

# **Vermont's Gift Ban and Disclosure Laws**

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# Prescription drug cost-containment: Acts 80 and 89

- Acts 80 (2007) and 89 (2008) included:
  - Limits on access to prescriber data for marketing purposes unless prescriber “opts in” (18 V.S.A. § 4631)
    - *IMS Health, Inc. v. Sorrell*
  - Academic detailing program (18 V.S.A. § 4622)
  - Generic drug voucher pilot program
  - Regulation of pharmacy benefit managers (PBMs) (in 18 V.S.A. chapter 221)

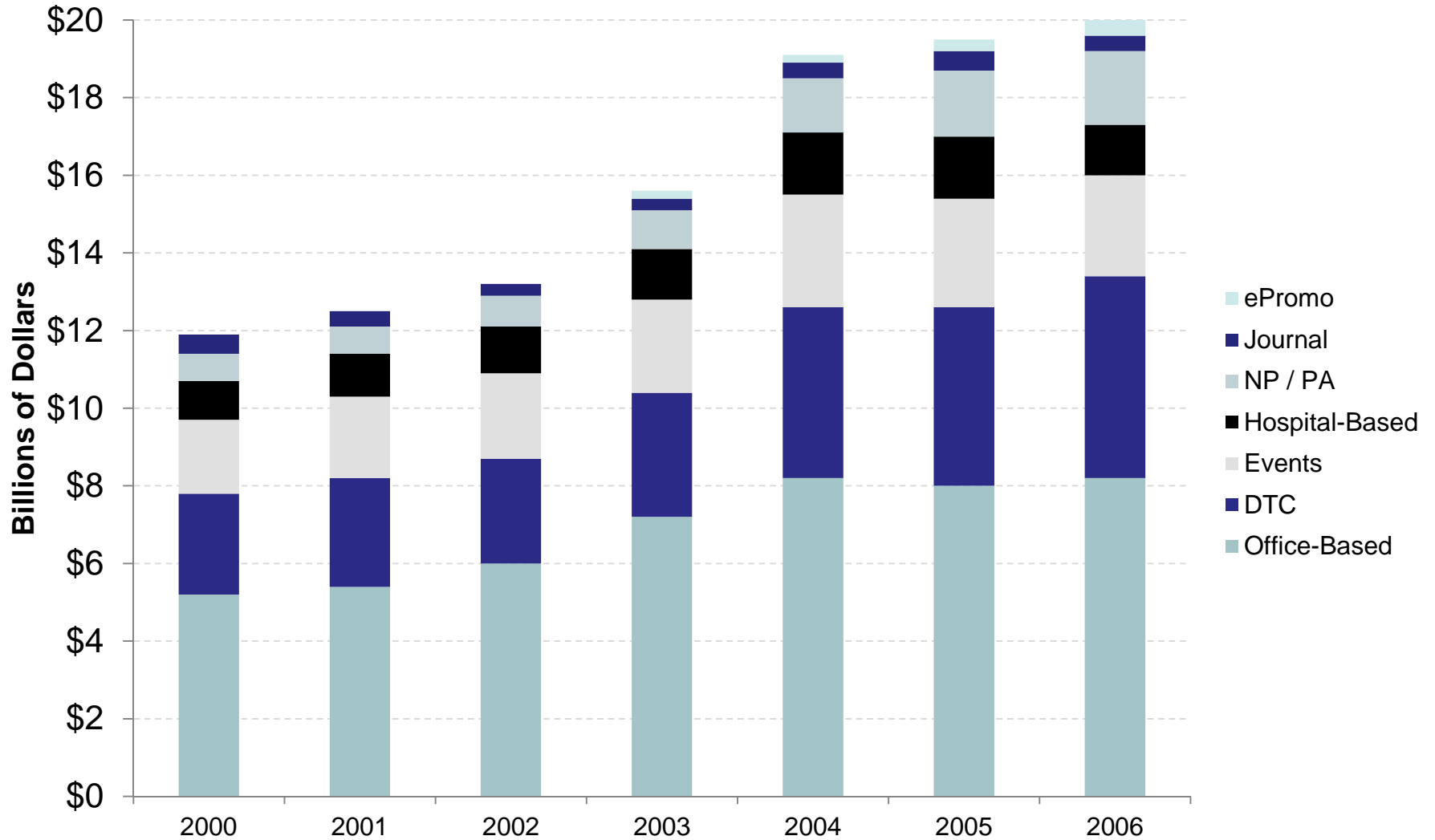
# Prescription drug cost containment: Act 59 (2009)

- Findings include:
  - 2007: \$572 million spent in Vermont on prescription/OTC drugs and medical supplies
  - 2002: \$377 million
    - 8.7% increase, higher than overall health care spending for the same period
  - Court in *IMS Health Inc. v. Sorrell* found research shows marketing to doctors affects prescribing
  - 2009 Institute of Medicine report found acceptance of meals and gifts influences doctors to prescribe a manufacturer's medicines even when evidence indicates another drug would be better for the patient

# Prescription drug cost containment: Act 59 (2009)

- More findings:
  - From July 1, 2007 to June 30, 2008:
    - Rx manufacturers reported spending \$2,935,248 in Vermont on fees, travel expenses, and other direct payments to Vermont doctors, universities, and others for marketing purposes
    - Payments went to 2,280 of Vermont's 4,573 licensed health care professionals
    - Approx. \$2.1 million of the \$2.9 million went to physicians
    - The top 100 individual recipients received almost \$1,770,000
    - Expenditures on food were \$861,911.70 (29.36%)
    - One individual received \$15,793.78 in food for self/staff

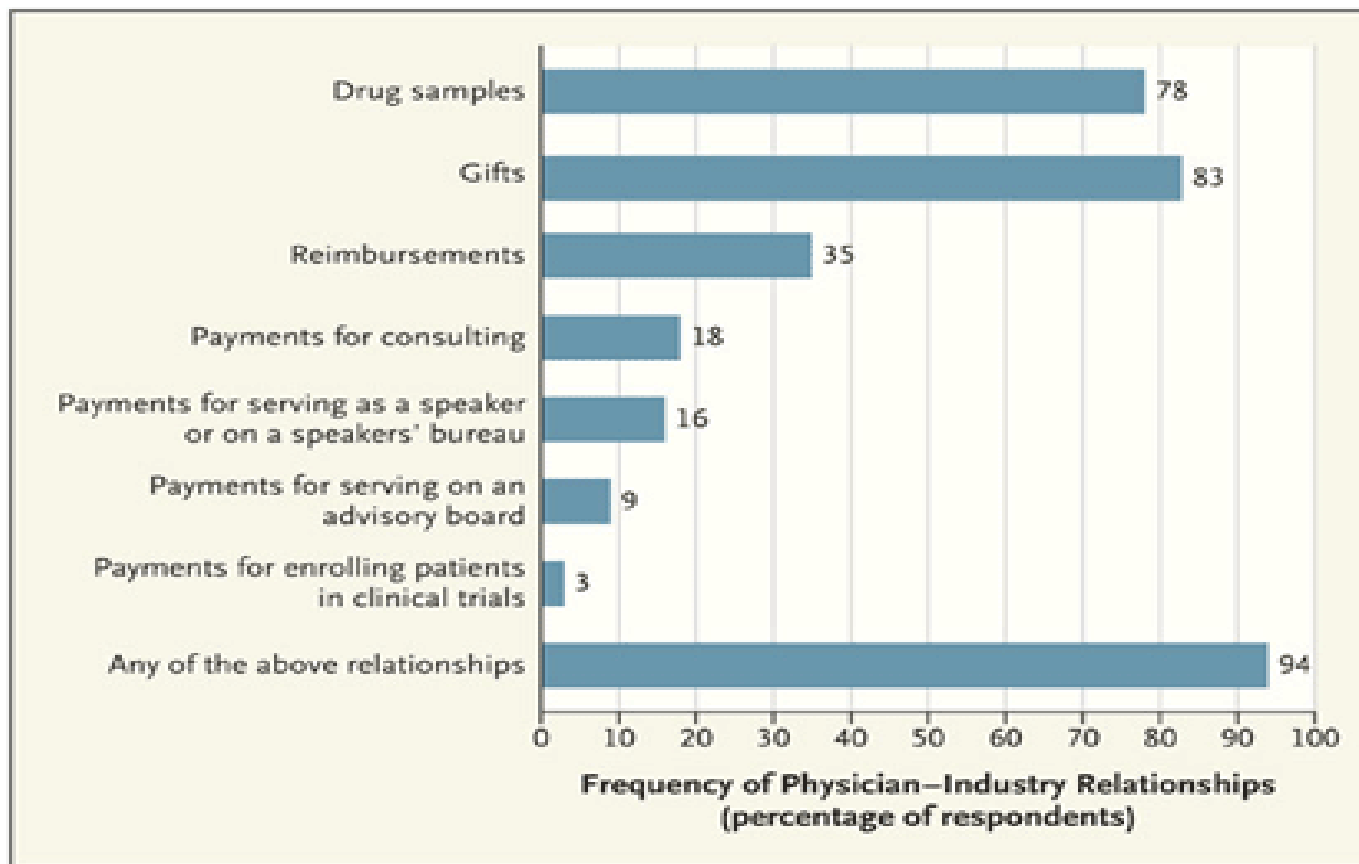
# Pharmaceutical Promotional Spending by Type, 2000-2006





# Percentage of Physicians with Industry Relationship

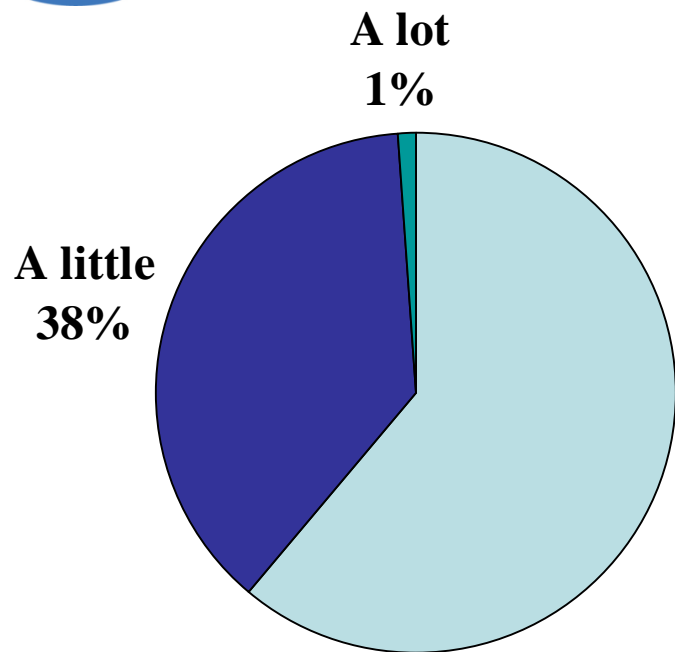
Campbell and Campbell et al, NEJM: 2007



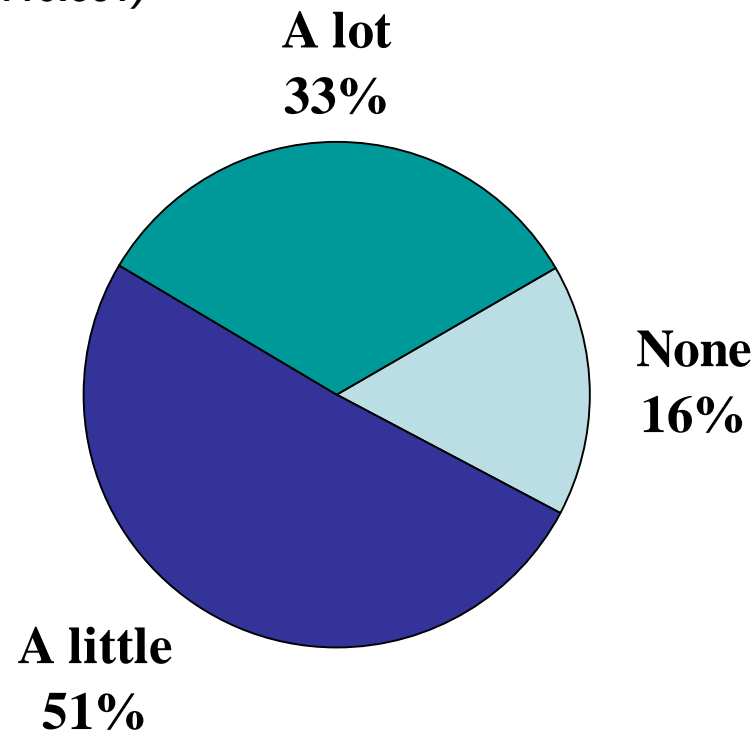
# Perceived influence of pharmaceutical reps on prescribing



(Am J Med 2001;110:551)



**“You”**



**“Other physicians”**

P<.0001

# **Prescription drug manufacturer gift ban and disclosure reqts.**

- Bans gifts from manufacturers of prescribed products to health care professionals, other providers, and Green Mountain Care Board (GMCB)
- Requires disclosure of allowable expenditures by manufacturers to Attorney general
- Some exceptions to gift ban and disclosure requirement



# Sunshine provisions in ACA

- Requires manufacturers of prescribed products purchased by Medicare, Medicaid, or SCHIP to report information to HHS about transfers of value to physicians and teaching hospitals
- States are preempted for:
  - Duplicative reporting requirements
  - Began on January 1, 2012
- States are not preempted for:
  - Restrictions or prohibitions on transfers or gifts (“gift bans”)
  - Additional or different reporting requirements

# Vermont's gift ban and disclosure laws: who must comply?

- Manufacturers of “prescribed products”
  - Pharmaceutical companies
    - Excludes wholesale distributors of biologics, retailers, and pharmacists
  - Medical device companies
  - Manufacturers of biologics

# Gifts to...?

- Bans certain gifts to:
  - Health care professionals
    - Includes doctors, nurses
  - Health care providers
    - Hospitals, nursing homes, pharmacists
  - Health benefit plan administrators
    - Insurers, PBMs
  - Anyone else authorized to dispense or purchase for distribution
  - Green Mountain Care Board members

# What is a “gift”?

- Anything of value provided to a health care provider or GMCB member for free; or
- Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider, unless:
  - it is an “allowable expenditure,” or
  - the health care provider reimburses the cost at fair market value, or
  - it is one of the listed exceptions

# What is an “allowable expenditure”?

- Reasonable fees, payments, subsidies, or other economic benefits provided at fair market value
- Includes:
  - Research/clinical trial contracts
  - Payment of expenses for CME/conferences
  - Honoraria for faculty at CME/conferences
  - Reasonable expenses for medical device training
  - Royalties and licensing fees
  - Interview expenses for a job with manufacturer

# Exceptions to gift ban

- Samples
- Short-term ( $\leq 120$  days) loans of medical devices
- Medical device demonstration units
- Clinical articles and journals
- Conference scholarships for medical students
- Rebates and discounts
- Labels approved by the FDA
- Donations to free clinics
- Patient assistance programs
- Fellowship salary support
- Coffee/snacks at conference booths

# What must be disclosed ?

- Value, nature, purpose of gift, name of the recipient
- To health care providers, GMCB members, academic institutions, hospital foundations, and provider/consumer organizations
- Exceptions:
  - Royalties and licensing fees
  - Rebates and discounts
  - Payments for clinical trials delayed until earlier of:
    - Approval or clearance of the product by FDA or
    - 4 calendar years
  - Interview expenses for health care professionals
  - Coffee/snacks at conference booths
  - Short-term loans of medical devices for trial
  - Products distributed as part of patient assistance program

# Samples Disclosure

- Free samples of prescribed products must be disclosed
- Free samples of over-the-counter products must be disclosed if manufacturer has other allowable expenditures/permitted gifts to report
  - Name of product, recipient, number of units, and dosage
  - Limitations on public reporting of information
  - Does not apply to samples of prescribed products required to be reported under ACA, if any



# Disclosure required

- Disclosures required to Attorney General by manufacturers
  - Annually by April 1
  - \$500 fee if any expenditures to report
  - Health care professionals and providers do not disclose
- AG prepares annual report by October 1
- Information available on AG's website
  - Searchable database

# Resources

- Vermont AG's website:
  - Prescribed products generally:  
<http://ago.vermont.gov/focus/consumer-info/health1/prescribed-products.php>
  - Guide to Vermont's law:  
[http://ago.vermont.gov/assets/files/Consumer/Prescribed\\_Products/Amended%202015%20Guide%20to%20Vermonts%20Prescribed%20Product%20Gift%20Ban%20and%20Disclosure%20Law%20-%20Final.pdf](http://ago.vermont.gov/assets/files/Consumer/Prescribed_Products/Amended%202015%20Guide%20to%20Vermonts%20Prescribed%20Product%20Gift%20Ban%20and%20Disclosure%20Law%20-%20Final.pdf)