

The Benefit

Summer 2009



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A Message From The President

As members of TABA we all owe Sam Francis, Kevin Chapman, Robyn Jacobson, Bob Kamm, and Burnie Burner a HUGE thank you. They were a very important part of the legislative process for our organization. Things can happen very quickly during the legislative session and having their valuable input helped TABA wade through all the proposed bills, amendments, and threats to our industry. Next time you see any of them, thank them for all their time and effort.

The TPA College of Knowledge was, again, a success. TABA is aware of the tough economic times and so we appreciate your attendance. We would also like to thank our vender exhibitors and sponsors. They truly are our partners in these uncertain economic times. Glenn McLellan's program was informative, timely, and challenging. We received positive feedback from the attendees and look forward to more events in the future.

Please put September 14-15 on your calendar for our Fall Conference to be held at the Marriott Plaza Hotel in San Antonio. This will be a time to start planning for the next Legislative Session. The threats are not going to go away. Remember—you're not paranoid if they really are out to get you! Hope to see you all there!

Jo Lester
TABA 2009 President



Don't Drink and Drive (or Expect Your Claims to be Paid If You Do)

Contributed by Adam Russo, Esq., The Phia Group LLC

If I earned a dollar for every call and email that I have received from claims administrators in the past ten years questioning whether claims should be paid in situations where drunk drivers hit a tree in the middle of the night, I could buy a nice American made Corvette, with a briefcase full of cash in the trunk.

The typical situation involves a client asking whether claims are payable. I always utter the same initial response – “What does your plan document say?” Too many administrators believe that they can process every claim the same way across the board, administering various plans, no matter what the provisions actually say (assuming there is a provision that addresses the matter). Nothing could be further from the truth! The wording (or lack thereof) in a plan document will specifically dictate the process of handling tough claim decisions.

I found some recent interesting cases involving injuries linked to intoxication and the related claims. As you will read, every case boils down to the same two issues – the facts of the case and the terms of the plan document.

In *Arnold v. Hartford Life Insurance Co.* (542 F. Supp. 2d 471 (W.D. Va. 2008)), Hartford denied a beneficiary’s claim for accidental death benefits, concluding that the insured’s death was not due to an “accidental” injury as defined in the policy. The insured died at the scene of a motorcycle crash. The immediate cause of death was a closed-head injury with cervical spine fracture.

At the time of the crash, the insured was legally intoxicated. Hartford denied the claim because the insured’s death was reasonably foreseeable and the assumption of a known risk by the insured did not constitute an “accident” under the terms of the policy. The plaintiff argued the policy included an alcohol/intoxication exclusion with regard to seat belt coverage, but not with regard to AD&D coverage. The plaintiff contended the specific exclusion for intoxicants under the seat belt coverage would not be necessary if the term “accident” was understood not to include a situation where the insured was legally intoxicated.

The court disagreed, noting that for the alcohol/intoxication exclusion under the seat belt coverage to apply, a person would simply have to be under the influence of alcohol, not necessarily intoxicated. The court held the insured’s death was reasonably foreseeable because his alcohol consumption placed him well above the legal limit at the time of the crash that ultimately led to his death. In the absence of any other reasonable explanation for the crash, the court found that it was reasonable for Hartford to determine the insured’s death was not an “accident” as that term was used in the policy.

Similar to *Arnold*, in *Grose v. Sun Life Assurance Co. of Canada* (568F. Supp. 2d 652 (W.D. Va. 2008)) the insurer denied a claim for accidental death benefits because the insured was intoxicated when he crashed his motorcycle because his injuries were reasonably foreseeable. The beneficiaries argued there was no evidence of intoxication at the time of the crash and the death was a result of an accident. The court first concluded the insured was intoxicated; the insured’s blood-alcohol content was twice the legal limit when his body was found, which was five hours after his death and twelve hours after his crash. The court next rejected the beneficiaries’ interest argument that, even if the insured was intoxicated, his death was still accidental because there was no evidence his intoxication was voluntary. The court noted that the beneficiaries failed to provide any evidence “in support of these fantastical, though not impossible, scenarios,” and “it would be unreasonable to conclude anything other than voluntary intoxication.”



As many of you know, I love to preach about the importance of asserting discretionary authority within the plan document. In another interesting case, the court found that a plan administrator’s interpretation of an alcohol exclusion, as written in an ERISA accidental death insurance plan coming within the purview of ERISA, was “legally correct” and granted the defendant’s motion for summary judgment in *Pando v. Prudential Insurance Co. of America* 524 F. Supp. 2d 848, 853-56 (W.D. Tex. 2007).

The exclusion provided that a loss involving a person’s illegal use of alcohol is not covered if it results while operating a motor vehicle. The plan defined neither “use” nor “illegal use”. Plaintiff contended that the decedent’s actual consumption of alcohol was legal since he was of legal age and there was no evidence he consumed alcohol while driving. Prudential argued that by driving while intoxicated under state law, the decedent illegally “used” alcohol.

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Don't Drink and Drive (or Expect Your Claims to be Paid If You Do)

Contributed by Adam Russo, Esq., The Phia Group LLC
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The court found the exclusionary provision ambiguous, analyzed legal authority within and outside the Fifth Circuit, and stated that the law is clear that an administrator's reasonable interpretation of an ambiguous provision is entitled to deference. The court held that Prudential's interpretation was reasonable and consistent with a fair reading of the plan. The court further held Prudential's factual determination that the decedent's use of alcohol was illegal at the time of his death and his intoxication significantly contributed to his death was supported by sufficient evidence, such as autopsy and police reports attesting to the decedent's blood-alcohol concentration and driving behavior.

The insured in *Smith v. Liberty Life Insurance Co.* 535 F.3d 308 (5th Cir. 2008) was a lifelong drug addict with seven arrests under his belt for driving under the influence. He was killed when the truck he was driving struck two trees. Toxicology reports established that he had potentially lethal doses of drugs in his system along with ethanol. Meanwhile, his policy excluded from coverage any death resulting directly or indirectly from an injury occurring while under the influence of alcohol or drugs.

The Fifth Circuit concurred with the lower court's determination that, under Louisiana law, the policy exclusion could be interpreted less favorably for insureds than a similar Louisiana statute mandating that an "insurer shall not be liable for any loss sustained or contracted in consequence of the insured's being intoxicated or under the influence of narcotics unless administered on the advice of a physician."

Interpreting Louisiana law, the court found Liberty proved the insured was "under the influence" of drugs sufficient to "lose normal control" of his faculties and proof of a complete loss of control was not necessary. The court held Liberty was only required to prove intoxication was a contributing cause, which it did when it presented uncontroverted testimony that the insured's level of intoxication impaired his faculties and contributed to his death.

Other than the obvious lesson of "don't drink and drive", I hope that there are other important lessons learned here. Review your standard plan document templates' alcohol, illegal act, and/or intoxication provisions (or whatever else they are called) with your attorney to ensure that the provision lives up to your expectations. Chances are it doesn't say exactly what you or your clients want it to say.



Eligibility For The COBRA Premium Subsidy Under The American Recovery and Reinvestment Act of 2009: What Constitutes Involuntary Termination?

Contributed by Barbra Rabinowitz, Berry, Odom & Rabinowitz, LLP

Question: Why did the chicken cross the road??

Answer: To get to the COBRA subsidy!!!

I know, I know. That is a lame attempt at a joke, but I had to try and get your attention so that you will continue reading this article! Exciting? No. Important? YES!

As we are all well aware by now, the American Recovery and Reinvestment Act of 2009 (“ARRA”) enacted February 17, 2009, provides certain eligible individuals with premium assistance for COBRA continuation coverage. Under ARRA, an assistance eligible individual is generally an individual who (i) is a qualified beneficiary as the result of an involuntary termination of employment during the period from September 1, 2008, through December 31, 2009, (ii) is eligible for COBRA continuation coverage at any time during that period, and (iii) elects the coverage. Group health plans must generally treat assistance eligible individuals who pay 35 percent of the premium otherwise payable for COBRA continuation coverage as having paid the full amount of the premium. The employer (or, in certain circumstances, the multiemployer health plan or the insurer) is reimbursed for the other 65 percent of the premium that is not paid by the assistance eligible individual through a credit against its payroll taxes.

The premium reduction applies as of the first period of coverage beginning on or after February 17, 2009 (the date of enactment of ARRA). An assistance eligible individual is eligible for the premium reduction for up to nine months and the premium reduction period ends if the individual becomes eligible for coverage under any other group health plan¹ or Medicare.

Unfortunately, ARRA does not define what constitutes an “involuntary termination” for purposes of subsidy eligibility. However, the Internal Revenue Service (“IRS”) has issued some specific guidance on this issue, and the definition of involuntary termination as contemplated under ARRA is broader than one would think.

The IRS, through Notice 2009-27² broadly defines involuntary termination (for purposes of ARRA) as a “severance from employment due to the independent exercise of the unilateral authority of the employer to terminate the employment, . . . where the employee was willing and able to continue performing services.” The IRS attempts to make clear that an involuntary termination would not include a situation where the employee implicitly or explicitly requests to be terminated; however, an employee-initiated termination would constitute an involuntary termination if the termination is due to “employer action that causes a material negative change in the employment relationship for the employee.” The IRS fails to define what is meant by a “material negative change” in employment (other than to suggest that an employer-imposed reduction in hours may be considered a material negative change in employment), but presumably a “material negative change” would include situations such as a hostile work environment, a request or demand by the employer that the employee commit a fraudulent or otherwise illegal act, or a discriminatory act against the employee. Of course, one could also go so far as to argue that an adverse change in the employee’s duties or title may be considered a “material adverse change,” but it is unknown if that argument would pass legal muster.

The IRS makes clear that for purposes of ARRA, even a voluntary termination or resignation will be considered an involuntary termination if the employer would have terminated the employee’s employment anyway (assuming the employee knew that he/she would have been terminated).

¹Eligibility for coverage under any other group health plan does not terminate eligibility for the premium reduction if the other group health plan provides only dental, vision, counseling, or referral services (or a combination of these), is a health flexible spending arrangement or health reimbursement arrangement, or is coverage for treatment that is furnished in an on-site medical facility maintained by the employer and that consists primarily of first-aid services, prevention and wellness care, or similar care (or a combination of such care).

²See *IRS Notice, 2009-27, Q&As 1 – 9.*

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Eligibility For The COBRA Premium Subsidy Under The American Recovery and Reinvestment Act of 2009: What Constitutes Involuntary Termination?

Contributed by *Barbra Rabinowitz, Berry, Odom & Rabinowitz, LLP*

Continued from page 4

Below are examples of circumstances which the IRS would deem an involuntary termination for purposes of ARRA:

- The employer's failure to renew a contract with the employee at the time the contract expires, if the employee was willing and able to execute a new contract on similar terms and conditions and to continue to provide the services. This essentially means that where an employer and employee had previously negotiated and entered into an employment contract for an agreed-upon, specific term, the employee would still be considered to be involuntarily terminated at the natural expiration date of the contract (assuming the employee would be willing to then extend the term of such contract).
- An involuntary reduction to zero hours, such as a lay-off, furlough, or other suspension of employment resulting in a loss of health coverage.
- An employer's action to end an individual's employment while the individual is absent from work due to illness or disability.
- An employee's retirement...if the facts and circumstances indicate that, absent retirement, the employer would have terminated the employee's services, and the employee had knowledge that the employee would be terminated.
- An employee's resignation as the result of a material change in the geographic location of employment for the employee (note that the term "material" is not defined, however).
- A lockout initiated by the employer.
- A termination elected by the employee in return for a severance package (a "buy-out") where the employer indicates that after the offer period for the severance package, a certain number of remaining employees in the employee's group will be terminated.

Third party administrators which administer COBRA on behalf of their client-employer groups should be aware of the broad scope of the circumstances which could conceivably constitute an involuntary termination to properly administer the COBRA premium assistance provisions under ARRA and to educate their clients regarding the scope of this important Act.

This document is not intended to be legal advice regarding any specific situation, nor does it encompass all provisions regarding the HIPAA privacy and security standards under the Act.

SAVE THE DATE!

September 14-15, 2009

Fall Conference & Exhibition

Marriott Plaza Hotel

San Antonio, Texas

The room block is open and you should make your reservation no later than August 21 to get the preferred rate of \$149 single and double by calling 800-266-9432.

MORE DETAILS TO FOLLOW!

The Lobbyist's Corner: *Legislative Update*

Bob Kamm, TABA Lobbyist

I. Billing practices of hospitals: HB 4183 by Smithee (R-Amarillo) and SB 1747 by Duncan (R-Lubbock).

The Texas Legislature adjourned its 140 day session on June 1 without passing legislation to regulate hospital billing practices. Senator Robert Duncan and Representative John Smithee co-authored legislation (SB 1747 and HB 4183) to amend provisions in the Health and Safety Code to improve a consumer's and third party payor's ability to obtain adequate and timely information of a hospital's billed charges.

The bill had several key provisions: (1) it would have required a hospital to provide an itemized statement with its billed charges if the charges exceeded \$20,000. (2) It would have allowed a third party payor (not defined) to request additional information from the hospital including medical reports and operative reports. And, importantly, it would have provided that however long it took the hospital to provide the requested information, that period of time would not be counted for purposes of calculating prompt pay periods under contract or statute. (3) It would have required a hospital, before it could take away a discount for failure to pay a claim accurately or timely, to provide notice to the third party payor within 180 days from the earlier of the date the hospital received payment from the payor or the date that payment was due. If a hospital failed to provide the notice, its claim would be barred. (4) If a hospital received an overpayment, it would have been required to repay within 45 days of receiving notice or face a 10% penalty for repaying late.

The Senate bill was heard on April 16th in Senate State Affairs Committee, chaired by Senator Duncan. Kevin Chapman testified in favor of the bill on behalf of TABA and the Texas Hospital Association ("THA") testified against the bill. The Committee never voted the bill out of committee presumably because of the THA opposition.

HB 4183 was heard in the House Insurance Committee, chaired by Representative Smithee, on April 28th. Robyn Jacobson, David West, Kevin Chapman, and Sam Francis appeared in support of the bill on behalf of TABA. The Texas Association of Health Plans and the Texas Association of Life Underwriters registered in favor of the bill. It was opposed again by THA, as well as the Scott and White Center for Healthcare Policy and the Teaching Hospitals of Texas.

The House Committee made several changes to the bill, such as requiring the itemized statement to be provided on bills greater than \$10,000 (instead of \$20,000) and increasing the 180 day notice provision to 12 months, and reported it out of the Committee on May 11th. At that point in the Session, it was too late to get the bill through the House floor and back to the Senate. And, as it turned out, when the House Democrats slowed House business down to prevent the "Voter ID" bill from being reached, it also prevented any chance of amending the provisions onto another bill.

II. HB 3749 by Coleman (D-Houston): itemized statement transparency.

TABA also supported HB 3749 by Representative Garnet Coleman. The bill, as modified, passed the House but died in the Senate as time ran out in the Session. This bill would have required hospitals to disclose their costs on such items as medical hardware, implants and prescription specialty drugs. Representative Coleman's purpose in filing the bill was to lower mark ups on these items by shedding light on what the hospital actually paid for the device or drug.

The bill was opposed by THA and manufacturers. Representative Coleman amended his bill in Committee to require the issue to be studied by the Legislature during the interim and to make recommendations for change during the 2011 Session of the Legislature. As noted above, time ran out on the bill in the Senate and did not pass.

III. HB 223 by Eiland (D-Galveston): regulation of "rental" networks or "silent PPOs".

Representative Eiland filed a similar bill in 2007 that passed out of the House Committee but did not pass the full House. His 2009 bill was substantially identical to the bill he passed out of the Committee in 2007. TABA had recommended several changes to the 2007 version but did not oppose the bill.

During the Session, Representative Eiland proposed a substitute to HB 223 that was based on model national legislation proposed by the National Council of Insurance Legislators ("NCOIL"). The substitute language that contained substantial notice and reporting provisions appeared to include third party administrators, even when they did not contract directly with providers.

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TABA proposed an amendment to HB 223 that would have clarified the responsibility of a TPA in the proposed notice and reporting requirements. The amendment provided that a third party who administers or processes claims on behalf of a payor and who does not resell or lease access to a provider's healthcare services and contractual discounts in any manner, except to make it available through a master contract to a client who is a payor, is not required to comply with the reporting requirements of the bill.

In the end, HB 223 did not pass. The Senate companion bill by Senator Van de Putte was defeated on the Senate floor after business and manufacturing groups claimed it would raise health care costs. Moreover, the slow down in the House, together with the failure of the Texas Department of Insurance ("TDI") Sunset bill, prevented HB 223 from being amended onto other legislation.

IV. Prompt Pay for Self funded Plans.

Late in the Session, Representative Eiland pre-filed an amendment to the TDI Sunset bill that would have created a state prompt pay law for ERISA self funded plans. In response, TABA prepared a number of amendments to the Eiland amendment in an attempt to help correct/improve it, but the Eiland amendment never came up because the House never took up the TDI Sunset bill on the House Calendar. TABA intends to meet with Representative Eiland during the interim to discuss the amendment and its potential impact on self-funded ERISA plans.

V. Special Session.

Governor Perry has announced a special session for July 1. The Governor put the following topics in the call for the special session:

- Extend the Sunset dates for the Texas Department of Transportation, Texas Department of Insurance, Texas Racing Commission, Office of Public Insurance Counsel and Texas State Affordable Housing Corporation.
- Allow TxDOT to issue general obligation bonds for highway improvement projects, and create a Texas Transportation Revolving Fund to provide financial assistance for transportation projects.
- Extend the authority for TxDOT and a regional mobility authority to use comprehensive development agreements for projects.

A special session called by the governor may last up to 30 days, but the legislature may adjourn sine die before that deadline. In keeping with his previously stated desire to keep the special session short, the Governor could be trying to keep the legislators focused on just the issues included in the call by starting it just before the July 4 weekend.

It is also possible that the Governor could open the call to more issues once the specified issues have been resolved. If the Governor opens up the TDI Sunset bill beyond merely reauthorizing its existence, then the Eiland amendment, HB 223 and other legislation that could impact TPAs might reemerge. TABA will continue to be involved in any special session and issues that might impact Texas TPAs.

To view the full history and text of any of the bills discussed above, go to www.legis.state.tx.us.

Helping TABA’s Legislative Efforts—Now is the time to make your contribution! Even though we can’t contribute to legislators while the legislature is in session, we still should continue the momentum of contributing to the PAC to be ready after the session is over. We contributed close to \$11,000 to legislators last year and as you know this money helps legislators with campaign costs, as well as costs of being in office that the State does not cover. Legislators are paid \$7200 per year (\$600 per month). Many spend their own money to cover costs that don’t get reimbursed by the State. You and your employers can participate in the legislative process by helping legislators with these costs. We encourage those of you who have not yet made your 2009 contribution to do so today! TABA is definitely making inroads within the legislative arena.

We still need to meet our goals and you can help by following this suggested plan: We are asking each member TPA to commit to contributions in an amount equal to their membership fee. This amount will come from personal contributions from TPA owners and key employees. Corporate contributions are prohibited by Texas law. Many of our member TPAs already contribute in this manner but many do not. We need the support of all members! Also, we would ask that any TPAs not contributing to the level of their membership fee, to solicit an increase in contributions or broaden the base of contributors in their office. A number of the TPAs whose contribution level already exceeds their membership fee have found that its success lies in its ability to attract contributions from a number of their key employees. This has been brought about by a payroll deduction plan that makes contributing much easier. They have found that it is much easier to make a contribution of \$5 a week than to make a one time donation of \$250. The president of each TPA member company convenes a meeting of key employees. In the meeting, the president explains TABA’s legislative goals and why those issues are important to the company and to the industry. Each company establishes an annual company goal based on the number of key employees. If, for example, there are six key employees, the annual goal could be \$1000 with five employees paying in \$100 and the president \$500. Along with the annual goal, a payroll deduction is instituted for this expense. Each key employee will contribute \$8.33 per month; the president, \$41.66 per month. Once in place, the goal is met every year. No golf tournaments, no fancy galas, no auctions – and none of the time and planning those events required. Not very flashy, but it would be dependable, predictable, simple, and hugely successful. **If you haven’t yet made your 2009 contribution, make it today!**

TABA Political Action Committee “TABAPAC” Contribution Form

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Pharmacy Benefit Spending Poised to Increase for Antithrombotic Drug Therapy—Prasugrel Versus Clopidogrel

Contributed by Frederic R. Curtiss, PhD, RPh, CEBS

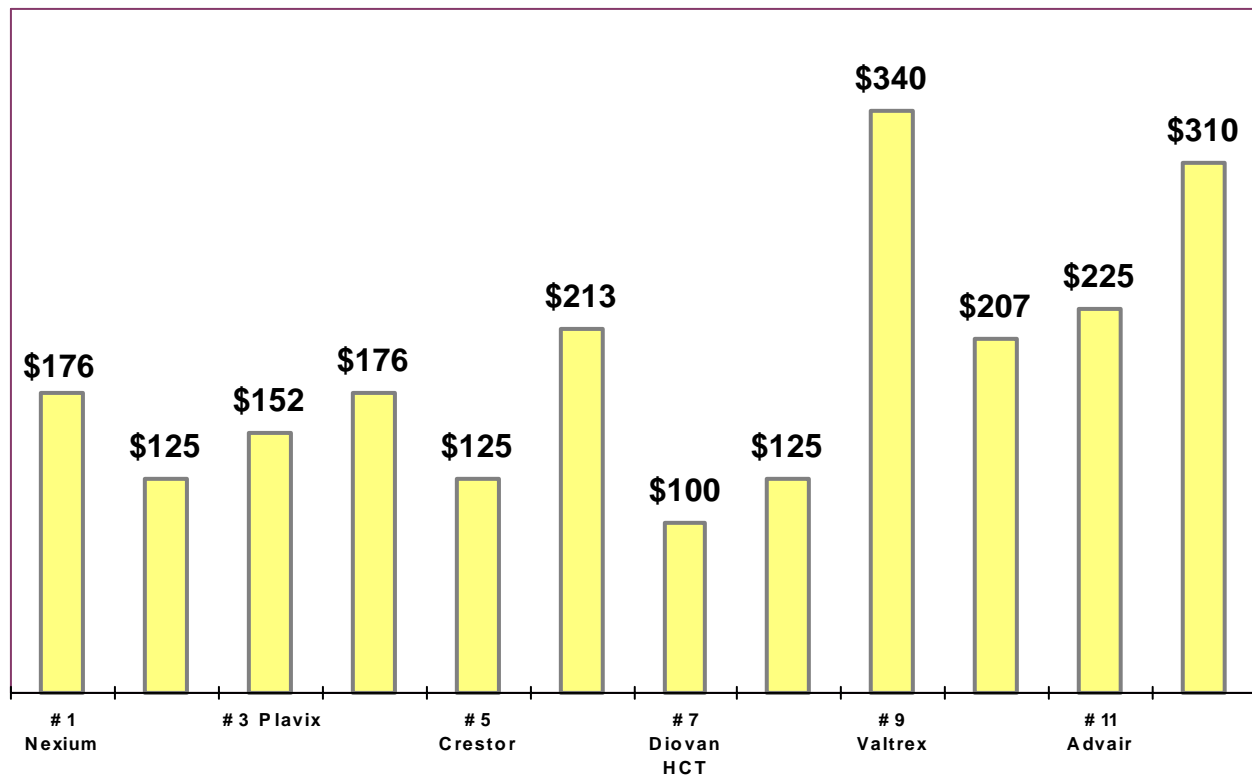
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Clopidogrel (Plavix) is now ranked among the top 5 drugs by expenditure in most pharmacy benefit plans. If price was a proxy for value (cost relative to efficacy and safety), clopidogrel would be high-value because its average wholesale price is \$5.60 per 75 mg tablet, or about \$152 per 30-day supply at discount price from www.drugstore.com.¹ This high per-unit price propels high expenditures; for every patient on clopidogrel, the annual drug cost is \$1825, before member cost-share. Clopidogrel had sales of \$3.80 billion in U.S. community pharmacies in 2008,² up 23% from \$3.08 billion in 2007 and pushing Plavix to rank #3 in 2008 from rank #5 in total community pharmacy brand drug sales.³ In just 6 years, Plavix annual sales have increased three-fold, from \$1.26 billion in 2002 when it ranked 25th by total community pharmacy sales.⁴

New Drug Entities Will Propel Spending on Antithrombotic Drugs

Drug benefit spending on antithrombotic drugs is poised to escalate. On February 3, 2009, the FDA Cardiovascular and Renal Drugs Advisory Committee recommended approval of prasugrel (Effient).⁵ Like almost all new drugs, the prasugrel clinical trials have been sponsored by the manufacturer (Daiichi Sankyo and Eli Lilly). In other words, all of the clinical evidence that we have today stems from drug trials sponsored by the manufacturer, and there is only 1 clinical study of end point outcomes that served as the basis for the FDA's consideration of prasugrel for marketing in the United States.⁶ The Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel-Thrombolysis in Myocardial Infarction (TRITON-TIMI) 38 is a comparative effectiveness clinical trial because it compared prasugrel+aspirin to the alternative agent clopidogrel+aspirin. TRITON-TIMI 38 has been criticized for using a low loading dose (300 mg) of clopidogrel, potentially handicapping the efficacy of clopidogrel, for which the recommended loading dose for percutaneous coronary intervention (PCI) is 600 mg.⁷

Figure 1. Top 12 Drugs By Expenditure in 2009 – Average Drug Cost Per Month



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Pharmacy Benefit Spending Poised to Increase for Antithrombotic Drug Therapy—Prasugrel Versus Clopidogrel

Contributed by Frederic R. Curtiss, PhD, RPh, CEBS

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Probably more important than the potential handicap for clopidogrel in a loading dose lower than recommended for PCI was the change in the definition of the primary end point of myocardial infarction (MI; heart attack) to include transient increases in biomarkers (i.e., not clinically observed heart attack). Victor Serebruany, MD, PhD, John Hopkins University Medical School, found that the clinical benefit of prasugrel would have disappeared in the overall TRITON-TIMI 38 study and in all of the patient groups. If the analysis had considered only MI (heart attack) reported by clinicians during PCI after the first 3 days of prasugrel+aspirin versus clopidogrel+aspirin therapy.⁸ Dr. Serebruany also hypothesized that the more powerful antiplatelet effects of prasugrel might explain a potentially higher rate of cancer that develops at 4 months of therapy with prasugrel compared with clopidogrel.⁸

Schafer et al. summarized the key findings from the primary analysis of the TRITON-TIMI 38 study including the conclusion that 24 cardiovascular end points (composite of nonfatal MI, nonfatal stroke, and death from cardiovascular causes) would be prevented for every 1,000 patients treated for a median duration of 14.5 months with prasugrel+aspirin compared with clopidogrel+aspirin.⁹ However, this relatively small reduction in the absolute rate of the composite end point (9.9% [643 events among 6,813 patients] for prasugrel+aspirin versus 12.1% [781 events among 6,795 patients] for clopidogrel+aspirin) was offset by increased risk of bleeding for all types of bleeding. The rates of death from cardiovascular causes were no different between prasugrel+aspirin (2.1% [n=133]) compared with clopidogrel+aspirin (2.4% [n=150]; hazard ratio [HR]=0.89, 95% CI=0.70-1.12, P=0.31), but death from bleeding was significantly more frequent with prasugrel+aspirin (0.3% [n=21]) in non-coronary artery bypass graft [CABG] patients and 0.9% [n=2] in CABG patients) compared with clopidogrel+aspirin (0.1% [n=5] in non-CABG patients and 0% in CABG patients; HR=4.19 for non-CABG-related bleeding, P=0.002).^{10,11} The FDA advisory committee on February 3, 2009 concluded that the benefit-risk profile of prasugrel+aspirin was acceptable but that “preference should be given to the use of prasugrel only following coronary angiography, as it was in the [TRITON-TIMI 38] study, so that coronary anatomy is known, to allow assessment of the likelihood of requiring coronary artery bypass (CABG) surgery.”⁵

Status of Drug Therapy for Antithrombosis

Four months after the FDA advisory committee recommended approval of prasugrel+aspirin for restricted indications for patients expected to undergo PCI, the FDA has not formally approved prasugrel (Effient) for marketing in the U.S. The delay is not surprising for a couple of reasons. First, the increased risk of bleeding with prasugrel compared with clopidogrel has been suspected for almost 2 years, which was highlighted just prior to release of the TRITON-TIMI 38 results when 2 smaller clinical trials of prasugrel were suspended in October 2007 by the prasugrel manufacturers without explanation.¹² Second, there was controversy surrounding the conduct of the FDA advisory committee meeting in February 2009 when the FDA “disinvited” Sajay Kaul, MD, a cardiologist at Cedars-Sinai Heart Institute in Los Angeles. The FDA later admitted that it had made a “mistake” in excluding Dr. Kaul from the advisory committee meeting based on questions from the prasugrel manufacturer associated with Kaul writing “several papers that had been critical of prasugrel.”¹³

At the present time, clopidogrel is approved by the FDA for secondary prevention in patients with (a) recent MI, stroke, or established peripheral arterial disease, and (b) NSTEMI including patients who are to be managed medically and those who are to be managed with PCI (with or without stent) or CABG.¹⁴ Based on the summary notes from the FDA advisory committee meeting on February 3, 2009, the approved indications for prasugrel will be more narrow, including restrictions against its use in patients with a history of stroke or transient ischemic attack (TIA), patients with body weight less than 60 kg, and in patients 75 years of age or older.^{5,10,15}

Clopidogrel had worldwide sales of more than \$7 billion in 2007¹⁶ and more than \$8 billion 2008, making it second only to Lipitor in worldwide sales. In addition to the anticipated FDA approval of prasugrel, a second new molecular entity is in the middle of safety testing in Phase 2 clinical trials for patients who receive balloon angioplasty and stents. In February 2009, Novartis agreed to pay Portola Pharmaceuticals (San Francisco) \$75 million to license elinogrel plus as much as \$500 million more if the company meets certain regulatory and commercial milestones.¹⁷ Elinogrel may have an advantage over clopidogrel and prasugrel in faster onset and faster reversal of antiplatelet effects.

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Pharmacy Benefit Spending Poised to Increase for Antithrombotic Drug Therapy—Prasugrel Versus Clopidogrel

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Patients with ACS undergoing PCI, the target group for prasugrel based on the TRITON-TIMI 38 results, are estimated to account for about 20% of the current market for clopidogrel. The other 80% of the prasugrel market is medical management of ACS patients; it will take trials like TRIOLOGY, currently in process, for the manufacturer of prasugrel to seek regulatory approval for additional indications. The TRIOLOGY results are not expected until 2012, and clopidogrel will be available by generic name in the U.S. sometime before that. Nevertheless, it is reasonable and prudent to expect that prasugrel will be used outside of the FDA-approved label indications. Choudhry et al. (2008) found that only 39% of clopidogrel (Plavix) users enrolled in the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) program met FDI-approved indications of use of clopidogrel. Prior authorization (PA) interventions can be used by managed care plans to prevent inappropriate use of prasugrel and clopidogrel for primary prevention (i.e., persons without a history of stroke, heart attack [MI] or heart disease) and to protect patients who will not benefit from prasugrel (e.g., persons aged 75 or older or with body weight less than 60 kg about 130 pounds) or who are at risk of harm from prasugrel (those with a history of stroke or TIA).

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TABA 2009 Calendar of Events

TABA

- Board of Directors Meeting
July 9, 2009
Group Resources Offices
Dallas, TX
- Fall Conference & Exhibition
September 14-15, 2009
Marriott Plaza Hotel
San Antonio, TX
- Board of Directors Meeting
September 16, 2009
Marriott Plaza Hotel
San Antonio, TX

SIIA

- 29th Annual National
Educational Conference &
Expo
September 21-24, 2009
Marriott Worldcenter Hotel
Orlando, FL

SPBA

- 2009 Fall Conference
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