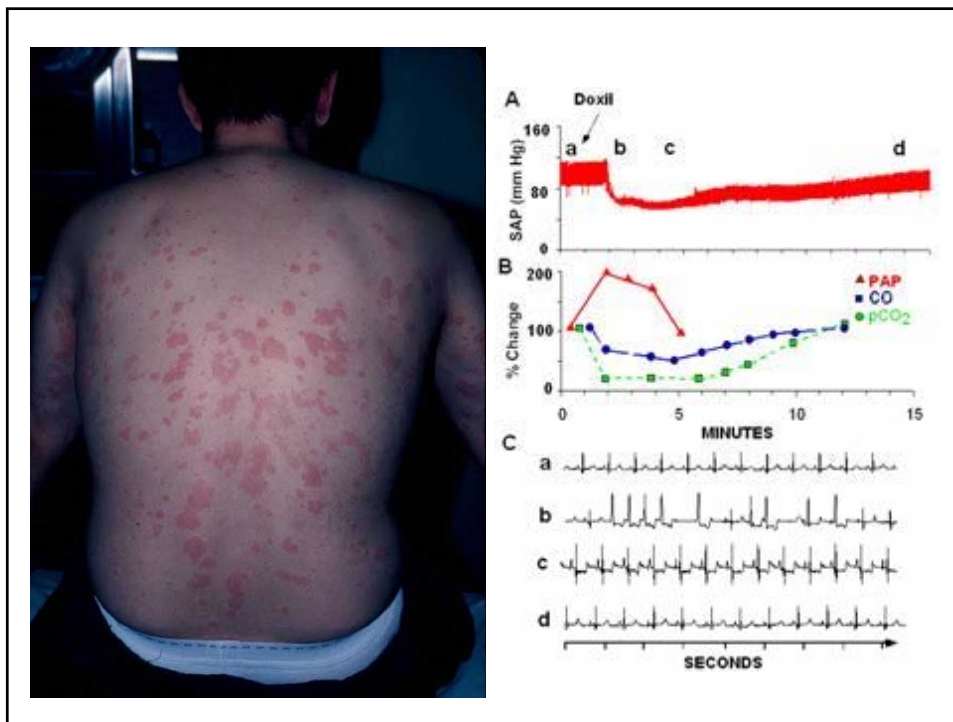
ORIGINAL ARTICLE

Outbreak of Adverse Reactions Associated with Contaminated Heparin

David B. Blossom, M.D., Alexander J. Kallen, M.D., M.P.H.,
Priti R. Patel, M.D., M.P.H., Alexis Elward, M.D., M.P.H., Luke Robinson, B.S.,
Ganpan Gao, Ph.D., Robert Langer, Sc.D., Kiran M. Perkins, M.D.,
Jennifer L. Jaeger, M.D., Katie M. Kurkjian, D.V.M., M.P.H.,
Marilyn Jones, R.N., M.P.H., Sarah F. Schillie, M.D., M.P.H.,
Nadine Shehab, Pharm.D., Daniel Ketterer, M.D., Ganesh Venkataraman, Ph.D.,
Takashi Kei Kishimoto, Ph.D., Zachary Shriver, Ph.D., Ann W. McMahon, M.D.,
K. Frank Austen, M.D., Steven Kozlowski, M.D., Arjun Srinivasan, M.D.,
George Turabelidze, M.D., Ph.D., Carolyn V. Gould, M.D.,
Matthew J. Arduino, Dr.P.H., and Ram Sasisekharan, Ph.D.



<http://www.fda.gov/bbs/topics/news/heparin/heparinmaps.html>



The New York Times

January 20, 2009

Drug Making's Move Abroad Stirs Concerns

By [GARDINER HARRIS](#)

WASHINGTON — In 2004, when [Bristol-Myers Squibb](#) said it would close its factory in East Syracuse, N.Y. — the last plant in the United States to manufacture the key ingredients for crucial [antibiotics](#) like penicillin — few people worried about the consequences for national security.

“If tomorrow China stopped supplying pharmaceutical ingredients, the worldwide pharmaceutical industry would collapse”

Nature Medicine, April 2010

FOCUS ON COUNTERFEIT DRUGS

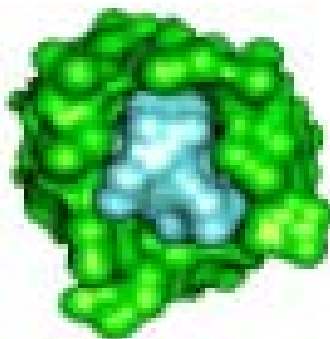
A dose of reality about fakes

The problem of fake medicines cannot be ignored. A report from the European Commission found that, of 32 million medicinal products stopped by customs officials in 2007, 15% were suspected of infringing on intellectual property rights. And at the fifth Global Forum on Pharmaceutical AntiCounterfeiting in Florida this past February, Jim Thomson, chairman of the European Alliance for Access to Safe Medicines, estimated that the cost of counterfeits to the healthcare systems in the EU was at least €50 billion (\$68 billion) in 2007. Countless reports have documented that phony meds cost human lives—for example, the bogus drugs that claim the lives of children stricken with malaria. In the following pages we take a close look at the problem of counterfeit drugs and the solutions proposed to address this growing problem.

What's in a name? Lots, when it comes to counterfeits in Uganda

“...estimated that the cost of counterfeits to the healthcare systems in the EU was at least €50 billion (\$68 billion) in 2007.”

Suggamadex



Anesthesiology 2008; 109:816-24

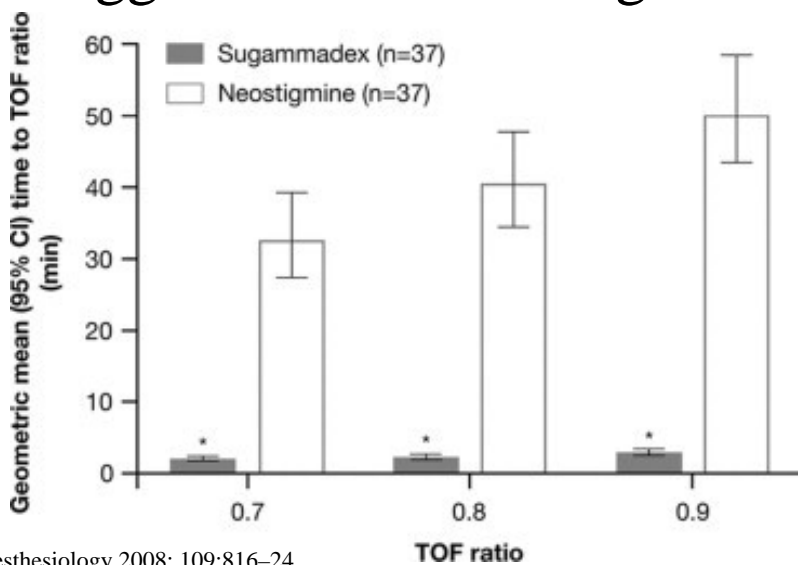
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Reversal of Profound Rocuronium-induced Blockade with Sugammadex

A Randomized Comparison with Neostigmine

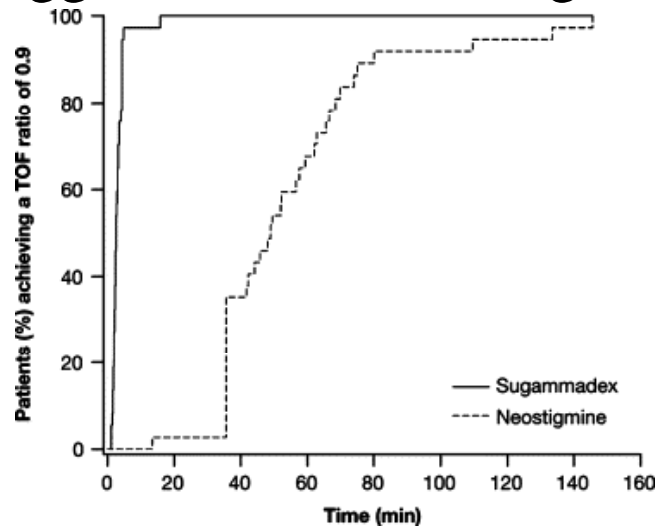
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Suggamadex vs. neostigmine



Anesthesiology 2008; 109:816-24

Suggamadex vs. neostigmine



Anesthesiology 2008; 109:816-24

And, residual block is bad

	TOF < 0.7	Postop Pulmonary Complications
Pancuronium	26%	16.9%
Atrac / Vecur	5.3%	4.8%

Acta Anaesthesiol Scand. 1997 Oct;41(9):1095-1103.

EU says “yes”
FDA Advisory Panel says
“yes”
FDA says “no”!

FDA concerns

- Anaphylaxis with repeat exposure?
- Patients with abnormal end-organ function
- Enamel formation in children
- “Some analysts have speculated that FDA has become more cautious about putting new drugs on the market following the safety concerns around drugs like ...Vioxx and ...Avandia. In both cases, there were older medications on the market with more established safety profiles.”

<http://groups.google.com/group/anesthesiologyig/web/fda-delays-release-of-sugammadex?pli=1>

Will patients suffer in the meantime?

Slow reversal with
neostigmine?

Tachycardia,
arrhythmias?

Conclusions

- Pharma industry is huge and powerful
- FDA still underfunded to regulate?
- Conflict-of-interest scandals in the news
- Several drug recalls made FDA cautious
- Counterfeit drugs may be deadly
- Drug shortages problematic
- Impacts anesthesia practice