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CATALYST

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Four Gross-to-Net Pitfalls to Avoid

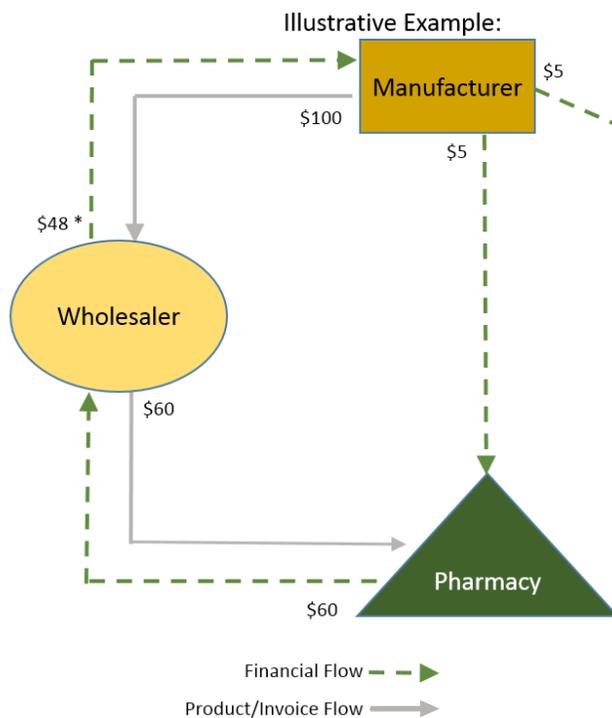
By Phil Bergamo

Gross-to-net (GTN) revenue accounting permeates life sciences, especially the sale of pharmaceutical products. Many companies use third parties to commercialize their products by working with distributors in order to maximize distribution efficiencies and penetrate a large customer network. In exchange for services, distribution companies receive discounts (typically between 2% and 5% of list price) and rebates that reduce the gross selling price realization. Other pricing adjustments impact the gross selling price such as chargebacks, government rebates and sales returns.

Rebates – Primarily relate to distribution fees paid to distributors and other service providers. The pricing adjustment can be a percentage of the selling price or a per-unit rebate (fixed dollar amount per product sold).

Medicaid Rebates – Discounts and rebates provided to governmental entities that are paid to the states by the manufacturer.

Returns – Manufacturers generally accept returns from six months before to 12 months after the products' expiration date.



| Category | \$\$ | Estimated Days Until Credit Is Taken |
|---|-------------|--------------------------------------|
| WAC (List Price) | \$100 | 0 days |
| Chargeback Deduction | (40) | 30 days |
| Rebate Deduction (Wholesaler Service Fee) | (10) | 30-60 days |
| Prompt-Pay Discount | (2) | 60 days |
| Wholesaler Discounts | (52) | |
| *Payment from Wholesaler | 48 | |
| Medicaid Rebate | (5) | 90 days |
| Pharmacy/Group Purchasing Organization | | |
| Rebate (Pharmacy) | (5) | 60 days |
| Return Accrual | (2) | 365 days+ |
| Net Sale (Revenue Recognized) | \$36 | |

GTN, the accounting for pricing adjustments, represents the difference between the gross price/wholesaler acquisition cost (WAC) and the net sale recognized. Pricing adjustments are a significant percentage of the WAC price and can reduce it by as much as 70%. The most prevalent pricing adjustments are:

Chargebacks – Distribution companies purchase drugs from a manufacturer at a gross price (the WAC) and sell them to consumers at a different contract price. When the consumer contract price is lower than the WAC price, the distributor minimizes losses by charging the manufacturer for the difference.

GAAP accounting requires that the selling price to the buyer is substantially fixed and determinable at the point of sale, and the amount of future returns can be estimated in order to recognize revenue. Pricing adjustments may not be deducted by customers for months, or even years, after the product is sold. The new revenue recognition standard—effective for public entities beginning after December 15, 2017, and one year later for all other entities—places a significant burden on companies to estimate all pricing adjustments when the product is sold. Thus, it becomes critical to develop systems and processes that can capture these deductions in detail and in a timely fashion. Pricing adjustments would be accounted for as contra-sales (sales

deductions) and as reductions to accounts receivable or liabilities at the time the product is sold. Accounting for pricing adjustments should result in a value that closely resembles the amount that companies anticipate collecting from their customers. Some common challenges companies face with respect to accounting for pricing adjustments include:

1. Insufficient systems and procedures to account for pricing adjustments

The amount and form of data related to pricing adjustments is substantial. With possibly a tremendous amount of data, the pricing adjustments can be communicated via electronic transfer, paper documents, PDFs or Excel spreadsheets. Companies without adequate systems and processes to accumulate and process this data are at a significant disadvantage when it comes to understanding their products and profitability. Robust processes and systems give companies the appropriate and detailed information that can ultimately lead to better decisions regarding the viability and profitability of products, forecasting and budgeting, negotiation of the price of products with customers, and accounting for the transactions such as including the set up of appropriate accruals and processing transactions in the order-to-cash cycle.

“THE NEW REVENUE RECOGNITION STANDARD—EFFECTIVE FOR PUBLIC ENTITIES BEGINNING AFTER DECEMBER 15, 2017, AND ONE YEAR LATER FOR ALL OTHER ENTITIES—PLACES A SIGNIFICANT BURDEN ON COMPANIES TO ESTIMATE ALL PRICING ADJUSTMENTS WHEN THE PRODUCT IS SOLD.”

2. Inability to verify pricing adjustments taken by customers

Recent consolidations in the pharmaceutical industry have resulted in a greater concentration of business with distributors—increasing the negotiating power that they have with manufacturers, and resulting in lower prices and more marketplace volatility. This volatility makes it paramount that companies understand the deductions their customers take so

that they can manage their portfolios. Without the ability to accumulate pricing at the product level, manufacturers are vulnerable to not having the ability to verify and substantiate pricing adjustments taken by customers or identify market trends that directly affect product profitability.

3. Audit compliance and financial reporting

The inability to accumulate and process data related to pricing adjustments could also result in significant true-ups in estimates of pricing adjustments, delays in the ability to recognize revenue until pricing adjustments can be determined and properly supported, and the inability to properly substantiate revenue recognition estimates.

4. Profit-sharing arrangements

In product profit-sharing arrangements, poor accounting for pricing adjustments could result in inaccurate information provided to partners, difficulties in responding to partner inquiries regarding developments in the market and pricing for specific products, and loss of partner trust as it relates to reporting of results and sharing of profits.

In order to mitigate the aforementioned challenges, you must develop an efficient model to accumulate, monitor, account for and analyze pricing adjustment data. Companies should also develop detailed analytics to understand trends and the magnitude and appropriateness of customer pricing adjustments. The most successful companies use a combination of in-house technology (adequate ERP and general ledger systems) and third-party resources. Take seriously having adequate and clearly documented controls and procedures to validate pricing adjustments. An appropriately designed system facilitates the information needed to fully understand and analyze the market, profitability and trends in products so that you can make informed business decisions.

Phil Bergamo is a senior manager overseeing engagement teams that perform audit, consulting and transaction services for clients in a variety of industries including technology and life sciences. Contact him at phil.bergamo@eisneramper.com or 732-243-7569.

3D Printing Puts the “Tech” in Biotech

By Phil DiBartolomeo

The life sciences sector has experienced several significant changes that have driven innovation over the past few decades. Advances in technology have dramatically changed how life sciences utilize genetic engineering to rapidly analyze human populations, viruses and bacteria—leading to much more effective treatments. Increases in computing power have allowed researchers to model viruses and protein folds with detail never thought possible, allowing them to better understand potential drug interactions and effects prior to animal and human testing. Finally, advances in material science have led to new categories and uses of medical devices.

Areas of material science that have enormous potential are 3D printing and its cousin, bioprinting. They can generally be defined as making a physical object from a three-dimensional model by layering many thin layers of material in succession and then using such three-dimensional

This let companies quickly and easily produce new tooling, dies and castings that allowed them to investigate new designs and product changes. In 2002, researchers created miniature functional kidneys by printing cells directly onto a synthetic scaffold. The industry took another major step forward in 2006 when selective laser sintering machines fused materials onto these scaffolds, which allowed for much more significant customization and higher manufacturing yields. This led to another milestone in 2008 when the first person walked using a prosthetic limb that was printed entirely without any assembly.

THE MARKETPLACE

According to *3D Printing Progress*, the 3D printing industry is estimated to grow to approximately \$6 billion by 2024. Prosthetics, knee and hip replacements, implants, hearing aids, tissue and medicines are expected to drive 3D-printed biotech products.



printing to layer living cells to create biological tissue and organs. 3D printers typically function like a standard inkjet printer, but they utilize materials such as plastics or polymers to create new objects.

HISTORY

3D printing began with industrial applications in the 1980s and 1990s and was initially focused on rapid prototyping.

Prosthetics are one of the major (and more obvious) choices for 3D printing. Fitting a prosthetic to an individual and his/her unique circumstances has been one of the challenges with traditional prosthetics. Additional surgery was often needed to modify implants and bones to fit a fairly standardized implant. Now, with 3D printing, it is easier to customize each implant for a specific fit and design. This has led to enhanced quality of life for many patients,

particularly children. These young patients would outgrow costly prosthetics at a rapid rate; now 3G-generated prosthetics can be utilized more quickly and affordably than before.

Implants are another area with multiple applications. These can range from knee and hip replacements to dental and oral implants to bone—again, enhancing quality of life at a lower cost.

Hearing aids have become another (so far little-noticed) area for 3D printing. Each person's ear canal is different, leading to fitting issues with mass-produced tips. According to *Forbes*, the majority of hearing aids are now manufactured using a 3D process. A patient can visit a doctor's office, have his/her ear scanned with laser and digital cameras, and receive the end product—all in under a day!

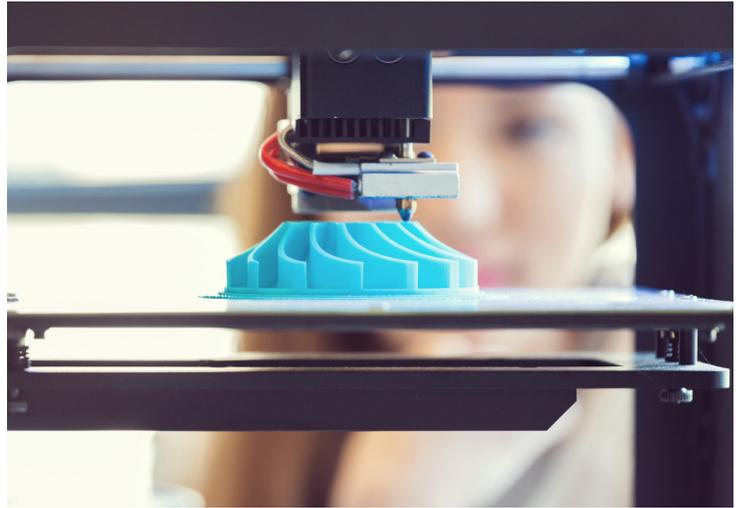
Tissue, organs, bones, muscle and skin 3D printed to match samples taken from a patient in order to decrease rejection are on the drawing board and will hopefully be the norm one day.

Medicines produced via 3D printing, which can be tailored to each patient to provide a more fine-tuned drug delivery, are being researched by biotechnology companies.

“A GOOD FIRST STEP IS UNDERSTANDING YOUR SUPPLY CHAIN AND HOW QUICKLY YOU MAY NEED TO ADDRESS PRODUCT CHANGES IN YOUR MARKETPLACE.”

HURDLES

The 3D printing industry continues to grapple with issues such as safety confidence, regulatory concerns and high expectations. And while 3D printers offer significant benefits, there are those who worry about such things as patent infringement or the production of products for nefarious purposes. Researchers will need to be vocal and thorough in conveying the efficacy of 3D bioprinting to the regulating authorities and end users. Those hurdles aside, the use of 3D and bioprinting may offer another golden age of medicine.



BUSINESS IMPACT

What should a CFO or someone in a similar position consider when it comes to 3D printing? A good first step is understanding your supply chain and how quickly you may need to address product changes in your marketplace. Are you rapidly developing a new product with multiple iterations, or do you have a need for an automated process to produce customized parts? A 3D printing process could help you to respond to these needs effectively and cost-efficiently. Alternatively, what if you're looking to invest in a company's 3D printing process? It is important to understand where that company is using its 3D printed parts, specifically related to their reliability, regulatory effect and cost.

Phil DiBartolomeo is an audit director at EisnerAmper LLP. He has significant experience assisting clients in the technology and life sciences sectors. As a member of the firm's innovation initiative, Phil also focuses on how companies are affected by rapid changes in technology. Contact him at 212-891-4228 or philip.dibartolomeo@eisneramper.com.

Meet the Practitioner

Allie Colman



Allie Colman is a senior tax manager with approximately 10 years of public accounting experience. She serves clients primarily in the life sciences, manufacturing and distribution, biotechnology and retail industries. Allie works with large corporations,

both public and private, on multistate returns and tax provisions. In addition, Allie created and leads the new-hire training, and she is involved in the recruitment of new employees in the firm's New Jersey office. She likes to spend time with her 10-month-old son, Sean, and enjoy a glass of wine with her family at the Jersey Shore.

Learn more about Allie at eisneramper.com/alexandra-colman.

App Spotlight

The Chemical Touch: Lite Edition



The Chemical Touch, Lite Edition, is a free and simple-to-use periodic table of elements for iOS devices. It consists of a simplified version of the periodic table of elements display that puts the masses, densities, melting and boiling points, radii and electro-negativities of the elements at your fingertips.

EisnerAmper LLP does not endorse this app or warrant that this app is appropriate for any particular business.

Events Calendar

| HOST | EVENT | DATE |
|-----------------------|--------------------------|-------------|
| NJ Technology Council | Venture Conference | April 12 |
| BioNJ | BioPartnering Conference | May 3 |
| Life Sciences PA | Spring Social | May 3 |
| PA PACT | Enterprise Awards | May 9 |
| NY Bio | Annual Meeting | May 16 & 17 |

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