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An E-Newsletter of the Global Biologics Supply Chain (GBSC) Spring 2008

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A Patient's Story:

REMICADE makes it possible for Vince Zinno to pursue his life's passions while lifting the burden of his pain. Read this comeback story...

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Celebrating your landmark years of service!

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a 2008 message from Bob Sheroff.



New J&J Cell Therapy Company

Holding the promise of new cures for a wide variety of diseases.



Devices and Biologics Converge at GBSC

Self-administering devices benefit patients and effectively position Centocor products in the marketplace.



Who is Brian Sherry?

Meet the GBSC's VP of Worldwide Engineering and hear his views on collaboration, driving positive change and supporting his team.



Clean Water, Better Health

You don't need to be an ecologist to see that our natural resources are in danger, especially water. Read about this global issue and learn how you can make a difference.

We welcome your input and feedback. Take a moment to tell us what you think by emailing us at [GBSC Global Link](mailto:GBSC.Global.Link).

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REMICADE makes it possible for Vince Zinno to pursue his life's passions



Vince Zinno is the consummate "come-back" kid. A warrior that's fought not one but two debilitating autoimmune diseases. His ultimate diagnosis unfolded slowly, however, long after he had begun to suffer the effects.

After a minor car accident back in 1989, a precautionary CT Scan alerted Vince that his then 32-year-old back looked more like the spine of a man twice his age. Vince was diagnosed with Osteoarthritis, a painful joint disease that wears away the cartilage between the joints. Vince recalls many subsequent doctors appointments when a nurse would look at his hands, with the gnarled, bony build-up in his fingers, and say "Oh, you have R.A." "No," Vince would respond, "I have OA."

Vince's RA remained undetected until severe pain in his left foot and ankle prompted his primary care physician to order an MRI. In January 2003, Vince was also diagnosed with Rheumatoid Arthritis (RA), an autoimmune disease that causes chronic, debilitating inflammation of the joints and surrounding tissue.



Vince Zinno

Vince's RA had gone undetected for two reasons: many of the symptoms were masked by the OA and most importantly, Vince is sero-negative, which means his RA did not show up in his blood work.

Despite the pain and stiffness he came to know so well, Vince, a senior content strategist for Vanguard, was determined to continue the active lifestyle he loved. An avid golfer and long-time drummer in his own band, *Family Affair*, Vince vowed "despite all of these maladies, I will not stop doing what I love to do!"

Once Vince began his Remicade treatments, he was able to differentiate between the symptoms of each disease. "For me, Osteoarthritis is a sharper, more localized pain in specific areas of the body. "Rheumatoid Arthritis," he clarifies, "is an overall dull ache, an oppressive burden like with the flu or a fever. After my second Remicade infusion, I could feel the burden lift and my rheumatologist says it has nearly halted the progression of my disease. It's truly a miracle drug!"

One of the "miracles" for Vince is his increased range of motion that enables him to continue wielding his golf clubs and drum sticks. "When I retire, I want to golf, play my drums and write creatively. Vince currently authors his own blog, theconsigliere.pbwiki.com, where he shares thoughts on politics, history, music, entertainment and sports. I gratefully credit Remicade that I can still do what I love."

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Planning for the Future By Bob Sheroff

Planning ahead is the first key step to success. The process, while challenging at times, allows us to define our value, establish our goals and allocate resources to achieve our objectives. I have always taken great pride in GBSC's ability to plan each year through the Business Cascade. This tool has helped us remain focused on our critical deliverables, while we navigate through the competing priorities of our organization. As you know, the 2008 Cascade introduced a new strategy that offers both an annual focus, as well as a more long-term perspective. Through this modified strategy, we set the stage for our longevity in an industry that's becoming more complex, more competitive and ultimately more challenging as health care costs continue to rise.



Bob Sheroff

Now, Always and Forever

Regardless of how we update our Business Cascade, our primary focus remains unchanged: We supply quality products to the market. We must never lose sight of the fact that as a supply chain, we must fulfill our responsibility of getting products to our patients. After all, the only way we can fund our future plan, is to deliver on today's obligations.

Your Personal Plan

While our Cascade objectives reflect large-scale initiatives and long-term priorities, every employee plays a definitive role each day. No matter what your position in the organization, you contribute to the GBSC objectives when you focus on **efficiency** and **compliance**.

Efficiency means working smarter – whether it's streamlining processes or eliminating non-value work. That's why I need you to challenge the status quo by asking, "is there a more efficient way to achieve my end result at the same level of quality?" You'll find that the end result may equal cost savings. Efficiency, however, is not simply a matter of cutting costs. Because no matter how our plans and processes evolve, our compliance requirements remain unchanged. A process is not efficient if it sacrifices compliance. There is a critical balance between the two, and it is our responsibility to ensure that compliance is never sacrificed.

The People Plan

In the years ahead, the GBSC plans to influence industry trends, as well as collaborate across the J&J landscape on new and convergent technologies. Only by engaging the best team can we expect to achieve these lofty goals. Our people are the foundation for our future. Our GBSC leaders are committed to an engaged workforce, and in turn, the GBSC asks for your ongoing commitment. We have strong momentum going in 2008, but we need you to help us stay the course.

I'm confident that the GBSC is up for the many challenges we face. And I'm excited about the opportunities that we'll generate as a result!

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New Cures on the Horizon at J&J's New Cell Therapy Company

For years, stem cell research has been debated in politics and in the media, but there is no dispute among medical researchers that this technology holds the promise of new cures for a wide variety of diseases.

Last year, Johnson and Johnson created a new company to focus specifically on cell therapy and its platforms of opportunities. "The formation of the Cell Therapy Company represents J&J's belief that this technology will yield important new treatments for diseases that currently have no available therapy," states **Rob Willenbacher, M.D.**, General Manager for Cell Therapy Company (NewCo) located in Radnor, Pennsylvania.



Stem cells are capable of sensing damage within the body and can travel to those areas to help repair them.

What is Stem Cell Therapy?

Stem Cell Therapy can be defined as the process of injecting stem cells into an organism with the intention that they will secrete factors or in some way interact with the recipient to promote repair or forestall disease or even differentiate and replace damaged tissue. Unlike adult cells in the body, which have a particular purpose that cannot be changed, stem cells are still at an early stage of development and retain the potential to turn into many different types of cells. According to **Fred Bader**, V.P. of New Technology and Business Management, GBSC, "Stem cells naturally occurring in the body are capable of orchestrating repair in the body. Once the cells sense damage, they can go to those areas and help repair them. We believe that stem cells can be used as a smart medical delivery system, sensing what is wrong and providing the right biomolecules to stimulate repair."

Willenbacher further explains, "Stem cells are a renewable source of cells that can be derived from a variety of different tissues, such as human umbilical cord tissue (hUTC). The team is working on applying cell-based technology to multiple platforms, including diabetes, a strategically important disease for us."

Bob Sheroff, President of the GBSC, sits on the new Cell Therapy Company Board of Directors. "We have had tremendous support from Bob Sheroff and his organization," states Willenbacher. "We look to the GBSC as our manufacturing partner for future products. We have already hired several people from the GBSC and have started to work with the St. Louis facility to help with clinical supply."

A recently formed entity called the Cell Therapy Manufacturing Working Group is a faction comprised of representatives from Centocor, the GBSC, the Cell Therapy Company, and Pharmaceutical sector QA who are charged with defining and executing the manufacturing strategy. "Our job is to make certain of the technology's manufacturability," says Bader, who sits on the Manufacturing Working Group. "When we became aware of the cell therapies available at J&J, we began seeking ways to assist." Ultimately, conversations with scientists allow the GBSC to assess the design for manufacturing. The early collaboration allows for better-designed products, and the ability to determine the necessary resources and timelines. According to Bader, "as we become more educated in cell therapies, we can better prepare for our future."

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Devices and Biologics Converge at GBSC

In today's world, it's amazing how quickly "progressive" and "advanced" can turn into "standard" and "status quo." Combined with the rapid evolution of patient self-care, the members of the Device Design Team find themselves working in a demanding environment that assumes innovation, while still fulfilling the meticulous controls and regulations of the FDA. How have they made it work? By focusing on patient needs, tapping into Johnson & Johnson's diverse talent pool and never losing sight of their commitment to compliance.



Pre-filled auto-injector

In the not so distant future, Centocor will be launching golimumab (CNTO 148) and ustekinumab (CNTO 1275) into the marketplace, providing life-changing treatment for people suffering from Psoriasis, Rheumatoid Arthritis and Psoriatic Arthritis and Ankylosing Spondylitis. These products will offer patients a significant level of convenience and control since they will be the first biologic drugs from Johnson & Johnson to be distributed in self-administering devices, specifically the **pre-filled auto-injector** or the **pre-filled syringe with needle guard**. These self-administering devices mean minimal doctors' visits for patients and a critical position in the marketplace for Centocor products.

The Device Landscape

While self-administering devices are certainly not new technology, they are relatively recent in the biologics environment. "Some of our competitors have already brought self-administering devices to market, and have definitely made the 'price of admission' more complex," says **Art Jurema**, Director of Project Management for several device initiatives. But rather than simply imitate what is already available, the team has taken a different approach.

As any patient can clearly see, the pre-filled auto-injector appears rather big and bulky. It's designed this way because Rheumatoid Arthritis patients often lack the dexterity needed to use a more delicate instrument. "It's not just about letting people administer a drug at home. We wanted to really address the unique needs of our patients," says **Judith Svarczkopf**, Autoinjector Project Team Lead. In addition to tailored design, the pre-filled auto-injector ensures a **full-dose delivery** every time with **automatic needle retraction**. "Yes, our competitors offer devices too, but this is how we distinguish ourselves among our patients and within the marketplace," says Jurema.

It Takes a Village

To say that the delivery of these two self-administering devices was a team effort is quite the scientific understatement. What culminates into a streamlined solution for our patients, actually represents the collaboration of several J&J businesses and external partners, a new design and development process for combination products, and a number of employees who played a role on the initiative, while still meeting the demanding needs of their day jobs. "Forty percent or more of future compounds will be in combination products that include drug and device, so we need to continue to build an infrastructure to support our future," explains Svarczkopf.

A key piece of that infrastructure is compliance. The design for a device in a combination product is highly regulated and must pass the same rigorous clinical trials as the drug. "The FDA needs to know what our process is from inception to fill-finish and they expect it documented according to their standards," says **Melissa Maret**, Senior Director of Market Support. "To consistently deliver in this area, we need to change our perspective," explains Maret. "To put it simply, we were a drug company. Now, we are a combination product development company."

Influencing the Future

The Device Design Team already has demonstrated why innovation and collaboration are key components of the GBSC business cascade year after year. While their achievements so far have been exemplary, they are still at the early stages of influencing the future of biologic treatments, and improving the quality of life for our patients.

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Who is Brian Sherry?



Education: BE, Chemical Engineering, University College Dublin, Ireland; MS, University of Missouri-Rolla

Family: Married, with one daughter

Outside of work, I most like to: Play the violin; when I was young, I traveled and performed as a member of Irish and European youth orchestras.

What's one thing that no one at the GBSC knows about you? I like to cook and would love to open a restaurant one day.

Career Philosophy: You learn by watching someone who is good at what they do; it could be a gardener pruning roses or a colleague making an effective presentation; but you need to be open to learning and interacting.

Brian Sherry joined Johnson & Johnson in 2001 after working as an outside consultant supporting several business units, including Noramco and corporate quality. Brian recalls that the J&J Credo is one of the main reasons he joined the organization. "Working as a consultant for many years, I saw the importance of the Credo and how it shaped the organization. Our Credo values are consistent with my own personal views, and it's an important part of why I joined J&J." Seven years later, Brian is now the VP of Worldwide Engineering at the GBSC and says he couldn't be happier.

A strong believer in collaboration, Brian insists "there is very little we actually sit down and do by ourselves." In his role as VP of Worldwide Engineering, Brian heads up a hosted engineering group, which encompasses chemicals, pharmaceuticals and biologics. The group depends on collaboration for its success, and on sharing processes, technologies, talent and other resources. Successful collaboration ensures that the group is leveraging expertise, know-how and resources to avoid duplication, which means positive cost implications for J&J.



Brian enjoys family time with his daughter.

Collaboration has also led Brian to be a believer in humility. "I am constantly reminded how little I know and how much I can learn from other people. A person cannot, in this fast changing world, be expected to know everything. We need to work with others and be flexible to gain understanding. It's about being open to new ideas and willing to change and adapt," lessons for Brian that were echoed in his recent studies of American history and the founding fathers.

Brian was born and raised in Ireland, and as a recent American citizen, he admires the founding fathers and their ideas and vision as a group. "I admire George Washington for his integrity and leadership, Thomas Jefferson for his clarity of vision and intellect, Ben Franklin for his constant curiosity and ingenuity, and John Adams for his determination and persistence. It was a group that came together despite their personal differences and weaknesses and collaborated to create something truly incredible and to drive change."

Driving positive change is also something that motivates Brian. His goals for Engineering include finding cost effective, innovative, engineering-based solutions to sustain best business practices. This means aligning project scope with business needs, supporting new product development, and ensuring effective project management to meet business benchmarks and contend with competition. Brian has also recently assumed responsibility for the newly integrated US Pharmaceuticals organization, affording him further opportunity to leverage best practices and competitive cost advantage for J&J.

Most important to Brian is developing his team. One of the biggest goals in his new position is identifying specific growth opportunities for his people. "I feel proud when I can look back at the people I've helped, and see how they've grown and achieved success."

For me, success is found when exploring new ideas, challenging what I've done in the past, and maintaining a sense of humility. It means looking outside of J&J at other parts of the pharma and non-pharma worlds for new and innovative solutions."

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World Water Day 2008 – Cleaner Water, Better Health

You don't need to be an ecologist to see that our natural resources are in danger, especially our most important natural resource - water. According to the World Water Council, booming growth in the human population correlates to an increased demand for freshwater that often goes unmet, especially in poorer, under-developed countries. What's worse is that areas with inadequate sanitation, the limited supply of fresh, clean water can become tainted with diseases. As a result, the United Nations has themed this year's World Water Day, celebrated on March 22, 2008, as the International Year of Sanitation.



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World Water Day stemmed from the 1992 United Nations Conference on Environment and Development (UNCED), and was quickly adopted as an international observance. Each year a different theme is recognized, and efforts are made to raise awareness and bring about change in that specific area. This year's theme, Sanitation, will narrow in on topics like promoting hygiene, sanitary facilities, water quality, the treatment of wastewater, and sewer systems.

According to WaterPartners International, every 15 seconds a child dies from a water-borne disease, the leading cause of death and illness in the world. The lack of access to safe water leads to a perpetual cycle of disease and death.

So how, as individuals and as the GBSC, do we help? We can study how we use water on a daily basis, both individually and as a company, and find ways to improve our water consumption. Water conservation is key, and the smallest change in our consumption habits can significantly contribute to a global effort.

"With our planet's changing climate, we don't know what's coming in the future," says **Sandy Yee**, Director, GBSC Worldwide Environmental, Health & Safety. "It's important to be as efficient as possible with our resources."

Tips for Conserving Water

- Shut off the water supply to equipment and areas that are unused.
- Wash only full loads in dishwashers.
- Avoid runoff. Make sure sprinklers are directing water to landscape areas, and not to parking lots, sidewalks, or other paved areas.
- Repair leaking faucets.
- Shut off water-cooled air conditioning units when not needed, or replace water-cooled equipment with air-cooled systems.
- Use a broom, rather than a hose, to clear sidewalks, driveways, loading docks and parking lots.

For more information on World Water Day [visit www.worldwaterday.net](http://www.worldwaterday.net).

"WaterPartners International Observes World Water Day." WaterPartners International, March 22, 2007.
"Water Conservation @ Work." Southwest Florida Water Management District.

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What Technology Has Changed Your Life?

Twenty years ago, who would have thought that we could download thousands of songs into a machine no bigger than a credit card, have immediate access to millions of resources from across the globe with the simple click of a button, or drive a voice-activated car? Yet we have witnessed the extraordinary evolution of technology in a relatively short period of time and each have a story of its impact on our lives.

Several of our employees took a moment to share a few personal experiences on how technology has made a difference to them:

Juan Salas OTS Scientist Manati, Puerto Rico

"The memory card has changed my life. While I worked on my master's degree a few years ago I had to carry a box of computer discs, each one containing a part of my thesis work. Shortly after that, the zip disks and CD writers became available, but nothing was as impressive and successful as the memory card. Today, I have memory cards with the same capacity as a small computer. I can easily use them in my computer, digital camera, or MP3 player, and no special connection or installation is required. The massive amount of information that can be stored in these small cards is amazing. I can use them to save or back up information, music, pictures, videos, presentations, tables and more."



Juan Salas



Arjan Schuijjer

Arjan Schuijjer BTO Shift Team Leader Leiden, Netherlands

"Three years ago, I had been visiting Internet cafes now and again to communicate with friends and family via email. I eventually decided to purchase my first Personal Computer. Once I started using it, I realized how much it influenced my life...more than I had expected. Soon daily activities were a little easier – I could check for movie times and locations, find cheap phone tariffs for international calls, download music, and even shop for airplane tickets. The computer has also helped me through my management studies, simplifying the writing and editing process of my papers. Soon I found using the computer became part of my daily life, switching it on, checking email and surfing the Internet. Now I can't imagine my life without it."

Jean Luo Senior Scientist Raritan, New Jersey

"The Internet has greatly changed my life, both at work and at home. As a scientist, the Internet is a remarkable research tool that has enabled me to work quickly and effectively. With the ability to search through millions of articles within seconds, I can learn about ongoing work that pertains to my research much more efficiently than in previous years when I would waste my time flipping through scientific journals."



Jean Luo

Two summers ago, the Internet proved to be a lifesaver when I broke my ankle playing volleyball. While I was immobilized for several weeks, I could keep in touch with friends and colleagues through email, as well as stay up to date on world news."



Sinéad Collins

Sinéad Collins Projects Accountant Cork, Ireland

"I was slow to warm up to popular technological trends. However a recent discovery has indeed changed my life. And rather than dragging me into the 21st century, I am now skipping merrily in that direction. While recently traveling across Dublin and cursing my inherited lack of direction, I had no choice but to adopt the Satellite Navigation System (or Betty, as I call her). I was fascinated by the ability to enter in the exact street and house number and watch the route being calculated. I was then carefully guided across the city, complete with traffic alerts, and as I drove up to my location Betty stated 'Your destination is on the right!' I am converted."

Reggie Lambert Technical Associate II, Production Support St. Louis, Missouri

"In all honesty, I cannot name a single technological advancement that has changed my life in comparison to changing my job. What has changed my life most profoundly has been working in the Bio Tech Industry. From the moment I started at this site in 1988 my friends and family commented on the change in me. After working 27 years in steel/hardware, working in biologics has shown me what it means to have meaning in what you do. Medicines make such a huge difference in the lives of our patients. Here, I feel I am doing something that is going to help people."



Reggie Lambert



Cortney Moak

Cortney Moak, Senior Process Engineer Horsham, Pennsylvania

"As a working mother who travels with my job, I would have to say the capability of remote access makes a significant difference in my life. It affects both my work and my personal life. Having the ability to work anywhere in the world, allows me to stay connected to other projects that are ongoing in the U.S. while I am working at one of our European sites. Work life balance is so important, and having remote access has allowed for flexible work arrangements and given me the ability to manage both my work and family life. It ensures that I can stay connected, no matter what situation arises. When I need to be home to take care of my daughter, I am still able to connect to work and contribute to the business. I don't know how I would live without it."

Polly Toomey Associate Scientist, Quality Control Malvern, Pennsylvania

"By and large the biggest technological advancement that has made my life easier is the LIMS (Laboratory Information Management System) system. LIMS is a tracking system that allows us to look up the location of samples and the status of testing. Prior to its introduction, every piece of information regarding each sample had to be manually logged into a book. Now people who submit samples for testing simply log onto LIMS and each sample is assigned a number. The system automatically shows what testing needs to be performed. This has literally saved at least 4 hours per day. Obviously anything that makes my job that much easier ranks at the top of my list."



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First Quarter 2008 Service Recognition

Congratulations to all our GBSC coworkers who are celebrating landmark years of service in the first quarter of 2008!

25 Years

Claudia Cobble Malvern
Iris Torres-Rodriguez Manatí

20 Years

Basant Sharma Horsham
Art Jurema Horsham
Ruud Huisman Leiden
Fenna van Bennekom Leiden
James Kozak Malvern

15 Years

Annabelle Villalobos Raritan
Renzhe Jin Raritan
Jackie Arnett Zug

10 Years

Dirk van Eck Leiden
Jochum Soetenga Leiden
Nienke Vriezen Leiden
Ton Peschier Leiden
Astrid Grisel Leiden
Leyla Terlemis-Kirin Leiden
Roderick Rijdsdam Leiden
Henk van 't Wout Leiden
Willem Verhoeve Leiden
Kassandra Pool Leiden
Linda Dofferhoff-Oversluisen Leiden
Anneke Schouten Leiden
Eunice de Meza Leiden
Tony Grune Leiden
Marijana Lorenc-Banic Leiden
Roelof Bosscher Leiden
Inge Batten-van Nieuwenhoven Leiden
Dewy Janssen Leiden
Chris van Veen Leiden
Paul van Westbroek Leiden
Carlos Colon-Torrado Manatí

5 Years

Mark Mischinski Horsham
Marsha Major Horsham
Ken Sabatino Horsham
David Zabele Horsham
Wayne Dotta Horsham
Peter Heckman Horsham
Bas Moleman Leiden
Karin van Cleef Leiden
Lucienne van Dorp Leiden
Noureddine Hashas Leiden
Ryashad Kallan Leiden
Margaret Hopkins Leiden
Edwin van Duyn Leiden
Gulsah Celik Leiden
Martijn Goedhart Leiden
Marcel Flikweert Leiden
Johnny Batten Leiden
Kariem El Haddad Leiden
Esther Poelwijk Leiden
Lex van Paassen Leiden
Jacqueline Mos Leiden
Jan Willem Nijgh Leiden
Martin Friemann Leiden
Michel Osephius Leiden
Myrto van Weerdenburg Leiden
Autumn Reese Malvern
B. Todd Yeager Malvern
Pamela Klingensmith Malvern
Michael Goldsmith Malvern
Ana Cataldo Malvern
Beth Glass Malvern
Brett Ware Malvern
Robert Myers Malvern
Patricia Kelleher Malvern
Lance Pinos Malvern
Michael Mcerlean Malvern
Jennifer Curvey Malvern
Kristen Baird Malvern
John Andrews Malvern
Jiemin Wang Malvern
Kenneth Moyer, Jr. Malvern
Sharon Quay Malvern
Bradley Rank Malvern
Kimberly Rapp Malvern
Chad Barshinger Malvern
Jamine Jesse Malvern
Melanie Antesberger Malvern
John Salley Malvern
Leslie Horton Malvern
Tam Lam Malvern
Lawrence Barnes Malvern
Michael Strehle Malvern
Christopher Rode Malvern
Chao Wang Malvern
Gilberto Valls-Torres Manatí
Peter Vera-Rivera Manatí
Marem Cintron-Lopez Manatí
Ana Llitera-Colon Manatí
Ediberto Jimenez-Torres Manatí
Mayra Rodriguez-Martinez Manatí
Michelle Coslit Raritan
Tridarshi Shah Raritan
Forrest Laramore St. Louis