



UPDATE

The nation's premier providers of specialty medical sales, service and education

June 2005



PRESIDENT'S *Message*

Coming to terms with 2 terms

By Bob Wahlenmaier

AT THE UPCOMING Annual Conference in San Diego, I will be completing my two-year term as president of IMDA. Although our association's presidents typically serve for one year only, I was asked last year — and I accepted the opportunity — to preside for a second year. I did so for three reasons.

First, we were continuing our transition to a new management team, ASI, in Westmont, IL. We wanted to make sure we had some continuity on the board as we moved ahead with our plans to increase membership and build up our Annual Conference and Manufacturers Forum. I think you'll see in San Diego

that those two objectives have been met. Rest assured that the incoming IMDA board (which you will vote on in San Diego) will continue to work with ASI on these very important goals in the months ahead.

Second, we had already entered into discussions with Medmarc Insurance Group concerning that company becoming IMDA's preferred provider of medical products liability insurance. As you know, we reached an agreement with Medmarc this spring, whereby our members now have access to reasonable product liability insurance and — just

see "Two terms," page 4
or click [HERE](#) to continue

Two members spread the word

IMDA MEMBERS ARE used to doing missionary work for innovative medical technologies. But recently, two members did some missionary work for IMDA itself and for specialty sales and marketing. Their remarks are a playbook for any IMDA member making the case for specialty distribution to manufacturers of innovative medical devices.

Shawn Walker of Bay State Anesthesia and Rick Pfahl of Bovie Aaron Medical spread the IMDA word at the recent annual meeting of the Medical Device Manufacturers Association in Washing-

MDMA

ton, DC. The two appeared on the dais with a manufacturer and manufacturers' rep speaking on behalf of the Health Industry Representatives Association. MDMA is a national trade association based in Washington, DC, which represents manufacturers of medical devices, diagnostic products and health-

see "Spreading the word" page 3
or click [HERE](#) to continue



See you June 8-11 at the Rancho Bernardo Inn in San Diego, site of IMDA's 25th Annual Conference and Manufacturers Forum.

IN THIS ISSUE

IMDA members acquired
Elections scheduled
Non-compete clauses
Product liability
Technology Briefs

Two IMDA members acquired

PRODUCTS FOR SURGERY and Flanagan Instruments have been acquired by ITOCHU International, the New York-based subsidiary of a 150-year-old Japanese trading company. Both companies will continue to operate with their existing management teams and will maintain their status in IMDA.

ITOCHU International has had a presence in the United States for 50 years. The company has a track record in distribution. Among the products it distributes in this country are automobile tires, fasteners, building products, specialty chemicals, coffee beans, cocoa, automotive parts and textile products. In addition, the company distributes a variety of goods to Japan, including American brand-name apparel such as Tommy Hilfiger, Nautica, Guess? and Tumi. It also exports grain, meat, oil and frozen foods.

Up until now, ITOCHU International has lacked a presence in the U.S. medical distribution market. (Its parent, ITOCHU Corporation of Japan, owns a medical distributor in Japan, which

generates approximately \$55 million of sales in that country.)

Not for sale

ITOCHU approached Forest Hill, TX-based PSI approximately a year ago with an offer to buy the company, says PSI Vice President Bob Wahlenmaier. "We said, 'We're not for sale, and why do you want to get in this business?' But they told us they understood distribution, so the talks continued."

As part of PSI's due diligence, Wahlenmaier and his partners (Butch Lawhon, Tom Madsen and Bryan Gregory) spoke to other U.S. companies that had been acquired by ITOCHU International. "Our due diligence told us they were telling the truth," says Wahlenmaier. ITOCHU International does, indeed, have a track record of buying U.S. companies and leaving them intact, he adds. In fact, the company offers long-term employment agreements with the owners and executives of the companies they acquire.

The acquisition "breathes longevity into Products for Surgery," says Wahlen-

maier. With an exit strategy in place for the company's founding partners, PSI's employees will be able to pursue opportunities within the company and with other firms owned by ITOCHU International.

The acquisition will also allow Products for Surgery to obtain cutting-edge technology from outside the U.S. market to help improve its operations, said Wahlenmaier. In addition, it should lend impetus to Products for Surgery's bid to carry more "orphan" products from the big medical device manufacturers.

Flanagan Instruments

Shortly after it acquired PSI, ITOCHU International acquired 24-year-old Flanagan Instruments, Mandeville, LA. The company is a multi-line specialty distributor with an emphasis on Carl Zeiss equipment, says founder and President Flagg Flanagan.

"ITOCHU is a very large distribution house who was trying to find synergies in the marketplace for their healthcare initiative," says Flanagan. "They came to us, and we worked out a deal where we joined the ITOCHU family of companies. We're extremely proud of that."

Flanagan will continue to serve as president and CEO, while Rob Byrne will maintain his position as vice president and CFO. "To a certain extent, it's business as usual, except we have a very large corporate distribution partner that will enable us to continue the business and, over the long term, continue to find the best possible way to serve the customers we do business with.

"It's an opportunity to maintain and increase our stability in the marketplace, while having a large corporate partner who's interested in healthcare distribution." ♦

ELECTIONS SCHEDULED

IMDA members will vote on a new slate of association directors at the Annual Business Meeting on Thursday, June 9, in San Diego. The nominating committee, chaired by Immediate Past-President Dave Campbell, has recommended the following slate for the 2005-2006 fiscal year:

- **President:** Ed Boracchia, Boracchia + Associates, Petaluma, CA.
- **President-Elect:** Shawn Walker, Bay State Anesthesia Inc., N. Andover, MA.
- **Secretary/Treasurer:** Terry Hinchliffe, Advanced Medical Systems Inc., Littleton, CO.
- **Director-At-Large:** Jim Herrmann, Med Alliance Group Inc., Carol Stream, IL.

- **Director-At-Large:** Kevin Trout, Grandview Medical Resources Inc., Bridgeville, PA.

Continuing on the board for the next year are:

- **Immediate Past-President:** Bob Wahlenmaier, Products for Surgery Inc., Scottsdale, AZ.
- **Director-At-Large:** Leo Mindick, DMA Med-Chem Corporation, Great Neck, NY.
- **Manufacturers Representative:** Bruce Brierley, Maxtec Inc., Salt Lake City, UT.

Leaving the board will be Dave Campbell, Vital/Med Systems Corp., Centennial, CO; and Stan Tangalakakis, Mercury Medical, Clearwater, FL.

care information systems.

"It was clear everyone listened to our presentations," said Walker. "We got some thoughtful questions."

Three options for manufacturers

IMDA allied member Pfahl pointed out to the manufacturers three options they have when bringing their technologies to market — a traditional sales force, manufacturers' representatives, and specialty distributors.

Each has its advantages, said Pfahl. For example, a dedicated sales staff devote all of their selling time to the manufacturer who employs them. And manufacturers' reps are effective at creating a "push" through distribution.

However, each has its drawbacks too, he said. Hiring salespeople is expensive. "Manufacturers typically require at least a million dollars of revenue to support one direct salesperson," pointed out Pfahl. And manufacturers' reps often rely on general-line distributor sales reps to "bird dog" leads at the end user level.

Specialty distributors however, offer several advantages, particularly for manufacturers of innovative devices, he said:

- As distributors, they have a strong incentive to "push" products through the channel.
- They focus their efforts on creating demand at the end user level, where they have the strongest relationships.
- They have strong clinical knowledge of products, and they creatively translate this knowledge into solutions for the end user.
- They offer quick feedback on the

device's clinical hurdles and competition.

- They can blend products from different manufacturers, and offer unique solutions to clinicians.

Manufacturers take note

The following types of manufacturers will find specialty distributors particularly valuable, said Pfahl:

- Those whose products require a sales force with detailed product knowledge, that is, whose products offer an advantage other than price.
- Those that are entering new specialty markets. This is true even for manufacturers who have an existing direct sales force, but who lack strong relationships with decision-makers in the new market.
- Those that desire 100 percent variable selling costs. This is particularly attractive to small manufacturers with unproven products, who can't afford the upfront costs of a sales force.
- Those with an exit strategy of being acquired. Manufacturers intent on building a revenue stream and then selling their company to a larger competitor may find that the acquiring company has no desire to take on a second sales force.
- Those requiring quick market penetration. "Recruiting, hiring, training and managing a direct sales force is time-consuming," said Pfahl. Add to that the time a new sales rep must take to get to know the decision-makers.

**It's still not too late to sign up for
IMDA's 25th Annual Conference and
Manufacturers Forum, June 8-11,
San Diego. Call (866) IMDA-YES.**

- Those whose products call for a "consultative sell." Only reps with strong, established relationships with clinical decision-makers can achieve such sales.
- Finally, those that prefer a sales team with an entrepreneurial spirit. Being entrepreneurial by nature, specialty distributors "are able to comprehend and contribute to overall business strategies much more so than one just focused on gaining new business regardless of the margins."

Questions about margins

Not surprisingly, the manufacturers attending the conference had questions for Pfahl and Walker about how much manufacturers must pay for the services of specialty distributors. "I brought out that there is a life cycle spectrum for products," said Walker. "It starts with a missionary-type sale, but then goes to a situation in which the technology becomes the standard of care, with pricing pressures, group purchasing organization contracts, and hospitals' desire to get the product through general-line distributors."

Walker advised manufacturers to make sure their list price includes at least a 50 percent gross margin for new, unproven technologies. That gives the specialty distributor the ability to move on price while subsidizing the missionary sale. Over the life of the product, as the business stabilizes and the selling time subsides, margins drop, she said.

Walker cautioned manufacturers about paying their distributors only on growth of the business. "The carrot works better than the stick," she told them. "Independent reps or specialty distributors need to make sure that if they sell something, they will get paid for it," she said. "They have different products to choose from, and will pick the ones for which they'll get paid." ♦

Two terms

...continued from page 1

as important — coverage for errors and omissions.

Third, I've learned — as past president Dave Campbell has pointed out before — that I could get more out of IMDA by putting more time into it. For that reason, I would encourage all members to consider getting involved on the IMDA board.

We have accomplished several other important things over the past two years. I'm particularly excited about the new Virtual Manufacturers Showcase, which gives manufacturers an opportunity to present products year-round, on the IMDA website, in a number of electronic formats, including PowerPoint and video. (Check out the "Members Only" section of the IMDA website at www.imda.org.) Thanks to Dave Campbell,

Janet Popp and Alan Campbell for moving this project forward.

I'm also proud of and grateful to Shawn Walker of Bay State Anesthesia and Rick Pfahl of Bovie Aaron Medical for taking the time to speak about specialty sales and marketing at the recent annual meeting of the Medical Device Manufacturers Association in Washington, DC. As the article in this month's newsletter points out, their remarks are a playbook for any of us who want to advance the cause of specialty sales and marketing.

I'm also grateful to Shawn for putting together — for the second year in a row — our Annual Conference. Always conscientious, Shawn spent many hours finding the right speakers and topics for you. Be sure to thank her for the educational offerings we'll all enjoy at this year's Annual Conference.

There's more work to do, of course.

For example, we're still looking at the possibility of securing access to health insurance for our members and their employees. I don't know if that will be feasible or not, but we'll find out. And, as I said before, we'll continue to work hard to increase membership and participation at next year's Annual Conference and Manufacturers Forum.

We'll be in good hands with incoming President Ed Boracchia of Boracchia + Associates. Ed has served as president in the past, and brings with him enthusiasm as well as experience. And the new board, working in tandem with ASI, will continue to push forward with new initiatives.

I began the second year of my term with optimism about IMDA and specialty sales and marketing. I end my term with even more. Thanks for the opportunity to serve you. ♦

IMDA Announcement

Insurance Protection For IMDA Members



Medmarc and The Hartford

Teamed to help medical distributors protect their world.

From surgical supplies and equipment to implantable products - we can meet your evolving needs.

IMDA-member specific insurance protection

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- *Business Income Interruption Protection
- *Coverage for Sales Representatives' Samples
- *Workers Compensation
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- *The Hartford A+
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Why distributors should care about product liability

By Kevin Quinley



CHECKED THE FORECAST lately? Today's FDA regulatory and legal environment presents storm clouds for medical device businesses. Don't assume that you need not worry about product liability because you're a device distributor. In most areas, injured plaintiffs can sue not only a medical product's manufacturer for defect, but courts can impose liability on device distributors as well. In many "shotgun" lawsuits, attorneys sue all companies that had any role in making or selling the medical product. That includes *you*.

If the product liability storm hits your company, don't assume you will be covered or that your defense will be picked up by the manufacturer or its insurance policy. For various reasons, a product manufacturer may be unwilling to protect you in the event of a claim or lawsuit alleging that a distributor did something wrong. That "something

wrong" might be that you misassembled the product, made grandiose over-representations, altered the product, or failed to adequately instruct the user or consumer of the product's proper use.

Allegations may include independent negligence on the distributor's part. If a claim or lawsuit alleges negligent activities on the part of the distributor, all bets are off as to the manufacturer and its insurance company picking up your defense. It may not matter that the allegations have little or no merit. The mere fact that they are alleged may remove the distributor from the orbit of a manufacturer's insurance coverage.

Seeking defense

Even if the allegations against the distributor ultimately are shown to be without foundation, the court system may take years to reach this level of certainty. In the interim, the medical device distributor needs its own defense to the

lawsuit.

On a practical level, this means hiring a defense attorney to file responsive pleadings, conduct discovery, and in general, protect the interests of the distributor. These costs can run to tens or hundreds of thousands of dollars, which is why it's so important to button down insurance coverage *before* a claim is filed. It also underscores the importance of leaving nothing to chance and not blithely assuming manufacturers will assume the defense of device distributors named as defendants in product-related lawsuits.

Do you want to entrust your defense to an insurer with whom you have no ongoing relationship? Even if you succeed in getting a manufacturer or its insurer to pick up your defense, there may be concerns by device distributors as to whether their interests will be fully protected. For example, how much will your input weigh in any decision to defend vs. settle the case? This is a sensitive area where distributors may have strong feelings.

In future articles, we will discuss more specifically what this means for device distributors, what they should expect, and how they can arm themselves to survive and thrive amidst a perilous liability climate.

The storm is coming. Are you ready? ♦

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Kevin Quinley is senior vice president, Medmarc Insurance Group, Chantilly, VA, IMDA's preferred provider of medical products liability insurance. He will be presenting many of these ideas at the IMDA Annual Management Conference on June 9 at the Rancho Bernardo Inn, San Diego.

Representation needed

The following manufacturer is seeking representation by specialty sales and marketing organizations.

Clinical Cell Culture/C3

Contact: Jordan Wittmeier, (954) 471-3456
6005 NW 68 Manor • Parkland, FL 33067
E-mail: jorcanw@clinicalcellculture.com
Website: www.clinicalcellculture.com

Product: Spray-on skin.

Product Description: Autologous cell spray. C3 has developed several, proprietary products that can be used to treat skin disorders. The company's products use small samples of the patient's own skin to rapidly produce skin that covers wounds and minimizes the formation of scars.

Marketed to: Burn surgeons, plastic surgeons, dermatologists, hospitals.

Territory: Nationwide.

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To view past "Representation Needed" listings, visit the IMDA bulletin board in the "Members Only" section of the Website (www.imda.org).

Non-compete clauses are for real

By Mitchell A. Kramer

WE HAVE ALL HEARD urban myths — crocodiles attacking people in sewers, Jimmy Hoffa under Shea Stadium. They sound real, but they are not.

The distribution industry has such an urban myth. The myth is that non-compete clauses in distribution contracts can be ignored because they do not mean anything. That myth is false. In almost every state, a tightly drawn non-competition agreement will be enforced by the courts. Even if the non-compete requirements are overly broad, the courts in many states will narrow them in order to enforce what the court feels is proper.

If you are sued to enforce a non-competition agreement, even if you “win”

beyond termination.

Does the provision end when your representation ends? Such restrictions are usually acceptable so long as you are only prohibited from carrying products that compete with what you are selling in only the geographic area in which you are selling them. Except in unusual cases, a distributor is comfortable agreeing not to compete with products it sells for its principal in the territory in which it represents the principal.

Post-termination agreements

Post-termination non-competition agreements are another matter. Almost any time a distributor loses a line and begins representing a competing line, it will lose a certain percentage of its business. If the distributor is out of the market for any length of time, it is much more difficult to hold onto customers.

Our clients have generally been successful in eliminating post-termination non-competition agreements. Manufacturers sometimes insist on retaining post-termination non-competition agreements when a distributor is terminated for cause. But before the contract is signed, most manufacturers will waive non-compete provisions if the contract is terminated by the principal or is not renewed. Certain states, such as Pennsylvania, have decided that when an employee is fired, a post-termination non-competition provision will not be enforced. The reason for this rule is that if the employee is not worth keeping, the employer does not need protection from him. It is likely that the same rule would apply to distributors. It should be emphasized, however, that most states have not adopted such a rule.

California is the only state, as of now,

that has a law prohibiting post-termination non-competition agreements in virtually every case. (There are certain exceptions, such as where the company is sold and the sellers are prohibited from competing with the new buyers.)

State by state

The treatment of non-competition clauses varies widely from state to state. Some states have laws governing limitations on competition. All states have court decisions dealing with such issues, and the decisions vary widely, both from state to state, and often from court to court within a state. Most non-competition issues that get to court result from the filing of an injunction action by the principal. An injunction is a request to the court to stop certain activities or to force one to do something. These are always cases in equity, meaning that they are always tried by a judge without a jury.

Preliminary injunctions, that is, a request to stop something that is imminent, are often tried by the court within days or weeks after the lawsuit is filed. There have even been cases where a party has gone into court without the other party being present or even given notice, and gotten a temporary restraining order, that is, an order stopping a party from doing something. Such an order generally is only good for 10 days. Within that 10 day period, the court will conduct a hearing on a preliminary injunction. Even though there is a procedure for a full trial on a permanent injunction, in non-competition cases the decision on the preliminary injunction is usually the end of the case. By

see “Non-compete,” page 7
or click [HERE](#) to continue

**In almost every state,
a tightly drawn
non-competition
agreement will be
enforced by the courts.**

(which is quite unlikely if the facts are against you), you will not win. Your legal fees will be very high. Even worse, if you have signed a broad agreement not to compete after you cease representing a manufacturer, it is probable that other manufacturers with even one overlapping product will refrain from engaging your company. Such principals will be more concerned with defending a claim for tortious interference with contract than it will be anxious to name you as its distributor.

Non-competition provisions in distribution contracts come in many forms. Some end when the distributor's representation ends. Others, however, extend



Technology Briefs

Multislice computed tomography (MSCT) may be better than angiography at detecting heart problems. According to a German study reported in the May 25, 2005, issue of the *Journal of the American Medical Association*, MSCT appears capable of detecting and ruling out problems in most cases. While MSCT has its drawbacks, such as patient exposure to radiation and a lack of quality in some images, the authors were, generally speaking, pleased with the results of the technology. Compared with invasive coronary angiography,

MSCT was reported to have a high discriminative power to detect obstructive coronary artery disease. Also, MSCT scanning is said to be more patient-friendly than angiography, which involves threading a catheter through the groin and into the chest, injecting a dye and taking X-rays to determine how well the blood is flowing. Angiography requires a two-day recovery period. During a typical MSCT procedure, the patient is placed on a table that moves through a doughnut-shaped device housing an X-ray tube and detector array. For each image, the X-ray tube rotates around the patient and the X-rays

pass through the patient to detectors, where thousands of measurements are taken. In a single rotation of the instrument around the patient, the system creates 16 images of a credit-card-thin layer of tissue.

www.jama.ama-assn.org

The **Greystone Medical Group** (Memphis) received FDA clearance to market and sell its Epi-Max® **wound care product** designed for the treatment of diabetic skin ulcers and other wound-related conditions. (Approximately

see "Tech Briefs," page 8
or click [HERE](#) to continue

Non-compete

...continued from page 6

the time the case would come to trial, the time for the non-compete to run is probably over.

Watch your contracts

You need a sharp eye to read a non-competition clause in a contract and figure out what it is that you are being asked to sign. Such clauses deal with products, territory and length of time.

Regarding products, clarify whether you are being asked to not compete with the products that you are selling, or with all products manufactured by the company that you are representing. Regarding territory, determine whether you are being asked to refrain from competing in the territory in which you represent the manufacturer, or in a broader area. Are you being asked not to sell to customers to whom you sold for the principal, or is the non-compete restriction something else? Regarding

the issue of time, clarify whether you are being asked to refrain from competition while you represent a manufacturer, or also for a period of time *after* you represent the manufacturer. If it is the latter, clarify for how long after you stop representing the manufacturer the non-compete is to continue.

Trade secrets

The trade secrets provisions of distribution contracts play into the non-competition area, but are usually somewhat less important. You should be aware, however, that sometimes a non-competition provision can be snuck into a trade secrets provision.

If a manufacturer comes to you with a substantial bank of business, it may not be unreasonable, if you resign the line, to require you not to compete for a few months so that the manufacturer can fill your company's slot and have sufficient time to hold onto the business. It is quite another thing if a manufacturer, with no business, engages you to represent

it, reaps the benefits of your successful market penetration, terminates you, and then has the right to keep you from competing.

As with many areas of your business, considering how to deal with a contract that includes restrictive covenants requires business judgment, negotiation and probably legal advice.

Our law firm is seeing more and more contracts offered with one and two year post-termination non-competes. We are also beginning to see the effect of such contracts on medical distributors that have recently been terminated by manufacturers that have gone direct or have sold out to larger companies.

The area of non-competition with principals is fraught with danger for the future success of your business. It should be treated as such. ◇

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Tech Briefs

...continued from page 7

mately 15 percent of diabetic patients are said to develop an ulcer, according to the company.) The FDA cleared Epi-Max as a combination drug/device product. It is reportedly one of the few advanced wound care products to receive that designation. Epi-Max is a sterilized wound dressing impregnated with Greystone Medical Group's patented Poly Hydrated Ionogens (PHI) composition. It is designed as the U.S. version of Greystone's DerMax® product, which has been approved as a medical device in Europe. Greystone has operations in the United States and Europe, where numerous clinical trials and studies are underway to evaluate the effectiveness of its PHI platform technology on several other medical conditions.

www.greystonemedical.com

Boston Scientific Corp. (Natick, MA) announced two-year follow-up data from its TAXUS VI clinical trial. The data demonstrated that the safety and efficacy benefits associated with a moderate-release formulation of the TAXUS® Express2™ paclitaxel-eluting stent system could be maintained for at least two years, according to the company. Co-principal investigator Eberhard Grube, M.D., presented the data at the annual Paris Course on Revascularization. The randomized, double-blind, controlled study of 448 patients at 44 international sites was designed to assess the TAXUS moderate-release paclitaxel eluting coronary stent system in reducing restenosis in high-risk patients, including diabetics, or patients with long *de novo* lesions with overlapping stents or small vessels. Lesion size ranged from 18mm to 40 mm in length and 2.5mm to 3.75mm in diameter. TAXUS VI is reportedly the

first clinical trial to support the durability of drug-eluting stents in complex lesions at two years.

www.bostonscientific.com

RITA Medical Systems Inc. (Fremont, CA) signed an exclusive worldwide license agreement with Emcision Limited for the Habib Sealer™ disposable radiofrequency resection device. The device, which is designed to coagulate a surgical resection plane to facilitate a fast dissection with limited blood loss, assists in the resection of vascular tissues, including liver, kidney, lung, pancreas, spleen and uterine fibroid resection. It is said to be compatible with the current RITA radiofrequency ablation (RFA) platform and can be used with the company's 1500X radiofrequency generators. The Habib Sealer is labeled with the CE Mark for distribution in Europe and will be available

to RITA Medical System's international distribution network for immediate sale. The company estimates the annual worldwide market opportunity to exceed \$300 million.

www.ritamedical.com

Smith & Nephew's U.S. Advanced Wound Management division (NYC) received FDA clearance for its newest absorbent **antimicrobial barrier dressing**, ACTICOAT™ Moisture Control. The dressing complements the company's existing ACTICOAT product line, which feature the company's patented Silcryst nanocrystalline silver technology for antibacterial protection. With an extended wear time up to seven days, ACTICOAT Moisture Control is said to reduce the number of dressing changes and the resources needed to change multiple dressings.

www.smith-nephew.com



UPDATE

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Always consult your tax advisor, attorney or CPA before putting them into effect.*