

First Annual Summit on Disclosure, Transparency and Aggregate Spend for Drug, Device and Biotech Companies

*Issues Raised by State Legislation for
Pharmaceutical and Device Companies*

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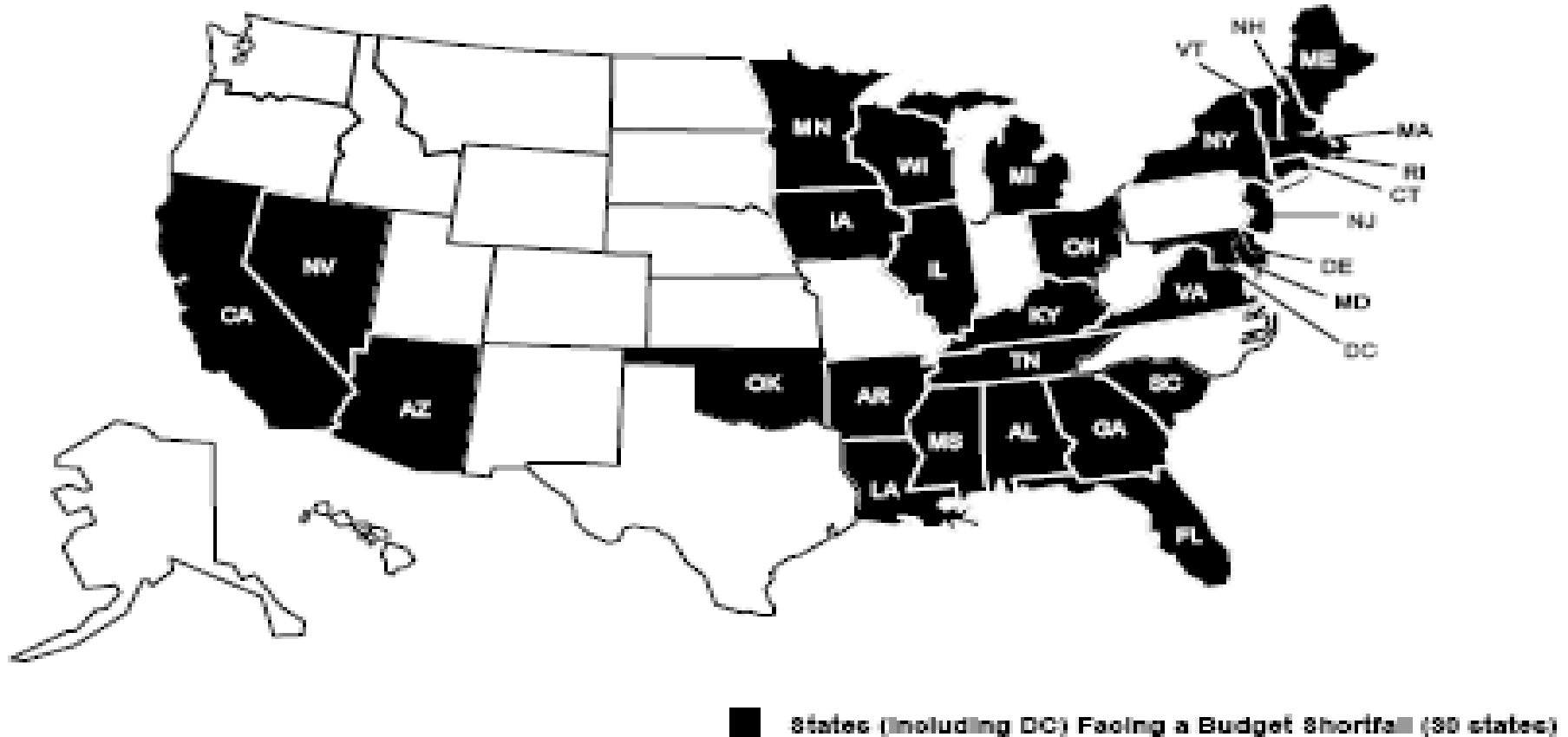
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A View From The States

- Unlike the federal government, some states have constitutional requirements for a balanced budget each year.
- Unlike members of Congress, many state legislators typically serve in a part-time capacity (and at least 15 states have term limits for their legislators)
- Combine these two factors with difficult economic times, and you have a perfect storm that can lead to the enactment of well-intended but not well-designed legislation. Efforts to contain health care costs are key examples.
- Governors and state legislators feel that they are under intense pressure to deliver, and perception often is reality in politics.

Many States Are Facing Serious Budget Problems

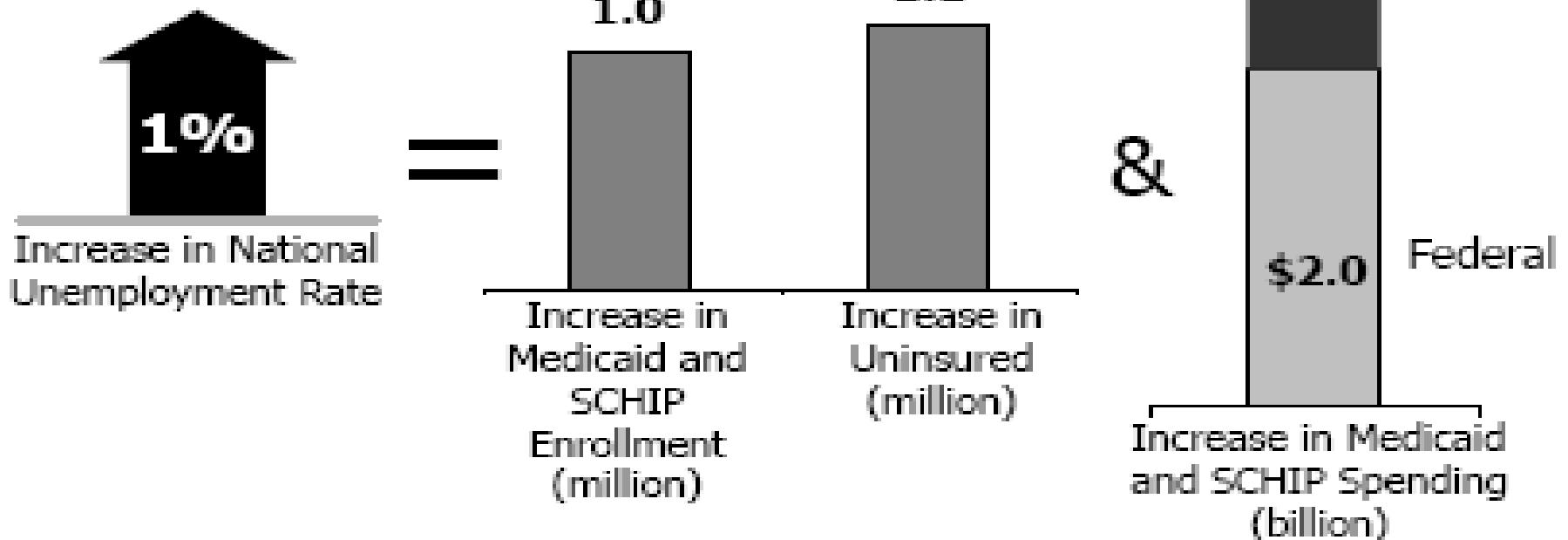
30 States Faced Budget Shortfalls Heading Into State FY 2009



And things are getting worse . . .

Impact of a 1% Growth in Unemployment

1% increase in unemployment also =
a 3-4% decline in state revenues



Source: *Medicaid, SCHIP and Economic Downturn: Policy Challenges and Policy Responses*, Kaiser Commission on Medicaid and the Uninsured, April 2008

KAISER COMMISSION ON
Medicaid and the Uninsured

You Can't Improve What You Don't Measure

“. . . chart a course for every endeavor that we take the people's money for, see how well we are progressing, tell the public how we are doing, stop the things that don't work, and never stop improving the things that we think are worth investing in.”

- President William J. Clinton, on signing the Government Performance and Results Act of 1993***

Are Pharmaceutical Marketing Disclosure Laws Accomplishing Their Stated Objectives?

Affordability

- ***District of Columbia:*** “[E]nables the District to take steps to make prescription drugs more affordable for qualified District residents.”
- ***West Virginia:*** “That there is an increasing need for citizens of West Virginia to have affordable access to prescription drugs. . . . In an effort to promote healthy communities and to protect the public health and welfare of West Virginia residents, the Legislature finds that it is its responsibility to make every effort to provide affordable prescription drugs for all residents of West Virginia.”

Cost Containment

- **Massachusetts:** “[P]romote cost containment, transparency and efficiency in the delivery of quality health care.”
- **Maine:** “Marketing costs for prescription drugs in this State must be reported to the department for the purposes of assisting this State in its role as a purchaser of prescription drugs and an administrator of prescription drug programs, enabling this State to determine the scope of prescription drug marketing costs and their effect on the cost . . . of health care services and furthering the role of this State as guardian of the public interest.”
- **West Virginia:** “That the rising cost of prescription drugs has imposed a significant hardship on individuals who have limited budgets, are uninsured or who have prescription coverage that is unable to control costs successfully due to cost shifting and disparate pricing policies;”

West Virginia Report: Minimal Effect on Affordability & Cost Containment

- As part of its Pharmaceutical Availability and Affordability Act, West Virginia created the Pharmaceutical Cost Management Council in 2004. One of the Council's specific tasks was to establish reporting requirements by labelers and manufacturers for all expenses associated with advertising and direct promotion of pharmaceutical drugs. The Council completed this task by adopting the state's marketing disclosure regulation in August 2007.
- According to a recently published report by the West Virginia Department of Administration, which audited the Council:
 - “The Council’s **effect on lowering pharmaceutical prices has been minimal**. The Legislative Auditor questions whether the savings were a result of the efforts of the Council or the efforts mainly of the Office of the Pharmaceutical Advocate.” (Emphasis added.)

West Virginia Department of Administration Audit Overview, “The Legislature Should Consider Several Options Pertaining to the Future of The Pharmaceutical Cost Management Council” (August 2008).

Are Pharmaceutical Marketing Disclosure Laws Accomplishing Their Stated Objectives?

Prevent Undue Influence

- ***Texas S.B. 414, Proposed in 2007:*** “Direct marketing of prescription drugs to healthcare providers causes providers to change their prescribing habits, even if other remedies are cheaper, more effective, or safer. The ability of pharmaceutical companies to monitor prescribing practices and target key healthcare providers with gifts may compromise the interest of the patient. Patients should be informed about this relationship.”

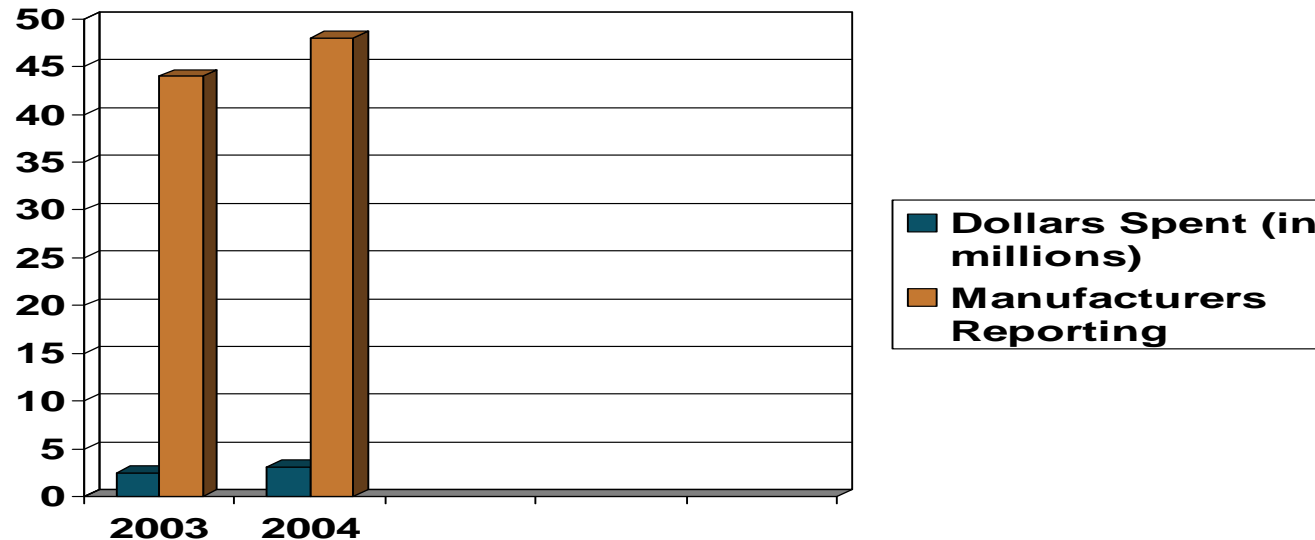
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Transparency & Accountability

- ***Federal Physician Payments Sunshine Act of 2009***: “Shedding light on industry payments to physicians would be good for the system. Transparency fosters accountability, and the public has a right to know about financial relationships.” (Press Release by Senator Grassley regarding proposed Act).

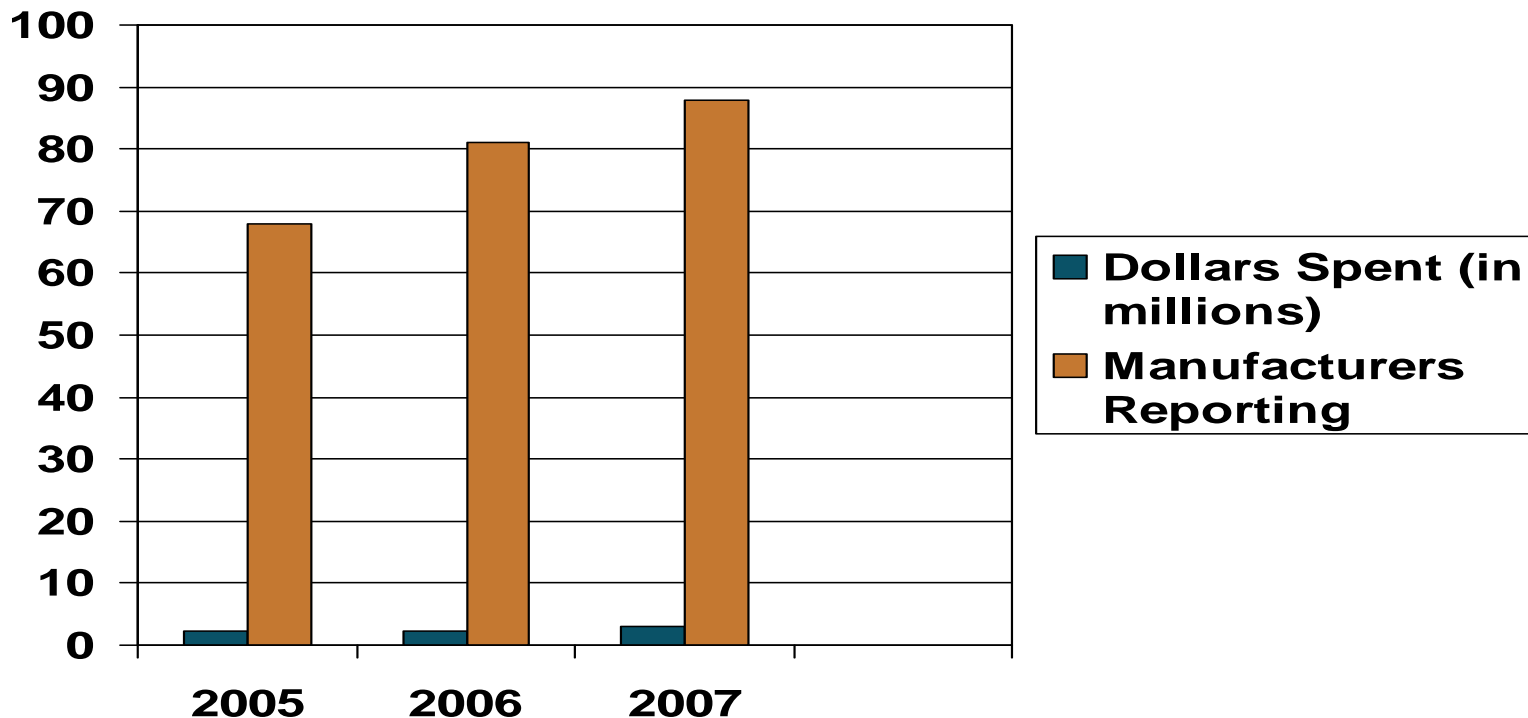
Vermont Reports: Marketing Expenditures Have *Increased!*

For Vermont's Fiscal Year 2003, a total of 44 manufacturers reported that they collectively spent approximately \$2.47 million on reportable advertising. For Fiscal Year 2004, a total of 48 manufacturers reported that they collectively spent approximately \$3.11 million.



Vermont Reports: Marketing Expenditures Have *Increased!*

After adjusting for an eliminated reporting category, Vermont saw similar increases in each category over Fiscal Years 2005-2007 (68, 81, and 88 reporting manufacturers; \$2.17 million, \$2.25 million, and \$3.13 million, respectively).



Missing The Point

Although meaningful transparency is laudable, many of these laws suffer from the same problems:

- They require voluminous reports to be submitted to state agencies that do not have sufficient resources to interpret them in a meaningful way (to the extent the reports include any meaningful data in light of the stated objectives).
- They implicitly attack the integrity of the medical profession.
- They fail to provide any meaningful tools to physicians to enhance quality care or promote cost effectiveness. (And the expansion to the device industry exacerbates the problem without any benefit.)
- And perhaps most importantly, they fail to comprehend or acknowledge some of the key reasons pharmaceutical costs are increasing (e.g., an aging baby boomer population and childhood obesity, which is a leading cause of adult onset diabetes)

Getting the Point

By 13-1 vote, New Hampshire H.B. 1518 (2008) voted “Inexpedient to Legislate.” House Report states reasons:

- Department of Health and Human Services recognized that analyzing the data “would require highly skilled individuals with knowledge of pharmacy and/or health economics, and no such individual current[ly] exists at the department.”
- Acknowledged the testimony at the public hearing indicating “doctors and community health centers use free samples for trial use or to save lower income patients the cost of the prescription.”
- Recognized that “literature and marketing by the pharmaceutical industry must be approved by the FDA.”
- Observed that pharmaceutical representatives “are forbidden to make claims not already approved, with penalties ranging from fines, criminal penalties and possibility of being excluded from Medicaid and Medicare programs.”

Different (And Successful) Approaches

Equip Physicians With Tools To Improve Care While Also Lowering Costs

- Florida's Gold Standard Pilot program began in the spring of 2003 when Florida Medicaid contracted with Gold Standard MultiMedia to provide 1000 handheld, wireless PDAs to the top prescribing Medicaid physicians. The PDAs provide the physician with 60 days' history of all the Medicaid prescriptions for their patients along with clinical information to assist in the appropriate prescribing of medications.
- According to a recent report, the Gold Standard pilot saved the Florida Medicaid program approximately \$50 million in pharmaceutical expenditures in 2007, while at the same time improving patient care.

Different (And Successful) Approaches

Establish an Effective Medicaid Preferred Drug List or Formulary

- State Medicaid programs have market power to negotiate for substantial rebates from drug manufacturers in exchange for 1:1, 2:1, or 3:1 listings on Medicaid preferred drug lists or formularies.
- Effective negotiations achieve significant savings for states, even if utilization remains constant or increases.

Different (And Successful) Approaches

Use Health Information Technology To Improve Care And Prevent Unnecessary Costs

- *Improve patient compliance and disease management*
- *Identify and prevent fraud and abuse*
- *Improve prior authorization process*

Questions?

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