DA BIZ

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In the last issue we rhetorically asked "does size really matter?" and we talked about something really, really small: aerosol drug particles. Among other things, we concluded that, in the context of aerosol therapy, size does matter and that a smaller particle might generally be preferable than a larger one. In this issue I would like to start with the first of a two-part series that looks at something really, really big: the respiratory drug biz. The business of manufacturing and providing respiratory drugs is very large indeed. We're talking tens of billions of dollars annually on a global scale. The global market segment for respiratory drugs includes both oral and parenteral preparations as well as aerosol solutions and a variety of inhalers. Drug types include antihistamines, anti-infectives, anti-inflammatory agents, immunotherapy/vaccine preparations and, last but not least, bronchodilators. Unlike tablets and injectables, aerosol drugs require a quasi-sophisticated and effective delivery system that is matched to the drug. Thus, a major subsegment of the aerosol portion of the respiratory drug market includes the manufacturing of aerosol delivery devices; namely, nebulizers, compressors, inhalers, inhaler propellants and the associated packaging and filling operations.

In addition, the business management aspects of this market include specific sales and marketing personnel, advertising and product placement functions, plus order fulfillment and distribution systems and personnel at the corporate level. Of course, before a drug gets to market, there is a long cycle of planning, development, clinical trials, clinical research and publication, reporting and compliance with numerous regulatory agencies. In this facet of the business alone, many millions of dollars are exchanged and a huge contingent of people is employed. Similarly, there is a large component that involves protection of the intellectual property associated with drugs and devices; specifically patents and trademarks. And then there is Wall Street. Most of the major drug companies, Big Pharma as they are collectively referred to, are public corporations who are as concerned with their stock performance as they are with whether their drugs work or not. Finally, let us not forget the prescribing physicians, the pharmacies and pharmacists, the home care companies, the hospitals and, of course, the respiratory therapists who all interact to bring these drugs to patient. In fact, let us also not forget the patient and the insurance companies that generally pay for medical care and medications. So, in addition to a nearly unimaginable annual monetary expenditure across the entire market, there are a huge number of companies and a countless number of people directly and indirectly involved with the respiratory drug business. In this context, the magnitude of this business is truly staggering.

Sometimes we are so involved in our own little world; we fail to see the larger universe we occupy. I would like to provide some fresh insight into the vast dimensions of the respiratory drug business in general, and perhaps the aerosol medicine business more specifically. These insights may not be readily apparent to the therapist in the trenches: those RTs who accomplish 20 or 30 or 40 aerosol treatments per shift. They are an integral, yet small, part of the biz, and they are virtually invisible to the Wall Street titans who control it. These insights may not be immediately obvious to the RT department head who is trying to find time to balance the budget, recruit enough warm bodies to do the work, and attend innumerable "quality" meetings. Likewise, these insights may not be readily apparent to the RT clinical managers who may have to select nebulizers for purchase, or write protocols for utilizing the latest aerosol bronchodilator or conduct the staff training that accompanies the new protocol.

Let us first take a whimsical, as well as nostalgic, look at that side of the biz with which we might be most familiar: the hospital-based aerosol treatment business. It's nothing new as far as I can tell. But the amazing thing about it is that it persists and sustains itself even though it is no longer a revenue producing activity for the hospital. As an "OJT" in 1965, one of the first things I was taught was how to give an IPPB treatment with a TV-2P and a Mark 7. And I was quickly dispatched to the wards to practice and become proficient at my newly-learned skill. I used the old-fashioned glass nebulizer on the TV-2P and the "new" Micronebulizer on the Mark 7 to administer a number of brand name drugs that are no longer available today: Alevaire, Tergemist, Dornavac, Isuprel and later, Bronkosol. Only Mucomyst seems to have survived. I became fairly proficient at administering a half-dozen or more treatments at a time, starting one within a minute or two of its predecessor, and so forth. At one hospital I practiced at in the late-1960's I developed the technique of traveling the back stairs with a Mark 7 on its shep-

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A NEW NAME FOR THE ASSOCIATION OF POLYSOMNOGRAPHIC TECHNOLOGISTS

On January 1, 2007, the Association of Polysomnographic Technologists (APT) changed its name to the American Association of Sleep Technologists (AAST). "The approval of this name makes the AAST and the profession of sleep technology more recognizable in the medical community and in the public eye," said AAST President Cynthia D. Mattice, MS, RPSGT. "Our new name also makes it clear that our members play a critical role in the provision of quality medical care for people with sleep disorders." Over the course of nearly 30 years, the role of the AAST has expanded as the profession of sleep technology has matured. The AAST's efforts are being realized through the creation of professional standards that ensure quality patient care, as well as through the development and implementation of standardized education and continuing education programs. Two educational programs being offered by the AAST in the first half of 2007 represent premier educational opportunities for sleep technologists, the first is the AAST's Spring Review Course which will be held April 16 to 17 in Louisville, KY. This course is designed for sleep technicians who are preparing for the certification exam of the Board of Registered Polysomnographic Technologists (BRPT). The second is the AAST's 29th Annual Meeting which will be held June 10 to 13 in Minneapolis, MN. The program includes an outstanding lineup of speakers that will make the 29th AAST Annual Meeting a remarkable educational event.

With more than 3,000 members, the AAST has been the leading voice for sleep technologists since it was established in 1978. As the sleep technology profession grows, the AAST continues to make sure that its members are recognized as qualified health care professionals who ensure the safe and accurate assessment and treatment of patients with sleep disorders. To learn more about the AAST, the Spring Review Course or the 29th AAST Annual Meeting, visit www.AASTweb.org.

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hard's hook stand in each hand. I had a couple dozen patients on my treatment card. At the hospital that had the courage to hire me off the street as one of its first inhalation therapy trainees, I looked forward to Mondays, Wednesday and Fridays because those were clinic days. Actually, "puffing parlor" would be a better term insomuch as our regular crew of COPDers would come in 3 days a week to simultaneously receive their IPPB and/or USN treatments while commiserating and socializing with their similarly situated friends and neighbors. What I did not realize then was that the treatments I was administering were a large part of a booming hospital-based business known as Inhalation Therapy. The clinic allowed us to perform "parallel processing" rather than "serial processing" and therefore made better business sense.

If we fast-forward to today, we know that inpatient aerosol medication treatments are generally not directly reimbursable. Thus, the "business" of inhalation therapy is not as lucrative to the hospital as it once was. IT and RT departments transitioned from being revenue centers to cost centers, as we like to say. The business of inhalation therapy took a couple serious hits many years ago. Starting with the Sugarloaf Conference on the Scientific Basis of Respiratory Therapy in 1974, the prevailing dogma surrounding inhalation therapy was challenged and a call was issued for specific studies of aerosol therapy techniques and procedures, medications for specific diseases, and the nature of bronchial secretions. The respiratory and chest medicine professional communities responded and we have begun to develop a more scientific rationale for aerosol therapy. In retrospect, the Sugarloaf Conference is widely regarded as having put the nail in IPPB's coffin. And for good reason; but that is a topic for another time. One of the concepts that emerged from Sugarloaf is that we do not necessarily need a positive pressure breathing machine to provide effective aerosol drug delivery. The IPPB machine was phased out and nebulizers and inhalers were phased in. In fact, an entirely new "industry" in aerosol delivery devices was spawned.

In 1983 Diagnosis Related Groups, or DRGs, were implemented to determine how much Medicare pays a hospital for care of patients with particular diagnoses. Similar systems were developed by most other insurers. Once again, as respiratory care services largely became non-reimbursable on an individual basis, that portion related to aerosol drug therapy, which was a major part of any departments overall workload, helped to turn the RT department into a cost center rather than a revenue center. However, it would appear as though that has not adversely influenced the overall state of the respiratory drug market or even the aerosol drug subsegment.

According to one of the market research firms, the respiratory drug market is the fourth largest therapeutic category by sales and generated nearly $32.4 billion in 2005. Over 50% of the respiratory drug sales were spent on asthma and COPD with the balance spread across cystic fibrosis, pneumonia, coughs and cold and allergic rhinitis. The global implications for the size of this market can be readily imagined from the epidemiology of just these two diseases: asthma affects over 100 million people worldwide (18 million in the US) while COPD is estimated at approximately 20 million people in Japan, 7-10 million in the US and 8-12 million in Europe.

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Crush Injury *continued from previous page*

When promoting healing we administer HBOT treatments 1 to 2 times daily at a pressure of 2 ATA (atmospheres absolute) for 1 to 11/2 hours per treatment. Microcirculation problems should resolve within 4 to 6 days with neovascularization in 10 to 14 days. For preserving tissue with profound ischemia, the protocol is to treat every 4 to 6 hours for 24 to 48 hours or using more intense scheduling of therapy until resolved. When fighting ischemia in order to save tissues, the frequency of therapy is dramatically increased, but the importance of immediate treatment following injury is critical for determination of outcome. Studies have shown that tissue necrosis can develop after just 6 hours of ischemia!

Unfortunately there are a few problems when it comes to effectively treating these injuries with HBOT. Many physicians are not aware of the benefits of using HBOT for these cases and/or may not realize the urgency required for treatment to be successful. Access is another problem since many hospitals simply do not provide this therapy and patient transfers can take an excessive amount of time. Lastly, even if a hospital has this service it is unlikely they provide around the clock on-call services. So don't get hurt on a weekend. Better yet don't get hurt at all. Prevention of crush injuries is important in all areas of life whether it be in work, sports, house and car repairs and even kitchen activities. Always use safe practices and be aware of your environment and potential dangers. Ten is a good number for digits.

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In the next installment on this topic, we'll take a closer look at the respiratory drug market itself. I'll break it down so we can see that portion that includes aerosol solutions, inhaler, nebulizers and unique delivery systems. We'll also examine the new drug pipeline for respiratory drugs, and specifically for inhalable agents that we might have to administer in the future. If I may end with a little teaser: we are in for some interesting and intriguing surprises in this business as we dust off the crystal ball and look at the new drug pipeline. Inhalation drugs are no longer used solely for targeting the respiratory system. On the horizon are a number of new drugs that target the brain and central nervous system, although they are first delivered to epithelium in either the nose or lung. This respiratory drug biz never ceases to amaze.

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**"The job candidate was underqualified.
I was just too overqualified to recognize it."**