

Pharmaceutical Marketing Disclosures

For the period July 1, 2002 to June 30, 2003

**Report of
Vermont Attorney General
William H. Sorrell**

February 25, 2004

Contact: Julie Brill
Assistant Attorney General
(802) 828-5479

Pharmaceutical Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell February 25, 2004

I. Executive Summary

This is the first report of Vermont Attorney General William H. Sorrell on Pharmaceutical Marketing Disclosures. It is based upon disclosures required by Vermont law from pharmaceutical manufacturers, listing the amount of money the companies spent during the past fiscal year on fees, travel expense, gifts, and other payments to physicians, hospitals, universities and others that prescribe or dispense pharmaceutical products. Vermont's Pharmaceutical Marketing Disclosure Law, 33 V.S.A. § 2005 ("Disclosure Law"), requires the manufacturers to file the disclosures with the Vermont Pharmacy Board, and requires the Vermont Attorney General to issue this report about the disclosures.

Vermont's Disclosure Law is the first in the nation requiring such disclosures. As this report evidences, the Disclosure Law provides useful information into how pharmaceutical manufacturers distribute money within the medical community to market pharmaceuticals.

According to the first round of disclosures filed by pharmaceutical manufacturers, from July 1, 2002 through June 30, 2003, 44 pharmaceutical manufacturers spent \$2.47 million on fees, travel expenses, and other direct payments to Vermont physicians, hospitals, universities and others for the purpose of marketing their products in Vermont. On a national basis, this would amount to an expenditure of \$1.14 billion on such marketing. The five largest spenders on this type of marketing during FY 03 in Vermont were GlaxoSmithKline, Bristol-Myers Squibb, Merck, Forest Pharmaceuticals, and AstraZeneca. These five companies spent 72.18% of the total expenditures. Physicians and other prescribers received 49% of the total payments and benefits, and all health care providers received 79% of the total.

The \$2.47 million expenditure in FY 03 does not describe the total marketing effort by pharmaceutical manufacturers in Vermont. The Disclosure Law does not require the manufacturers to report expenditures on advertising or salaries of employees, known as "detailers", who promote products to prescribers and others in Vermont. The Disclosure Law only requires reporting of economic benefits given directly to physicians, hospitals, universities and others in the course of the manufacturers' promotion programs.

The \$2.47 million expenditure in FY 03 also potentially underestimates the actual amount of money spent by these companies in Vermont on economic benefits given directly to prescribers and others. There was confusion among

manufacturers over whether the Disclosure Law required reporting of discounts and rebates, which are potentially large in value. In addition, some categories of expenditures may have been underreported. In particular, there was wide disparity among the companies in how they reported marketing expenditures for the purpose of “detailing” and “education”, due in part to the absence of more specific direction in how to distinguish between these two categories.

The Vermont Attorney General recommends changes in the Board’s Guidelines to correct some of these problems, including:

- ***The Pharmacy Board should explicitly require disclosure of discounts and rebates paid to purchasers of pharmaceutical products.***
- ***The Pharmacy Board should prescribe a form based upon specific categories or descriptions for recipient, purpose and nature of the expenditures, and require the pharmaceutical manufacturers to use such categories or descriptions in filing their report. The Attorney General will provide the Board with recommended specific categories.***

II. Description of Vermont’s Disclosure Law

The Vermont Legislature enacted the Disclosure Law in 2001. The Disclosure Law requires pharmaceutical manufacturers to report to the Vermont Pharmacy Board, on forms and in a manner prescribed by the Board, regarding marketing payments made to persons in Vermont who are authorized to prescribe, dispense or purchase pharmaceutical products. In particular, the Disclosure Law requires every pharmaceutical manufacturer to disclose to the Board:

the value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacists, health benefit plan administrator or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state.

33 V.S.A. §2005(a)(1).

Exempted by statute from disclosure are the following:

- Free samples of prescription drugs intended for distribution to patients;
- Payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials;

- Gifts, fees, payments, subsidies or other economic benefits valued less than \$25.00; and
- Certain scholarships and other financial support for medical students, residents and fellows to attend significant educational, scientific or policy-making conferences of medical or professional associations.

33 V.S.A. §2005(a)(4).

The Disclosure Law prohibits the Board and the Attorney General from disclosing information that constitutes “trade secrets” under Vermont’s Access to Public Records Law, 1 V.S.A. §317(c)(9). The Disclosure Law requires the Board’s disclosure form to permit the reporting companies to identify any disclosed information that they believe constitute such “trade secrets”. See 33 V.S.A. §2005(a)(3).

The complete text of the Disclosure Law is appended as Attachment 1.

As contemplated by the Disclosure Law, the Vermont Pharmacy Board issued a “Guide to Vermont’s Pharmaceutical Marketing Disclosure Law” in August 2002. The Pharmacy Board set forth certain additional exemptions and clarifications – not specifically described in the statute – to the companies’ reporting obligations, including:

- The name of the recipient need not be disclosed;
- Gifts and other payments to “a person authorized to purchase prescription drugs” means persons authorized to purchase prescription drugs “for resale or distribution”, thus exempting gifts and other payments to consumers; and
- Unrestricted grants for continuing medical education (CME) programs need not be disclosed.

The complete text of the “Guide” can be found at <http://vtprofessionals.org/opr1/pharmacists/forms/guiderxdisclosure.pdf>.

As a result of concerns raised about enforcement of the Disclosure Law, the Board will require disclosure of recipient names and date of payments, beginning with payments made on January 1, 2004. The Board’s policy requiring disclosure of recipient names is described in a memo accessible on its website at <http://vtprofessionals.org/opr1/pharmacists/forms/rxdisclosenames.pdf>.

III. Summary of Pharmaceutical Marketing Expenditures

The Attorney General's Office organized the data submitted by the pharmaceutical manufacturers in four ways:

- Payments of each pharmaceutical manufacturer, organized by rank;
- Payments of all manufacturers organized by type of recipient;
- Payments of all manufacturers organized by nature of expenditure;
- Payments of all manufacturers organized by purpose of expenditure.

1. Total Payments of Each Pharmaceutical Manufacturer

According to the reports filed by pharmaceutical manufacturers, 44 pharmaceutical manufacturers spent, for the purpose of marketing the companies' pharmaceutical products, more than \$2.47 million from July 1, 2002 through June 30, 2003, on fees, travel expenses, gifts and other direct payments to Vermont physicians, hospitals, universities, and others who are authorized under Vermont law to prescribe, dispense or purchase pharmaceutical products in Vermont.¹ On a national basis, this would amount to an expenditure of \$1.14 billion on such fees, travel expenses, gifts and other direct payments to physicians, other prescribers, hospitals and universities.² The list of expenditures, ranked by company, is appended as Table 1.³

The following companies were the five largest spenders during FY 03 in Vermont:

- GlaxoSmithKline
- Bristol-Myers Squibb
- Merck
- Forest Pharmaceuticals
- AstraZeneca

These five companies spent 72.18% of the total expenditures in Vermont.

2. Payments by Recipient

¹Of the 51 companies that have filed reports, seven claimed that they were not subject to the law and/or had no reportable expenditures in Vermont.

² The \$2.47 million expenditure in Vermont amounts to \$4.02 for every person in Vermont (pop. 613,090). If the same level of expenditures existed throughout the United States (pop. 284,796,887) the total national expenditure would be \$1,144,883,485.

³ Table 1A ranks the companies' expenditures by combining the Johnson & Johnson pharmaceutical subsidiaries.

Table 2 describes the expenditures in FY 03 by the type of recipient of the reported payment or other economic benefit. Persons authorized to prescribe pharmaceuticals in Vermont, including Vermont physicians, received \$1.22 million, or 49% of the total payments. Other health care professionals, including recipients who were only identified as “health care professionals” in the companies’ disclosures forms, received \$718,979.00, or 29% of the total payments. Together, all health care professionals received \$1.94 million, or 79% of the total. Hospitals, clinics and universities received \$500,334.19, or 20% of the total.

There are 10 categories of professionals authorized to prescribe in Vermont: dentists; naturopathic physicians; nurse practitioners; optometrists; osteopaths; physicians; physician’s assistants; podiatrists; scientific investigators; and veterinarians. The Vermont Secretary of State and Department of Health currently list 5,344 persons as licensed in all of these categories. If the \$1.22 million expended on prescribers were spread evenly throughout the prescribing community, then each person authorized to prescribe pharmaceuticals would have received \$228 in FY 03. Next year, when the Board requires the companies to identify the name of the recipient, it will be possible to calculate the actual spread within the Vermont medical community of the payments to prescribers.

3. Payments by Nature of Expenditure

Table 3 describes the expenditures in FY 03 by the “nature” of the expense. “Nature” of marketing expenses, as set forth in the Disclosure Law, means a description of the kinds of payments or benefits that were provided. Examples of nature of expenditures include cash, checks, honoraria, or other direct payments to physicians; payments of food and beverages; payments of lodging and other travel expenses; discounts, rebates and other payments that lower the price of pharmaceuticals; books; and other gifts.

The majority of the expenditures in FY 03 were for fees, cash, checks, honoraria, and donations, which amounted to \$1.4 million, or 57%, of the total expenditures. Food amounted to \$518,032, or 21%, of the total. Discounts and rebates, which were only reported by one pharmaceutical manufacturer, amounted to \$357,242, or 14.5%. As discussed below, discounts and rebates should be reported by all manufacturers, and it is expected that next year this category will increase as the manufacturers comply by reporting expenditures in this category.

4. Payments by Purpose

Table 4 describes the expenditures in FY 03 by the “purpose” of the expense. The listings for purpose were the most disparate, and therefore difficult for the Attorney General to categorize for this report. The area that appears to

have created the most confusion is the distinction between expenditures for purposes of detailing and those for purposes of education. “Detailing” means a discussion with prescribers, either in a group or one-on-one, primarily about the therapeutic value of particular products. “Education” should be reserved for Continuing Medical Education, seminars and symposiums that do not focus on particular products, but instead relate primarily to discussions about diseases and other medical conditions.

An examination of the disclosures indicates that the manufacturers were confused as to whether expenditures should be listed as “detailing” or “education.” Manufacturers used a wide variety of descriptions to describe the “purpose” of the payments, including:

- “Attendee expenses”
- “CET/STS attendance”
- “Educational Mtg”
- “Educational program”
- “Medical Education”
- “Medical Seminar/Conference”
- “Medical/Scientific presentation”
- “Nursing program”
- “Physician Education Program”
- “Preceptorship”
- “Prof Ed Event”
- “Speaker Program”
- “Study Discussion”
- “Teleconference”
- “TeleTopics Program”

The Attorney General’s Office could not determine whether payments for these and other similarly confusing descriptions were for detailing, education, or some other purpose. As a result, the “unclear” category amounts to \$475,017, or 19% of the total expenditures by purpose. Below, the Vermont Attorney General recommends to the Board that it prescribe a new reporting form that lists approved descriptions of purposes, and require each expenditure to be listed as one of the approved descriptions.

IV. Problems Noted in Current Reports and Recommendations for Corrective Action in Reporting Guidelines

The \$2.47 million figure for FY 03 Vermont expenditures by the pharmaceutical companies potentially underestimates the actual amount of money spent in Vermont on fees, travel expenses and other economic benefits given directly to prescribers and purchasers of pharmaceuticals. The Attorney General notes the following areas as leading to potential underreporting of actual expenditures on marketing, as well as creating other problems in the reports.

1. Discounts and Rebates

Discounts and rebates paid to purchasers and prescribers of pharmaceutical products presents the potentially largest problem area. The Disclosure Law requires disclosure of discounts and rebates that manufacturers give to entities authorized to purchase pharmaceuticals. However, the Pharmacy Board's Guide to manufacturers on compliance with Vermont's Disclosure Law was silent on whether discounts and rebates should be reported. Companies were left to decide on their own whether or not discounts and rebates were required to be reported under Vermont's law, and as a result did not consistently report discounts and rebates. Indeed, only one company reported paying discounts and rebates to purchasers.

Recommended action: the Pharmacy Board should explicitly require disclosure of discounts and rebates paid to purchasers of pharmaceutical products.

2. Treatment of "Purpose" and "Nature" of Payments

As noted above, the manufacturers' reports were not consistent in how payments were described, particularly in terms of the "purpose" of the payments. To ensure consistency in treatment of payments, and to ensure the State's ability to appropriately group payments, the Attorney General will recommend to the Board categories for describing the payments by recipient type, purpose and nature. The Attorney General recommends that the Board require the manufacturers to report each expenditure based upon the approved list of descriptions.

Recommended action: the Pharmacy Board should prescribe a form based upon specific categories or descriptions for recipient, purpose and nature of the expenditures, and require the pharmaceutical manufacturers to use such categories or descriptions in filing their report. The Attorney General will provide the Board with recommended specific categories.

ATTACHMENT 1

Vermont's Pharmaceutical Marketing Disclosure Law

33 V.S.A. § 2005 Pharmaceutical marketers

(a)(1) Annually on or before January 1 of each year, every pharmaceutical manufacturing company shall disclose to the Vermont board of pharmacy the value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure shall be made on a form and in a manner prescribed by the board. Initial disclosure shall be made on or before January 1, 2004 for the 12-month period ending June 30, 2003. The board shall provide to the office of the attorney general complete access to the information required to be disclosed under this subsection. The office of the attorney general shall report annually on the disclosures made under this section to the general assembly and the governor on or before March 1.

(2) Each company subject to the provisions of this section shall also disclose to the board, on or before October 1, 2002 and annually thereafter, the name and address of the individual responsible for the company's compliance with the provisions of this section.

(3) The Vermont board of pharmacy and the office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1. The disclosure form prescribed by the board shall permit the company to identify any information that is a trade secret.

(4) The following shall be exempt from disclosure:

(A) free samples of prescription drugs intended to be distributed to patients;

(B) the payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials. As used in this subdivision, "clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies or new ways of using known treatments;

(C) any gift, fee, payment, subsidy or other economic benefit the value of which is less than \$25.00; and

(D) scholarship or other support for medical students, residents and fellows to attend a significant educational, scientific or policy-making conference of

a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(b) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorneys fees, and to impose on a pharmaceutical manufacturing company that fails to disclose as required by subsection (a) of this section a civil penalty of no more than \$10,000.00 per violation. Each unlawful failure to disclose shall constitute a separate violation.

(c) As used in this section:

(1) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

(2) "Pharmaceutical manufacturing company" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a wholesale drug distributor or pharmacist licensed under chapter 36 of Title 26.

-- Added 2001, No. 127 (Adj. Sess.), § 1, eff. June 13, 2002.

Table 1

Ranking by Company

<i>Company</i>	<i>Ranking</i>
GlaxoSmithKline	1
Bristol-Myers Squibb Company	2
Merck and Company, Inc.	3
Forest Pharmaceuticals Inc.	4
AstraZeneca Pharmaceuticals LP	5
Eli Lilly and Company	6
Aventis Pharmaceuticals Inc.	7
Pfizer Inc.	8
Serono Inc.	9
Wyeth Pharmaceuticals	10
Ortho Biotech Products LP *	11
Ortho-McNeil Pharmaceutical, Inc. *	12
Sankyo Pharma Inc.	13
Amgen, Inc.	14
Schering Plough Pharmaceutical Company	15
TAP Pharmaceutical Products Inc.	16
Novartis Pharmaceuticals Corporation	17
Reliant Pharmaceuticals	18
Boehringer Ingelheim Pharmaceuticals, Inc.	19
Sanofi-Synthelabo Inc.	20
Allergan, Inc.	21
Millennium Pharmaceuticals, Inc.	22
McNeil Consumer & Specialty Pharmaceuticals *	23
Takeda Pharmaceuticals North America, Inc.	24
Novo Nordisk Pharmaceuticals, Inc.	25
UCB Pharma, Inc.	26
MedImmune, Inc.	27
Abbott Laboratories	28
Janssen Pharmaceutica Products L.P. *	29
Bayer HealthCare Pharmaceuticals	30
Cephalon, Inc.	31
Hoffman-LaRoche Inc.	32
Organon USA Inc.	33
Fujisawa Healthcare, Inc.	34
Purdue Pharma L.P.	35
Berlex, Inc.	36
Centocor *	37
Baxter International Inc.	38
Elan Pharmaceuticals, Inc.	39

Company***Ranking***

Salix Pharmaceuticals, Inc.	40
Dey, L.P.	41
MGI PHARMA, Inc.	42
Daiichi Pharmaceutical Corp.	43
Bioglan Pharmaceuticals Company	44
Cell Tech Pharma	45
CollaGenex Pharmaceuticals, Inc.	45
Dentsply Pharmaceutical	45
Galderma Laboratories, L.P.	45
Gilead Sciences, Inc.	45
Proctor & Gamble Pharmaceuticals, Inc.	45
Sepracor Inc.	45

* Indicates a Johnson and Johnson pharmaceutical company

TOTAL \$2,466,363.37.

Number of Companies 51

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Table 1A

Ranking by Company
(Johnson and Johnson subsidiaries combined)

<i>Company</i>	<i>Ranking</i>
GlaxoSmithKline	1
Bristol-Myers Squibb Company	2
Merck and Company, Inc.	3
Forest Pharmaceuticals Inc.	4
AstraZeneca Pharmaceuticals LP	5
Eli Lilly and Company	6
Johnson & Johnson pharmaceutical company *	7
Aventis Pharmaceuticals Inc.	8
Pfizer Inc.	9
Serono Inc.	10
Wyeth Pharmaceuticals	11
Sankyo Pharma Inc.	12
Amgen, Inc.	13
Schering Plough Pharmaceutical Company	14
TAP Pharmaceutical Products Inc.	15
Novartis Pharmaceuticals Corporation	16
Reliant Pharmaceuticals	17
Boehringer Ingelheim Pharmaceuticals, Inc.	18
Sanofi-Synthelabo Inc.	19
Allergan, Inc.	20
Millennium Pharmaceuticals, Inc.	21
Takeda Pharmaceuticals North America, Inc.	22
Novo Nordisk Pharmaceuticals, Inc.	23
UCB Pharma, Inc.	24
MedImmune, Inc.	25
Abbott Laboratories	26
Bayer HealthCare Pharmaceuticals	27
Cephalon, Inc.	28
Hoffman-LaRoche Inc.	29
Organon USA Inc.	30
Fujisawa Healthcare, Inc.	31
Purdue Pharma L.P.	32
Berlex, Inc.	33
Baxter International Inc.	34
Elan Pharmaceuticals, Inc.	35
Salix Pharmaceuticals, Inc.	36
Dey, L.P.	37
MGI PHARMA, Inc.	38
Daiichi Pharmaceutical Corp.	39
Bioglan Pharmaceuticals Company	40
Cell Tech Pharma	41

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Company***Ranking***

CollaGenex Pharmaceuticals, Inc.	41
Dentsply Pharmaceutical	41
Galderma Laboratories, L.P.	41
Gilead Sciences, Inc.	41
Proctor & Gamble Pharmaceuticals, Inc.	41
Sepracor Inc.	41

* Includes Centocor, Inc., Janssen Pharmaceutica Products L.P., McNeil Consumer & Specialties Pharmaceuticals, Ortho Biotech Products LP, and Ortho-McNeil Pharmaceutical

TOTAL \$2,466,363.37.
Number of Companies 47

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Table 2

Recipients of Payments

Recipient Type	Amount	% of Total
Prescribers	\$1,218,576.80	49.41
Other healthcare providers	\$718,979.58	29.15
Hospitals, Clinics, Universities	\$500,334.19	20.29
Pharmacists	\$22,264.37	0.90
Unknown	\$6,208.43	0.25
Not Disclosed	\$0.00	0.00
Total Amount	\$2,466,363.37	

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Table 3

Nature of Payments

Nature	Amount	% of Total
Fees, cash, checks, honoraria, donations	\$1,406,869.09	57.04
Food	\$518,032.62	21.00
Discounts	\$357,242.00	14.48
Other	\$81,064.55	3.29
Grants	\$72,445.00	2.94
Books	\$22,071.34	0.89
Transportation	\$4,841.72	0.20
Lodging	\$3,797.05	0.15
Not Disclosed	\$0.00	0.00
Total Amount	\$2,466,363.37	

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Table 4

Purpose of Payments

Purpose	Amount	% of Total
Education	\$777,743.80	31.53
Unclear	\$475,017.36	19.26
Detailing	\$364,055.03	14.76
Discounts and Rebates	\$357,242.00	14.48
Speaker	\$292,422.85	11.86
Other	\$103,182.05	4.18
Consulting	\$92,906.28	3.77
Not Disclosed	\$3,794.00	0.15
Total Amount	\$2,466,363.37	

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