Business Briefs

AtheroGenics Seeks Chapter 11

AtheroGenics Inc., a pharmaceutical company that had been developing a diabetes drug, said it has consented to the involuntary Chapter 7 petition filed against it on Sept. 15 in federal bankruptcy court, and is seeking to convert the case under Chapter 11 of the U.S. Bankruptcy Code. It said the filing was necessary because of the company's substantial debt, which has created a significant impediment to AtheroGenics' ability to effectively develop its primary drug, AGI-1067, for the treatment of type 2 diabetes. During bankruptcy proceedings, AtheroGenics said it expects to sell the company and/or its key assets. Proceeds will be distributed first to stakeholders, including creditors, so it is not clear whether any of the proceeds will be distributed to shareholders. Dr. Russell M. Medford, the company's president and chief executive, said the company remains "hopeful that AGI-1067 will ultimately continue to be developed." AtheroGenics had a net loss of $29.2 million, or 74 cents a share, for the 6 months ending June 30.

Lilly to Buy ImClone

Eli Lilly & Co. announced last month that it is acquiring cancer drug manufacturer ImClone for $6.5 billion. The acquisition gives Lilly its first targeted cancer drug, Erbitux, and five additional drugs in clinical development, including a number of biologics. The $6.5 billion purchase price makes ImClone Lilly's largest acquisition to date. In recent weeks, Lilly's stock price has been hit hard by negative news, including increased risk of pancreatitis associated with its diabetes drug Byetta and the delay in U.S. approval of prasugrel. The ImClone purchase seems to be signaling a shift away from riskier primary care blockbuster drugs to the specialty-focused oncology arena, where unmet medical need is greater and the regulatory path to market is more certain. The company's purchase of ImClone comes in the wake of a hostile takeover bid by BristolMyers Squibb, which had a 17% stake in the company. Eli Lilly's offer represents a 51% premium over ImClone's closing stock price on June 30.

GSK Declines to Option Thyroid Drug

GlaxoSmithKline has decided to decline its option to license XL184, Exelixis' late-stage small-molecule oncology drug candidate and four earlier-stage compounds, effectively ending a 6-year research collaboration between the two firms. XL184 is being studied in a phase III trial in patients with medullary thyroid cancer. In an interview, Exelixis president and CEO George Scangos said GSK's decision did not reflect poorly on the company's research and development programs or chances of success with XL184 and the other compounds. "I can speculate that [GSK's decision] on XL184 was largely because of a mechanistic overlap with XL880," another small-molecule cancer compound from Exilixis that GSK is already developing, he said.

Phenomix, Forest Diabetes Partnership

Phenomix, a privately held biotechnology firm, signed a licensing pact last month with specialty pharmaceutical company Forest Laboratories to develop and commercialize Phenomix's dutogliptin, a dipeptidyl-peptidase-4 inhibitor drug for type 2 diabetes that is now in phase III trials. The deal will provide much-needed financial resources for Phenomix, which recently scrapped a public stock offering, citing market conditions. Forest, meanwhile, is facing impending generic versions of several of its own drugs and badly needs late-stage products. Under terms of the agreement, Forest will pay Phenomix $75 million up front and as much as $265 million in additional milestones. The two companies will develop and commercialize the drug jointly in this country, with both parties equally sharing profits and expenses. Phenomix will promote the product to diabetologists and endocrinologists, while Forest will market it to primary care physicians.

Chattem Launches Updated Dexatrim

Chattem Inc. hopes to increase sales of its Dexatrim weight-loss brand and compete with GlaxoSmithKline's Alli (orlistat) with the recent launch of Dexatrim Max Complex 7, a reformulated version of the over-the-counter dietary supplement. Meanwhile, the European Medicines Agency recently recommended Alli for nonprescription status across the European Union. Complex 7 contains the same ingredients as other Dexatrim products, but also contains "7-Keto," an ingredient provided by Humanetics, of Eden Prairie, Minn. Humanetics says 7-Keto is a natural metabolite produced from dehydroepiandrosterone (DHEA) in the body.

—From staff reports

Reporters and editors from Elsevier's "The Pink Sheet" and "The Tan Sheet" contributed to this column.

Law & Medicine

Concierge Concerns

As the debate about health care reform continues, one concept springing up from the private sector is concierge medicine. It is an innovative "product" created, as author Sandra Carnahan wrote 2 years ago, "to reclaim the heart and soul of medicine." Roberta Greenspan, president of Specialdocs Consultants Inc., a company that organizes these practices, stated, "Physicians no longer wish to be known as 'service providers' but as physicians once more."

BY MILES J. ZAREMSKI, J.D.

Concierge medicine started a few years back, with about 500 physicians—typically internists or general practitioners—converting to concierge practices; today that number is about 5,000 nationwide. The greatest concentration of concierge practices appears in Florida and in Washington state, but there are also a fair number in those metropolitan areas with enough well-off patients to afford this type of practice. Concierge medicine has been variously described as "pay to play" or "country club" medicine.

Most concierge practices require patients to pay an annual fee. This fee entitles the patient to receive "24/7" access to his or her physician by cell phone or pager, an annual physical examination, and perhaps other amenities. The fee also enables the provider to limit the number of patients he or she will see, and thus cut down on the enormous amount of paperwork required of a typical practice.

With the smaller practice, a concierge physician will provide as much time as necessary for each patient visit, rather than making sure he or she sees so many patients per hour in order to make ends meet. That comports with the *sine qua non* of a concierge practice—to foster closer patient-physician relationships.

Concierge medicine also can provide different levels of care, such as silver, gold, and platinum (same-day or next-day appointments, extended office hours, weekend appointments, even house calls). Regardless of how this type of practice is marketed, and despite the annual fee, most patients still must pay for office visits and for ancillary costs, such as laboratory fees incurred outside the practice.

Are there legal issues attendant to such practices? Absolutely.

The first question is how these arrangements affect payer-provider relationships. The answer depends on what a particular payer-provider contract covers. For example, does the contract cover an annual physical? If it does, and the physician's annual fee also includes a physical, then the physician would be getting paid twice. Also, the premise upon which a concierge practice is based is 24/7 coverage; yet, the typical health care plan ensures that covered services will be made available 24/7. Is the annual fee reflective of this?

Additionally, a typical payer-provider agreement contains a hold-harmless clause. Such clauses generally obligate the provider to look to the managed care organization for payment of services rendered, and not plan enrollees, except for copays or deductibles. States such as Washington have cautioned providers that charging mandatory access fees would subject them to legal liability. New York and New Jersey health commissioners have also made it clear that concierge physicians were engaging in impermissible practices, principally because services provided with the access fee were not readily distinguishable from care previously contracted through health plans.

Regardless of what the physician wishes to do, or what states may look at, an insurer that is reluctant to reimburse a concierge practitioner can always pressure the preferred provider organization or independent practice association to which the physician belongs for payment. There are instances of insurers doing this in places such as Texas, Illinois, and Arizona.

Then there is Medicare. Any concierge practice must ensure that what is being provided to a Medicare patient does not overlap with services deemed covered under the Medicare program. Among these are a one-time physical examination, supplies, self-management training, and diabetes screening. Another slippery slope is how consults are factored into the annual fee versus what is covered by the Medicare contract. Any overlap of services could result in expulsion from the program and having to pay monetary penalties.

On March 31, 2004, the Office of Inspector General issued a Medicare "Fraud Alert" that dealt with concierge practices. Its focus was on liability for billing Medicare patients for services already covered by Medicare, except for deductibles and coinsurance. Rarely do physicians who go into this new type of medical practice drop their Medicare participation; however, if the practice is not charging for Medicare-covered services, then staying in the program would not be problematic.

But to be absolutely certain that no rules are being violated, opting out of the Medicare program is the safest avenue to take—although in that situation, Medicare patients who wish to have the government pay for their services could no longer go to such a physician because they would have to pay an access fee, which may be a violation of Medicare rules depending upon whether any portion of the fee goes toward duplicating coverage already being provided by Medicare.

Additionally, any physician leaving a general practice to go into concierge medicine should consider whether that move would violate any non-compete agreement that may be in place with the former practice. I would say no, since patients seeking a concierge physician are not the same population satisfied with a general practice.

In the end, concierge medicine is a product of the private sector whose time has now come. While it may not reduce overall health care costs, and may be really only for the well heeled, its creation reflects the notion that patients no longer wish to be treated like a number, and that physicians don't want to be known only as service providers where the measure of success is something other than patient satisfaction. As long as its various models abide by reimbursement guidelines, concierge medicine may be here to stay. ■

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