



# **Playing by Their Own Rules**

---

**An Analysis of Drug Company Gifts to Doctors**

**CALPIRG**  

---

**Standing Up  
To Powerful Interests**

**MARCH 2008**

# **Playing by Their Own Rules**

**An Analysis of Drug Company Gifts to Doctors**

Michael Russo, CALPIRG

March 2008 (Updated August 2008)

# Acknowledgments

The editorial oversight and suggestions made by U.S. PIRG Senior Policy Analyst Steve Blackledge are greatly appreciated. Design assistance from Nathan Proctor of Public Interest GRFX, and helpful suggestions and feedback from CALPIRG staff are also gratefully acknowledged. The *Rx Compliance Report* newsletter provided significant, helpful data.

The author alone bears responsibility for any factual errors. The recommendations are those of CALPIRG. The views expressed in this report are those of the author and do not necessarily reflect the views of our funders.

*Update note: an initial edition of this report was released by CALPIRG in March, 2008. This updated version adds further information about Cephalon's gift practices.*

For a copy of this white paper, please visit <http://www.calpirg.org>, or send a check for \$10 payable to CALPIRG to the following address:

CALPIRG  
1107 9<sup>th</sup> St, Suite 601  
Sacramento, CA 95814

*CALPIRG takes on powerful interests on behalf of Californians, working to win concrete results for our health and our well-being. With researchers, advocates, organizers and students, we stand up to powerful special interests to stop identity theft, fight political corruption, provide safe and affordable prescription drugs, strengthen voting rights and more.*

© 2008, CALPIRG

**Playing by Their Own Rules: An Analysis of Drug Company Gifts to  
Doctors**

**TABLE OF CONTENTS**

EXECUTIVE SUMMARY..... 1

INTRODUCTION..... 2

ANATOMY OF A COMPLIANCE PLAN..... 5

SURVEY RESULTS..... 6

DELVING DEEPER INTO COMPLIANCE PLANS..... 8

SOLUTIONS..... 12

APPENDIX..... 14

## Executive Summary

Drug companies spend billions annually marketing their latest, most expensive drugs to doctors. These marketing efforts do not rely solely on scientific research and medical benefits, however; they employ a barrage of gifts, expensive meals, and wine-and-dine events to gain access to doctors. The result is that doctors looking for objective data about the efficacy and safety of pharmaceuticals are ensnared by this system, and find it increasingly easy to look to the drug companies for information.

The result of these drug company marketing practices is an over-prescribing of the newest drugs, those behind which the drug makers are throwing their marketing muscle. This over-prescribing causes three problems for consumers. First, these drugs are the most expensive for consumers – who end up paying twice, as they ultimately pay for the gifts given to doctors as well. Second, because the newest drugs have been on the market for a shorter time than the older ones, they are among the least-tested, with potentially unknown side effects. Finally, drug company marketing to doctors damages the exclusivity of the doctor-patient relationship, as drug marketers shoulder their way into the consulting room.

Currently, drug companies are allowed to set their own standards for their marketing to doctors. They are required by California's Senate Bill 1765, however, to adopt a limit on the total value of the gifts they can give to a particular doctor in a given year, and post this information to their web sites.

This white paper examines the rules the drug companies have set for themselves, assesses whether they comply with the minimum requirements of SB 1765, and identifies aspects of the drug company rules that are deeply problematic. Among our findings:

- Drug companies fail to count some meals and other payments as “gifts,” and therefore not subject to the limit;
- Some companies reserve the right to exceed their limits if they so choose;
- Others assert that they are following a limit, but do not disclose what that limit actually is, while one even fails to post its policies at all.

It is clear that drug companies cannot be trusted to actually protect consumers through voluntary restrictions on their direct-to-doctor marketing. By playing by their own rules, the manufacturers have created limits that in many cases fail to constrain their actions at all. Fortunately, there are common-sense policies that will restrain direct-to-doctor marketing to an appropriate scope. These include:

- Putting in place hard, enforceable limits on per-doctor gifts;
- Publicly disclosing all gift and non-gift payments;
- Encouraging access to disinterested, third-party informational resources on drug safety and efficacy.

## Introduction

### Drug Company Marketing

There are few products as important to consumers' well-being as prescription drugs. Properly prescribed and used, these medicines can provide great help to patients. But drug makers have not been content to rely solely on scientific research and the medical benefits to sell their products. Instead, they employ a sophisticated apparatus aimed at marketing to the doctors who can prescribe their drugs, urging them to prescribe the newest, most expensive drugs. And because these drugs have been on the market for a shorter time than the older ones, they are among the least-tested drugs, with potentially unknown side effects.

These promotional efforts include brigades of marketing representatives called "detailers," who lavish gifts and free meals on the doctors they woo as well as sponsorship of expense-paid trips to continuing medical education programs that tout the benefits of company-produced drugs, and a web of speaker honoraria and consulting fees that reward doctors for extolling a drug's virtues to their fellow practitioners.

The result is that doctors looking for objective information about the efficacy and safety of pharmaceuticals are ensnared by this system, and find it increasingly easy to look only to the friendly drug representative who comes bearing free food and other gifts, rather than trying to find the time to confirm all their claims by examining the peer-reviewed literature. And detailing has an effect, as doctors who receive gifts or attend all-expenses-paid drug company events are more likely to prescribe that company's drugs.<sup>1</sup>

The scope of pharmaceutical marketing is often breathtaking. In 2004, drug companies employed over 100,000 detailers (the number of their targets – office-based physicians – was roughly 500,000).<sup>2</sup> They spent some 7 billion dollars on direct-to-doctor marketing.<sup>3</sup> And that year the average primary care doctor had 28 interactions with a drug company detailer every week.<sup>4</sup> Drug company marketing is not a once-every-few-months phenomenon; it is a concerted, systematic, ubiquitous, and expensive campaign directed squarely at the doctor's office.

Nor is the marketing spread evenly across all doctors. The companies are able to purchase detailed prescribing histories of individual doctors, and engage in enormously sophisticated data-mining to target those doctors who because of the nature of their practice and prescribing habits are in the best position

---

<sup>1</sup> See CALPIRG Education Fund, 'TIS ALWAYS THE SEASON FOR GIVING, Sept. 2004, available at <http://www.calpirg.org/uploads/Le/LW/LeLWJ1Gv4Nwd9MVJapxdkQ/TistheSeasonForGiving04.pdf>.

<sup>2</sup> The Prescription Project, THE CONSTITUTIONAL BATTLE OVER STATE REGULATION OF DATA MINING (Aug. 2007), available at [http://www.prescriptionproject.org/tools/solutions\\_resources/files/0005.pdf](http://www.prescriptionproject.org/tools/solutions_resources/files/0005.pdf).

<sup>3</sup> Kaiser Family Foundation, PRESCRIPTION DRUG TRENDS, May, 2007, available at Overall marketing spending reached \$27 billion in 2004 – just a hair shy of the \$30 billion spent to research and develop new drugs. See Marc-Andre Gagnon, Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, PLOS MEDICINE, Jan. 2008.

<sup>4</sup> The Prescription Project, THE CONSTITUTIONAL BATTLE OVER STATE REGULATION OF DATA MINING.

to increase sales of the newest, least-tested, most expensive drugs. Thus the above aggregate numbers do not tell the full story – those doctors predicted to be potentially lucrative by the data models employed by the drug manufacturers are specifically targeted for increased visits and gift spending.<sup>5</sup>

In short, currently doctors' decisions about what drug to prescribe for a patient's symptoms are not based simply on state-of-the-art medical knowledge – rather, a barrage of gifts, payments, and questionable information tilts the playing field towards the newest drugs behind which the big companies are throwing their marketing muscle.

Consumers pay for these practices in three ways. First, the \$27 billion the drug industry annually spends on marketing is ultimately passed on to consumers in the form of increased drug prices.<sup>6</sup>

Second, the new drugs doctors are urged to prescribe are universally more expensive than older, established treatments, but may be no more effective – as was the case with the new cholesterol medication Vycorin, which a study has suggested may be even less effective than a generic alternative<sup>7</sup> – and in fact may be more dangerous, since there has been less time to monitor the newer drugs for deleterious side effects.<sup>8</sup>

Finally, the appearance of quid-pro-quo exchanges of gifts for the writing of prescriptions undermines the doctor-patient relationship, as patients may second-guess and distrust the decisions their doctors make when there are potentially thousands of dollars at stake.

For these reasons, drug company detailing would be objectionable even if the information drug reps provide were scrupulously accurate. But CALPIRG research has shown that drug marketing efforts are often false or misleading. In our survey of FDA enforcement letters from 2001 to 2005, for example, we found that pharmaceutical sales reps misstated the results of clinical studies, misrepresented the risks of their products, and urged doctors to prescribe medicine for non-FDA-approved uses.<sup>9</sup> We found as well that misleading and false information was provided to doctors not just in the context of one-on-one detailing visits, but also at the panels and conferences drug companies often sponsor.<sup>10</sup> The infamous case of Vioxx provides perhaps the most egregious example, as a memo entitled “Dodge Ball” instructed drug reps to affirmatively avoid answering doctors' questions about the safety of the drug.<sup>11</sup>

In short, drug company marketing to doctors inflates drug prices, leads to prescribing decisions that do not serve the best interests of the patient, undermines the doctor-patient relationship, and may actively

---

<sup>5</sup> Daniel Carlat, *Dr. Drug Rep*, NEW YORK TIMES MAGAZINE, Nov. 25, 2007.

<sup>6</sup> See DATA MINING, at 4.

<sup>7</sup> Rob Stein, *Drug Doesn't Slow Artery Clogs*, WASH. POST, Jan. 15, 2008, at A3.

<sup>8</sup> See 'TIS ALWAYS THE SEASON FOR GIVING.

<sup>9</sup> See CALPIRG Education Fund, TURNING MEDICINE INTO SNAKE OIL (May 2006), available at <http://www.uspirg.org/home/reports/report-archives/health-care/health-care/turning-medicine-into-snake-oil-how-pharmaceutical-marketers-put-patients-at-risk>.

<sup>10</sup> *Id.*

<sup>11</sup> *Tens of Thousands of Cases Seen in Vioxx Litigation*, ASSOCIATED PRESS, May 23, 2004.



spread misinformation. These are strong reasons to believe that allowing drug companies untrammelled discretion to set their marketing policies will ultimately hurt consumers.

### **A Case Study in Direct-to-Doctor Marketing: “Dr. Drug Rep”**

These reasons go beyond the realm of mere theory. Last year, psychiatrist Dr. Daniel Carlat spoke out on his experiences as a paid representative of the drug company Wyeth Pharmaceuticals.<sup>12</sup> He was paid between \$500 and \$750 dollars to give marketing presentations to his fellow doctors about Wyeth’s depression drug Effexor. After a dazzling “training weekend” in a New York hotel, which included complimentary Broadway tickets and a paid honorarium, he began his career as a marketer for the drug.<sup>13</sup>

Dr. Carlat would give his presentations over gourmet lunches provided gratis to the targeted doctor and his or her staff, emphasizing the advantages of Effexor and soft-pedaling the side effects (which increased the risk of high blood pressure). Full-time drug reps would aid him in his pitch, including passing along information about the number – and brand – of prescriptions the targeted doctor was writing. His medical presentation, combined with the gifts and personal rapport provided by the drug rep, convinced physicians to alter their prescribing habits.

This idyll began to come to an end, however, as Dr. Carlat became familiar with the results of newer studies and clinical trials. This new information suggested that Effexor’s advantages over competing drugs were slimmer than first advertised – and that the blood-pressure dangers it posed were higher. Additionally, “withdrawal” symptoms were beginning to come to light, as patients prescribed this exciting new drug had a hard time weaning themselves away from it.

Initially, Dr. Carlat continued to downplay the disadvantages of Effexor, but eventually decided to cease moonlighting as a paid marketer of a drug he could no longer wholly endorse in good conscience. After having made \$30,000 in a year doing marketing for the drug companies, Dr. Carlat found himself wiser to their tactics. Yet even then, he recognized that he was still occasionally tempted to attend fancy dinner seminars and speaker events, for the great food, free wine, and frisson of rubbing elbows with high-profile researchers.

Dr. Carlat’s story demonstrates just how seductive drug company marketing can be. Gifts and payments smooth the way of information that provides less than the full story, leading doctors to make prescribing decisions that are not motivated solely by the best interests of the patient. And the more expensive the gifts, the greater that temptation will be.

### **Assessing the Problem: California’s Senate Bill 1765**

However powerful individual stories may be, more comprehensive information is necessary to fully understand what the industry as a whole is up to. In 2004, the California Public Interest Research Group

---

<sup>12</sup> All information in this section from Carlat, *Dr. Drug Rep*.

<sup>13</sup> Tickets to Broadway musicals are no longer allowed under the PhRMA guidelines.



(CALPIRG) sponsored and helped enact California's SB 1765 (Sher).<sup>14</sup> The bill made binding in California marketing guidelines promulgated by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), an industry group, and a similar guidance prepared by the U.S. Health and Human Services Department Office of the Inspector General ("OIG"). It also required drug companies to self-regulate by voluntarily setting an upper limit on the dollar value of gifts they could give to a doctor in a given year.

In order to prove their compliance with the legal requirements of SB 1765, drug manufacturers are required to produce a plan for how to implement the PhRMA and OIG guidelines, choose and abide by an annual per-doctor gift limit, and post this information on their web sites, alongside a declaration that the company is in compliance with their plan. These requirements took effect on July 1, 2005. Nearly three years later, because of SB 1765, we now have a better sense of the scope of the problem of drug company marketing to doctors – and how it is getting worse.

This white paper examines the rules the drug companies have set for themselves, assesses whether they comply with the minimum requirements of SB 1765, and identifies aspects of the drug company rules that are deeply problematic. It then proposes common-sense policy solutions to ensure that when a doctor prescribes a drug for a patient, the decision is made based on science, not marketing.

## Anatomy of a Compliance Plan

Companies' plans for complying with SB 1765's requirements vary in many important respects – in length, in level of detail, in definitions employed, and in the dollar value of the limit set on drug company gifts to doctors. They boast several uniform features, however.

First, they identify the compliance office or officer that bears primary responsibility for implementing the policy. A company may further discuss the details of how its compliance division is structured, how it interfaces with the rest of the corporate structure, and set out particular areas of specialization. Its procedures for reporting and resolving complaints or alleged violations of the compliance plan are also discussed, alongside the company's self-auditing policies.

The compliance plan also will discuss the various written policies and standards of the company, possibly including business codes of conduct, ethical standards, and specific policies governing marketing activities. These may consist solely of references to other, separate documents, or they may be incorporated into the compliance plan itself. There is a wide variety in how various companies address this portion of their plan, with some merely stating that written policies exist, and others providing specific additional limits on particular kinds of activities, such as prohibiting sales representatives from providing entertainment as an element of their promotional efforts.

Because a compliance program is hardly self-executing, it also must include information on how the company educates its employees about the plan's requirements, as well as training them in how to implement it.

---

<sup>14</sup> Currently codified as part of the California Health and Safety Code, §§119400-402.

The most constraining portion of the compliance plan – and a key focus of this report – is the requirement, per SB 1765, that the company set an upper boundary on the combined value of all the gifts it provides to a given medical professional in a single year. The compliance plan includes not only the dollar value of the limit itself, but often also defines what gifts and expenditures it considers to count against the limit, and which remain unregulated. As discussed below, there is wide variation in the definitions adopted by various companies – some merely track the language of SB 1765, but others expand upon the statute’s exemptions by asserting that the company simply does not deem certain additional items or spending to fall under the limit’s aegis.

Finally, a compliance plan must be accompanied by a declaration that the company is in fact in compliance with its terms and those of SB 1765.<sup>15</sup>

## Survey Results

CALPIRG took advantage of the disclosures mandated by SB 1765 to audit the major drug companies’ current marketing practices, as well as their compliance with the law. The following sections present the bottom-line monetary limits set by the drug companies, and then turn to the specific details of their compliance plans, highlighting areas where these self-set rules fail to protect the public. While it is tempting to look simply to the numbers to determine how much marketing a given company is doing, there is wide variation between what items and expenditures a given company includes or excludes from this total. Because drug companies freely use whatever definitions they prefer, straight apples-to-apples comparisons are impossible – the later sections of this chapter examine some of these issues in more detail.

With that caveat in mind, the following table sets out drug companies’ self-chosen limits on the total value of all gifts they may provide to a given doctor in a single year (see the appendix for notes on how this data was collected, and where the limits may be found):

Company Name	July 2005 Limit (Dollars)	Current Limit (Dollars)
Pfizer	\$960	\$3,500
Glaxo Smith Kline	\$2,500	\$2,500
Sanofi-Aventis	\$2,000	\$2,000
Johnson and Johnson	?	\$1,500
Merck	\$900	\$2,000
Novartis	\$2,500	\$3,000

---

<sup>15</sup> See California Health and Safety Code, § 119402(e).

AstraZeneca	\$1,900	\$1,900
Hoffmann-La Roche	?	\$1,850
Bristol-Myers Squibb	?	\$2,500
Wyeth	?	?
Abbott Labs	?	?
Eli Lilly	\$3,000	\$3,000
Amgen	\$2,150	\$2,150
Takeda	?	\$3,000
Boehringer-Ingelheim	\$2,500	\$2,500
Schering Plough	\$1,000	\$1,000
Bayer	?	\$1,000
Eisai	\$2,000	\$2,000
Teva	?	?
Astellas	?	?
Otsuka	?	\$1,400
Novo Nordisk	\$2,000	\$2,000
Baxter International	\$2,500	\$2,500
Allergan	?	\$1,500
Amylin	\$3,500	\$3,000
Biogen Idec	\$1,000	\$1,500
Cephalon	\$4,000	\$2,500 <sup>16</sup>

<sup>16</sup> An earlier version of this report stated that Cephalon's compliance plan was not available on their website, as targeted Google searches of the cephalon.com domain and examination of the site map revealed only a page labeled "State Compliance" that failed to address California law. According to later communications from Cephalon, the State Compliance page was outdated, and their compliance plan is available at a separate internet domain. The current compliance plan is available at [http://media.corporate-ir.net/media\\_files/IROL/81/81709/CorpGov/ComplianceProgram\\_califlawposting2008FINAL.pdf](http://media.corporate-ir.net/media_files/IROL/81/81709/CorpGov/ComplianceProgram_califlawposting2008FINAL.pdf).

Forest	\$7,440	\$3,000
Genzyme	\$500	\$1,500
InterMune	\$1,500	\$1,500

A number of trends emerge from the above data. First, the range separating the highest from the lowest limits has shrunk over time. When SB 1765 first went into effect, the lowest limit was set by Genzyme, at \$500 annually; the highest was Forest, at \$7,440. Both of these extremes have converged, so that currently the lowest limit is that set by Bayer, at \$1,000,<sup>17</sup> and the highest Pfizer's limit of \$3,500. Of the 27 drug companies whose current limits are available, 14 are in the range of \$2,000 to \$3,000. SB 1765 has thus seemed to have fostered a convergence – companies that initially set very high limits have reduced them to better fit in with their peers, while those who saw that their marketing expenditures were lower than average correspondingly decided to raise their limits to keep pace with the crowd.

Further, while most companies have kept their limits at the same level from 2005 to the present, seven have varied them. Two – Forest and Amylin – reduced their limits, respectively from \$7,440 to \$3,000 and from \$3,500 to \$3,000. It is worth noting that these were two of the three highest limits in 2005. However, the other five increased their limits, some quite precipitously. The first year that the law went into effect, for example, Pfizer set its limit at \$960 per doctor per year.<sup>18</sup> In 2006, they increased the limit to \$2,500; it currently stands at \$3,500.<sup>19</sup>

These increases greatly outpace inflation, of course, reflecting the fact that the drug companies are increasingly relying on promotional spending to maintain their profits in the wake of drug safety scandals and with fewer new “blockbuster” drugs coming down the pipeline. The predictable results – ever-greater marketing-related intrusions into a doctor's decision of which drug to prescribe – will lighten consumers' wallets and even harm their health.

## Delving Deeper Into Compliance Plans

### Exclusions and Additional Requirements

Almost all of the companies listed above set a dollar limit on their marketing expenses (see immediately below for discussion of those that do not). SB 1765 sets out some expenditures as not being subject to the limit: in general “drug samples given to physicians and healthcare professionals intended for free

<sup>17</sup> Schering Plough also reports a limit of \$1,000; however, as discussed below, it reserves the right to exceed the \$1,000 per doctor cap at its leisure.

<sup>18</sup> See *Rx Compliance Report*, Vol. IV, Issue 12 (July 21, 2005).

<sup>19</sup> See Pfizer Corporate Compliance Program, at

[http://www.pfizer.com/responsibility/values\\_commitments/pfizer\\_corporate\\_compliance\\_program.jsp/](http://www.pfizer.com/responsibility/values_commitments/pfizer_corporate_compliance_program.jsp/)

distribution to patients, financial support for continuing medical education forums,... financial support for health educational scholarships [and] payments made for legitimate professional services provided by a health care or medical professional” are exempt.<sup>20</sup>

Beyond these standard exemptions, however, different companies have set different standards for what qualifies as a marketing expense subject to the limit. Johnson and Johnson, for example, states that its limit applies to “meals and educational or practice-related items.”<sup>21</sup> While this surely encompasses many marketing expenditures, only a few lines above the policy explicitly contemplates reimbursing a “very limited” number of attendees at promotional functions for their travel and lodging – payments that would not be included in the marketing limit.<sup>22</sup>

This is hardly the only definition or exclusion, however. Pfizer, as do many other companies, does not count some items of “minimal value” – defined as costing \$25 or less – against its aggregate limit.<sup>23</sup> This exclusion is gone one further by Schering-Plough, which excludes even meals costing \$25 or less from its limit.<sup>24</sup>

Glaxo Smith Kline, by contrast, counts all items with a value of over \$10 against its limit.<sup>25</sup> It is less stringent in excluding the value of meals provided gratis at speaker trainings or at advisory board meetings.<sup>26</sup> Potentially the largest exclusion is the company’s statement that it does not consider gifts made to medical students “who currently lack a GSK customer identity number” to be subject to the limit – SB 1765 explicitly includes all medical students in its definition of “medical or health professional,” it should be noted.<sup>27</sup>

Finally, some policies provide more information than the minimum required by the law. Johnson and Johnson, for example, sets guidelines for the appropriate cost of meals provided as gifts. Its policy says that its representatives may “occasionally offer a modest meal as part of an educational presentation or a business discussion.” While “modesty is to be judged by local standards,” the policy offers a rule of

---

<sup>20</sup> California Health and Safety Code §119402(d).

<sup>21</sup> Johnson and Johnson Declaration for California Compliance Law, at <http://www.jnjgateway.com/home.jhtml?loc=USENG&page=viewContent&contentId=09008b9880f104ef&parentId=09008b9880f10381> (July 1, 2007).

<sup>22</sup> Johnson and Johnson Declaration for California Compliance Law, at <http://www.jnjgateway.com/home.jhtml?loc=USENG&page=viewContent&contentId=09008b9880f104ef&parentId=09008b9880f10381> (July 1, 2007).

<sup>23</sup> See Pfizer Corporate Compliance Program, at [http://www.pfizer.com/responsibility/values\\_commitments/pfizer\\_corporate\\_compliance\\_program.jsp/](http://www.pfizer.com/responsibility/values_commitments/pfizer_corporate_compliance_program.jsp/).

<sup>24</sup> Schering-Plough Corporation Compliance Program, at <http://www.schering-plough.com/pdf/CaliforniaDisclosure1.pdf>.

<sup>25</sup> See Glaxo Smith Kline Compliance Program – U.S. Operations, at <http://www.gsk.com/about/corp-gov/ca-comp-usops.pdf>.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*; California Health and Safety Code § 119400(b).

thumb for individual meals: the cost “should not exceed \$25 for breakfast, \$50 for lunch, or \$125 for dinner.”<sup>28</sup>

A definition that accounts a \$125 dinner as “modest” certainly appears oxymoronic, but these more specific numbers give a glimpse of how drug marketing is actually conducted – while drug companies may claim that they need to provide meals in order to fit their visits into doctors’ busy schedules, if this were the primary motivating factor they could easily provide lunches for far less than \$50.

### **Low Averages**

Many company compliance policies note that their spending limits represent maximums that are infrequently reached in practice, emphasizing that their average per-physician expenditure is significantly lower. For example, Novartis’ compliance program points out that “[t]he average medical or health professional in California receives less than \$100 worth of promotional materials, healthcare practice items, and activities from NPC on an annual basis.”<sup>29</sup>

This is certainly good news, not the least for Novartis – there are over 100,000 non-federally-employed physicians alone in California, meaning that if Novartis reached its limit of \$3,000 with all of them, it conservatively would be spending a third of a billion dollars on direct-to-doctor marketing in California alone.<sup>30</sup> But this and similar protestations that average marketing expenditures are low should give consumers little comfort.

First, “medical or health professionals,” as defined in the California Health and Safety Code, includes some, such as medical students, who do not have the ability to issue prescriptions. Second, many doctors will not work in areas of practice in which a given drug company offers a product – a company specializing in cholesterol medications will do little marketing to an oncologist, for example. Even if a company sells a diverse portfolio of drugs, in any given year its marketing will be focused on their newest drugs, especially those for which no generic alternative is available. Since the number of new drugs approved by the FDA for sale each year is relatively low – a total of only 38 in 2007<sup>31</sup> – the set of doctors who will be high-priority targets in a given year is much smaller than the overall number of health care professionals in the state. Indeed, as discussed above, drug companies are very discriminating in their targeting, concentrating their marketing efforts on those doctors who can provide the most “bang for the buck.” The fact that any given company is concentrating its money to where it can cause the greatest alteration in doctors’ prescribing habits is cause for concern, not complacency.

---

<sup>28</sup> Johnson and Johnson Declaration for California Compliance Law, at <http://www.jnjgateway.com/home.jhtml?loc=USENG&page=viewContent&contentId=09008b9880f104ef&parentId=09008b9880f10381> (July 1, 2007).

<sup>29</sup> See NPC Comprehensive Compliance Program – State of California, at <http://www.pharma.us.novartis.com/about-us/business-conduct/state-laws/california-state.jsp>.

<sup>30</sup> See Kaiser Family Foundation, State Health Facts – Total Nonfederal Physicians – California, at <http://www.statehealthfacts.org/profileind.jsp?ind=429&cat=8&rgn=6>.

<sup>31</sup> *FDA is Rejecting More Drugs Than in the Past*, ASSOCIATED PRESS, Aug. 17, 2007, available at <http://www.msnbc.msn.com/id/20321830/>.

## Missing Limits

The table above has a few holes. For the most part, these represent companies whose 2005 limits were impossible to determine. But several other drug companies have blank entries under their current limits. This is because their self-set spending limit is not available on their websites, as SB 1765 requires.

Abbott Labs, Astellas, and Wyeth make their compliance policies available online. But while all assert that they have set and abide by a limit on the aggregate value of their gifts to doctors, they neglect to state the value of that limit. SB 1765 specifically requires drug companies to “establish explicitly in [their] Comprehensive Compliance Program a specific annual dollar limit on gifts.”<sup>32</sup> The reason for this requirement is easy to grasp: without knowing the value of the limit, it is impossible to know whether a company’s marketing efforts are appropriate, and a company’s compliance with its limit likewise cannot be audited if the limit is not disclosed. A secret limit provides no assurance of protection.

Teva Pharmaceuticals falls into a different category – its compliance policy makes no mention of setting or complying with a limit on gifts to health care professionals. This appears to constitute a failure to comply with the requirements of SB 1765, as the omission of this information prevents the public from knowing that Teva abides by any limit at all. Again, this makes it impossible to determine whether the company is failing to comply only with SB 1765’s disclosure and declaration requirements, or with its substantive regulation of marketing as well.

## Illusory Limits

The terms of SB 1765 are clear: a drug company must set “a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide” to a given health care professional.<sup>33</sup> There is no indication that “limit” has any meaning other than its ordinary one – the limit is a hard cap that the drug company is free to set but, once set, may not exceed.

But two companies explicitly reserve to themselves the right to violate their limits. After setting its limit, Schering-Plough offers the caveat that “[i]n rare circumstances, an exception may be made to this limit.”<sup>34</sup> Astellas goes into more detail, saying that “[o]n rare occasions, management may authorize additional spending based on circumstances such as the revision or expansion of product labeling, the launch of a new product, or the availability of new scientific information.”<sup>35</sup>

The list of circumstances which must be satisfied is scant protection – surely a drug company would not spend larger-than-usual sums on marketing unless there was a reason for it. And while Schering-Plough

---

<sup>32</sup> California Health and Safety Code, §119402(d)(1).

<sup>33</sup> California Health and Safety Code, §119402(d)(1).

<sup>34</sup> Schering-Plough Corporation Compliance Program, at <http://www.schering-plough.com/pdf/CaliforniaDisclosure1.pdf>.

<sup>35</sup> Astellas U.S. Declaration and Comprehensive Compliance Program, at [http://www.astellas.us/docs/cal\\_ccp\\_description.pdf](http://www.astellas.us/docs/cal_ccp_description.pdf).



at least has a comparatively low “limit” of \$1,000 per doctor, Astellas, as mentioned above, adds injury to insult by failing even to disclose the size of its self-set illusory limit.

A limit that may be exceeded at will is no true limit – and it is difficult to see how companies that refuse to abide by these false limits can credibly claim to be in compliance with SB 1765’s requirements.

### **Non-Gift Payments**

Beyond the direct gifts discussed above, there is another full category of payments regularly excluded from the compliance plan limits and declarations: non-gift payments to doctors for services rendered. These may take many forms, from honoraria for doctors who give presentations to their peers on the virtues of particular drugs, to consulting fees paid to those who review the results of clinical trials for the drug companies. As with gift-based marketing efforts, these payments tend to be highly targeted, as drug marketers aim to recruit doctors as spokespersons and allies in their promotional efforts.<sup>36</sup>

If anything, these kinds of systematic, repeated, professional connections between drug companies and doctors do more to undermine the fact and appearance of doctor impartiality than do more isolated gifts. A doctor who derives significant monetary income from praising and auditing a drug company’s products will necessarily face a conflict of interest when deciding which drug to prescribe. And there is little more damaging to the trust in medical impartiality necessary to the doctor-patient relationship than the impression that a doctor is a paid shill of the drug industry.

The fact that these fee-for-service payments are currently subject to no limits and no disclosure requirements means that consumers lack confidence that their doctors have no financial interest in the companies producing the drugs they prescribe. Further, these payments allow larger, richer companies to stifle competitors by bidding highest for the promotional services of doctors with the best reputations.

## **Solutions**

Examination of how major drug companies have complied – or failed to comply – with SB 1765’s requirements has shown that the companies cannot be trusted to voluntarily adopt restrictions on their direct-to-doctor marketing that will actually protect consumers. By playing by their own rules, the manufacturers have created limits that in many cases fail to constrain their actions at all. While this may be freeing for the drug companies involved, consumers are left to pay the price, as they are prescribed drugs that are more expensive and less safe than the ones they should be getting. Fortunately, there are simple, common-sense policy solutions that will help protect the public.

### **Put in place hard, enforceable limits on per-doctor gifts**

The current per-doctor limits are weak in two respects: they are self-chosen, and there is no clear mechanism to audit and enforce compliance. A firm, uniform limit should be set, to prohibit lavish

---

<sup>36</sup> See Carnat, *Dr. Drug Rep.*

spending that has no legitimate informative purpose. A cap will mean that drug companies will have to compete on the benefits of their products, rather than the cash they spend marketing them, and limiting the amount of money that may be spent on direct-to-doctor marketing will help contain the rising costs of prescription drugs.

### **Disclose all gift and non-gift payments**

As discussed above, flat-out gifts are only half the problem – the for-service payments, such as speaker honoraria and consulting fees, that drug companies give also distort doctors' decisions. While we recommend a cap be made on all gifts, a limit on non-gift payments may be premature. But the nature and size of these payments, as well as all gifts, should be publicly available and posted online. Disclosure of the recipients of drug company largesse will help identify potential conflicts of interest, as well as allowing members of the medical community to better audit their level of involvement with the drug industry. The reporting requirement will also help ensure that the gift limit is complied with. Finally, public disclosure of the payment information will help patients make their decision when picking a doctor.

### **Encourage access to impartial, third-party informational resources on drug safety and efficacy**

Today, drug company detailing often proves the most convenient way for doctors to learn about the safety and efficacy of prescription drugs. Unfortunately, as discussed above, this information may be inaccurate or misleading, and comes packaged with gifts and other inducements that attempt to sway doctors on non-scientific grounds. Even looking up the latest studies in medical journals may not invariably provide a sufficiently neutral source of information, as drug companies often sponsor or themselves conduct – and in fact may manipulate the results of<sup>37</sup> – journal-published studies. Medical professionals – including academics and privately- and publicly-employed physicians – should work to create and distribute alternatives to drug-company generated information on prescription drugs. If doctors have easy access to genuinely neutral, impartial data and information, the less effective drug company marketing will be if it attempts to convince them to prescribe something other than the scientifically superior medicine.

### **Prohibit the sale of doctors' prescribing habits and subsequent data-mining**

An especially pernicious aspect of drug company direct-to-doctor marketing is the reliance on commercially-purchased databases containing a doctor's entire prescribing history – how frequently they prescribe any given drug. The commercial availability of these private records of a doctor's choices of what prescription is in the best interest of their patients is simply inappropriate. Further, the bad effects of drug marketing are amplified by the ability of the drug companies to target their efforts at those doctors who are likely to write the most prescriptions, and therefore can be swayed to prescribe the newest drugs. The most expensive gifts and most generous payments are directed towards doctors

---

<sup>37</sup> See Third Amended Purchase Claims Master Celebrex Complaint, In Re: Celebrex Marketing Sales Practices and Product Liability Litigation (M:05-cv-01699-CRB), filed July 24, 2007, *available at* <http://prescriptionaccess.org/docs/celebrex-3rd-AMCC.pdf>.

who will be most profitable for the companies. Because data mining makes direct-to-doctor marketing most cost-effective, it induces drug companies to spend even more money on these efforts. Banning the sale of prescription databases would therefore reduce such spending by making direct-to-doctor marketing less effective, and would also strengthen the privacy rights of patients – and their doctors.

**The California Attorney General should investigate those companies that do not appear to be complying with SB 1765**

Finally, SB 1765 is the law of the land. While the choice of what limit to abide by is entirely voluntary, whether to choose – and publish – one is not. Companies that fail to post their compliance plans or the value of their self-chosen limit on gifts to doctors are not abiding by the law’s requirements. The California Attorney General should initiate an investigation to determine why these companies are by all appearances violating the law, and take the necessary steps to bring them into compliance.

\* \* \* \* \*

These policies, taken together will move us towards a world where drug company interactions with doctors are more professional, with junket-style trips and the constant barrage of gifts and meals off the table. Limiting these gifts will also limit the overall dollars spent on marketing, which have been one source of the upward pressure on prescription drug prices. Finally, and most importantly, taking these extravagant marketing efforts out of the doctor’s office means that when it’s time to prescribe a drug, the doctor will be more likely to choose the safest, most reliable, and cost-effective treatment available, rather than the untested, new one just pitched by a drug company detailer.

## APPENDIX

### Methodology

SB 1765 requires all drug companies who engage in marketing efforts in California to post their compliance plans on their web sites. Information for this report was gathered by searching these company web sites for their compliance policies, either via built-in search tools or Google. In some cases this information was only available on the sites of U.S. subsidiaries of international corporations. Often the relevant policies were found in documents clearly marked as “California Compliance Policy” or something similar, but occasionally they were included in general business codes of conduct, or were otherwise difficult to find. Data on limits set in 2005 was obtained either from the July 21, 2005 issue of the *Rx Compliance Report* newsletter (Vol. IV, issue 12) or by looking up 2005 versions of the relevant pages via the Internet Archive, a web site that stores periodic snapshots of sites around the web.<sup>38</sup>

### Sources for Gift Limit Data

RC = *Rx Compliance Report*, Vol. IV, Issue 12 (July 21, 2005).

---

<sup>38</sup> See Internet Archive: Wayback Machine, at <http://www.archive.org/web/web.php>.

IA = Internet Archive version of company website.

Pfizer – 2005: RC. Current: Pfizer Corporate Compliance Program, at [http://www.pfizer.com/responsibility/values\\_commitments/pfizer\\_corporate\\_compliance\\_program.jsp](http://www.pfizer.com/responsibility/values_commitments/pfizer_corporate_compliance_program.jsp).

Glaxo Smith Kline– 2005: RC. Current: Glaxo Smith Kline Compliance Program: U.S. Operations, at <http://www.gsk.com/about/corp-gov/ca-comp-usops.pdf>.

Sanofi-Aventis– 2005: IA. Current: Sanofi-Aventis California Compliance Law, at <http://www.sanofi-aventis.us/live/us/en/layout.jsp?scat=3B30E44E-4CF3-440D-8DB6-4821D9B10CA2>.

Johnson and Johnson – 2005: Unavailable. Current: Johnson and Johnson Declaration for California Compliance Law, at <http://www.jnigateway.com/home.ihtml?loc=USENG&page=viewContent&contentId=09008b9880f104ef&parentId=09008b9880f10381>.

Merck– 2005: RC. Current: Merck: Comprehensive Compliance Program, at <http://www.merck.com/about/compliance/ccp.html>.

Novartis – 2005: RC. Current: Novartis Pharmaceuticals Corporation Comprehensive Compliance Program – State of California, at <http://www.pharma.us.novartis.com/about-us/business-conduct/state-laws/california-state.jsp>.

AstraZeneca– 2005: RC. Current: AstraZeneca U.S. Compliance Program, at <http://www.astrazeneca-us.com/search/?itemId=1372313> (follow link to “California Compliance Program Law”).

Hoffmann-LaRoche – 2005: Unavailable. Current: Description of Roche’s Comprehensive Compliance Program and Declaration, at <http://www.rocheusa.com/ROCHELEGAL-155825-v1.pdf>.

Bristol-Myers Squibb – 2005: Unavailable. Current: 2007 Annual Description of Comprehensive Compliance Program, at [http://www.bms.com/aboutbms/corporate\\_compliance/content/data/desc\\_comp.pdf](http://www.bms.com/aboutbms/corporate_compliance/content/data/desc_comp.pdf).

Wyeth – 2005: Unavailable. Current: U.S. Pharmaceutical Product Promotion and Marketing, at [http://www.wyeth.com/marketing\\_practices](http://www.wyeth.com/marketing_practices) (note that gift limit is not stated).

Abbott Labs – 2005: Unavailable. Current: Abbott Comprehensive Ethics and Compliance Program Declaration – State of California, at [http://www.abbott.com/pv\\_obj\\_cache/pv\\_obj\\_id\\_F8AD6E4ADEB0DB92D9A60749C1978E12D0810000/filename/ca\\_compliance\\_prog.pdf](http://www.abbott.com/pv_obj_cache/pv_obj_id_F8AD6E4ADEB0DB92D9A60749C1978E12D0810000/filename/ca_compliance_prog.pdf) (note that gift limit is not stated).

Eli Lilly – 2005: IA. Current: Summary of Comprehensive Compliance Program, at [http://www.lilly.com/investor/compliance/annual\\_limit.html](http://www.lilly.com/investor/compliance/annual_limit.html).

Amgen – 2005: IA. Current: Amgen – Corporate Compliance, at [http://wwwext.amgen.com/about/corporate\\_compliance\\_limits.html](http://wwwext.amgen.com/about/corporate_compliance_limits.html).

Takeda – 2005: Unavailable. Current: Corporate Ethics & Compliance Program Charter, at <http://www.tpna.com/compliance.asp>.

Boehringer-Ingelheim – 2005: IA. Current: Corporate Compliance – California State Requirements, at [http://us.boehringer-ingelheim.com/about-us/compliance/docs/ca\\_compliance.html](http://us.boehringer-ingelheim.com/about-us/compliance/docs/ca_compliance.html).

Schering Plough– 2005: RC. Current: Schering-Plough Corporation Compliance Program, at <http://www.schering-plough.com/pdf/CaliforniaDisclosure1.pdf>.

Bayer – 2005: Unavailable. Current: Compliance Program Policies, at <http://www.governance.bayerweb.com/governance/080116-Policy%20Text%20for%20CA%20Website.pdf>.

Eisai– 2005: RC. Current: Declaration of Compliance Pursuant to Chapter 8, Section 119400 et seq. of Part 15 of Division 104 of the California Health and Safety Code, at [http://www.eisai.com/pdf\\_files/California%20Certification%20of%20Compliance.pdf](http://www.eisai.com/pdf_files/California%20Certification%20of%20Compliance.pdf).

Teva – 2005: Unavailable. Current: Corporate Compliance Program, at <http://www.tevausea.com/default.aspx?pageid=39> (note that program does not mention a limit on gifts to doctors).

Astellas – 2005: Unavailable. Current: Astellas U.S., Declaration and Comprehensive Compliance Program, at [http://www.astellas.us/docs/cal\\_ccp\\_description.pdf](http://www.astellas.us/docs/cal_ccp_description.pdf).

Otsuka – 2005: Unavailable. Current: Otsuka America Pharmaceutical, Inc., Comprehensive Compliance Program, at [http://www.otsuka.com/documents/Compliance%20Program%20for%20California%20Law%20\(6%2023%2005\)-FINAL-Rev%207-01-07%20\(2\).pdf](http://www.otsuka.com/documents/Compliance%20Program%20for%20California%20Law%20(6%2023%2005)-FINAL-Rev%207-01-07%20(2).pdf).

Novo Nordisk – 2005: IA. Current: Corporate Compliance Program, at [http://www.novonordisk-us.com/documents/article\\_page/document/Corporate\\_Compliance\\_Program.asp](http://www.novonordisk-us.com/documents/article_page/document/Corporate_Compliance_Program.asp).

Baxter International – 2005: IA. Current: Ethics and Compliance – Baxter’s Procedures and Standards of Conduct, at [http://www.baxter.com/about\\_baxter/doing\\_business\\_with\\_baxter/global\\_business\\_practice\\_standards/ethics\\_and\\_compliance.html](http://www.baxter.com/about_baxter/doing_business_with_baxter/global_business_practice_standards/ethics_and_compliance.html).

Allergan – 2005: Unavailable. Current: Comprehensive Compliance Program, at <http://www.allergan.com/responsibility/compliance.htm>.

Amylin– 2005: RC. Current: State of California Comprehensive Compliance Program Declaration, at <http://www.amylin.com/InvestorDocs/CAComplianceProgramDeclaration01july2007.pdf>.

Biogen Idec– 2005: RC. Current: Biogen Idec Comprehensive Compliance Program, at [http://media.corporate-ir.net/media\\_files/IROL/14/148682/corpgov/compliance0807.pdf](http://media.corporate-ir.net/media_files/IROL/14/148682/corpgov/compliance0807.pdf).

Cephalon– 2005: RC. Current: Cephalon Inc. Compliance Program, at [http://media.corporate-ir.net/media\\_files/IROL/81/81709/CorpGov/ComplianceProgram\\_califlawposting2008FINAL.pdf](http://media.corporate-ir.net/media_files/IROL/81/81709/CorpGov/ComplianceProgram_califlawposting2008FINAL.pdf).

Forest– 2005: RC. Current: Schedule A Comprehensive Compliance Program, at <http://www.frx.com/about/compliance/119402%20Schedule%20A%207-1.pdf>.

Genzyme– 2005: RC. Current: Genzyme Corporation Corporate Compliance Program, at [http://www.genzyme.com/commitment/governance/compliance\\_program.pdf](http://www.genzyme.com/commitment/governance/compliance_program.pdf).

InterMune– 2005: RC. Current: California Pharmaceutical Marketing Compliance Law, at [http://www.intermune.com/pdf/Cal\\_Marketing\\_Compliance\\_Law\\_Declaration.pdf](http://www.intermune.com/pdf/Cal_Marketing_Compliance_Law_Declaration.pdf).