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Genentech Move Nixes Hospital Discounts **Avastin, Herceptin, Rituxan Now Sold Under Tighter Control by Drug Maker**

By Paul Goldberg

A move by Genentech has eliminated discounts and rebates hospitals receive when they purchase three of the company's top-selling infused cancer drugs.

Beginning Oct. 1, hospitals can now order Avastin (bevacizumab), Herceptin (trastuzumab) and Rituxan (rituximab) exclusively from six specialty distributors authorized by the drug maker.

Genentech said the move will bypass more than 80 full-line wholesale drug distribution centers, with the objective of enhancing efficiency and security of the supply chain for these widely used medications.

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Conversation with The Cancer Letter

"These are Life-Saving Drugs. I'm Not Going To Stop Treating Patients, Right?"

The loss of discounts and rebates hospitals received for administering Genentech's Avastin, Herceptin and Rituxan will increase costs to patients, said Scott Soefje, director of pharmacy at University Medical Center Brackenridge in Austin.

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Fake Avastin, Paid for by Medicare, Administered to U.S. Patients

By Will Craft

Two years ago, British authorities tested a shipment of chemotherapy drugs headed for North America.

They found that the agent, labeled as Genentech's Avastin, contained no trace of Avastin's active ingredient. The drugs were on the way to Canada, where they were to be sold to doctors throughout the U.S.

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Discounts were Worth Millions To Some Cancer Centers

(Continued from page 1)

The switchover and the reactions it has triggered over the past two weeks offers an opportunity to observe the workings of the byzantine system of drug distribution in the U.S.

To America's cancer centers and hospitals, Genentech's move will mean the end of discounts and rebates hospitals received from wholesalers. At some institutions contacted by The Cancer Letter, rebates on these three drugs added up to hundreds of thousands of dollars. The largest centers expect to lose millions.

According to the IMS Health National Sales Perspectives, in 2013, U.S. sales of Rituxan were \$3.3 billion; Avastin made \$2.7 billion; and Herceptin \$1.9 billion. The prices are tracked on the wholesale level.

"Genentech is committed to patient safety, to protecting the integrity of our medicines as they move through the supply chain, and to ensuring patients and healthcare professionals are able to access its medicines when they need them," the company [said in a letter](#) to hospital pharmacy and purchasing managers. "As part of this commitment, Genentech regularly assesses its distribution models and works with its authorized distributors to ensure we utilize the most appropriate distribution model for each of its medicines based on its unique characteristics."

In the letter, dated Sept. 16, Genentech said there would be no change to the list price or wholesale acquisition cost of these three drugs. Change was swift. Hospitals had only two weeks to mount opposition.

Editor & Publisher: Paul Goldberg

Associate Editor: Conor Hale

Reporter: Matthew Bin Han Ong

Intern: Will Craft

Editorial, Subscriptions and Customer Service:

202-362-1809 Fax: 202-379-1787

PO Box 9905, Washington DC 20016

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"The loss of wholesaler rebates will transfer a significant financial burden directly to care providers, which ultimately will be passed on to patients," the Hematology/Oncology Pharmacy Association [said in a letter to Genentech](#). "This dramatic increase in the overall cost of healthcare comes at a time when reducing costs is a primary focus for institutions and providers who strive to provide the highest quality care for cancer patients."

Responding to questions from The Cancer Letter, Genentech spokeswoman Charlotte Arnold said that the company is "not privy to the terms between hospitals and distributors, or what hospitals charge the patient for the medicine." Arnold said the company doesn't anticipate the switchover will result in any change in patients' insurance or out of pocket cost responsibility.

Specialty distribution services are owned by the wholesalers. The six chosen distributors are [ASD Healthcare](#) (a division of AmerisourceBergen Specialty Group); [BioSolutions Direct](#) (also a division of AmerisourceBergen Specialty Group); [Cardinal Health Specialty Distribution](#); [McKesson Plasma and Biologics](#), [Morris & Dickson Specialty Distribution](#), and [Smith Medical Partners](#) (a division of H.D. Smith).

The structure of Genentech's relationship with full-line wholesalers and specialty distributors isn't publicly known.

Genentech, a unit of Roche, first tried to move these same drugs to specialty distributors in 2006, but reconsidered after triggering fierce opposition from cancer centers. Though distribution of Avastin, Herceptin and Rituxan remained unchanged at that time, newer cancer drugs made by Genentech as well as other manufacturers were being launched into the specialty drug distribution channels.

Avastin recently emerged as the target of counterfeiting, which exposed U.S. patients to agents that either contained no traces of the active ingredient or weren't properly stored during shipment.

A story about the U.S. federal government's pursuit of smugglers of counterfeit drugs and the doctors who purchased these drugs and infused them in patients appears on page 1 of this issue of The Cancer Letter.

"We are committed to patient safety, to protecting the integrity of our medicines as they move through the supply chain, and to ensuring patients can access them when they need them," Arnold said to The Cancer Letter.

"We believe the specialty distribution model best serves patient safety and access to our infused cancer medicines, which are complex medicines that have lengthy manufacturing processes. They require special storage and handling, and require tighter inventory

management than many other medicines.”

Critics point out that pharmacists at hospitals and cancer centers were not among people prosecuted for importation, distribution and infusion of fake Avastin. Counterfeit drugs went to small private practices, which were seduced by low prices and, for whatever reasons, suspended disbelief when drugs arrived in small boxes from Canada. (Labels in Turkish might have been a clue as well. See story on page 1.)

Private practices aren't affected by the change that took effect Oct. 1. Office-based oncologists have been buying drugs from specialty distributors for years, and the counterfeit Avastin caper was an effort to bypass those channels.

“I do believe that in their heart and mind [Genentech officials] believe that this is going to improve their supply chain and their ability to supply drugs,” said Scott Soefje, director of pharmacy at the University Medical Center Brackenridge in Austin and president-elect of Hematology/Oncology Pharmacy Association. “But reality of the world is, there has never been a shortage, and we have never had an issue in the hospital setting with counterfeit drugs at this point in time.”

A conversation with Soefje appears on page 1 of this issue of The Cancer Letter.

Genentech Sales Reps Banned from Campuses

Several institutions said they have barred Genentech sales reps from showing up on campus. However, an all-out boycott of the company is not an option for hospitals and cancer centers.

“These are life-saving drugs,” Soefje said to The Cancer Letter. “I am not going to stop treating patients; right? So what happens is I am going to end up eating whatever loss I have. It basically becomes an unbudgeted price increase for me. And, at some point in time, because we can't afford to go bankrupt, we are going to start passing on the increased costs to patients.

“And ultimately, whether Genentech believes this or not, the long-term impact of this is to harm patients. They are the ones who will individually end up paying for this, because their copays are percentage copays.”

Reacting to the company's move, the American Society of Clinical Oncology said it's “concerned about the potential impact of Genentech's business decision on patient access and quality of care, especially for the vulnerable populations served by 340B-covered entities.”

Many drug-makers dislike the 340B program because it forces them to extend deep discounts to clinics that serve rural or underprivileged populations. The program allows these clinics to get discounts on

drugs used to treat the insured and paying patients alike.

According to ASCO's [statement](#), “the impact of this development underscores the need to reform a patchwork payment system, which is increasingly challenged in its ability to cover the cost of patient care.”

Genentech officials say the 340B program isn't being singled out in the shift. “The change applies to all hospitals, regardless of 340B status,” Arnold said. “It does not impact access to 340B discounts for hospitals that are 340B eligible.”

Since 340B hospitals buy drugs at heavily discounted prices, the loss of rebates and discounts may be smaller at these institutions (The Cancer Letter, [June 13](#)).

“Genentech's decision to move the world's top three cancer drugs to a specialty distribution channel will raise the cost of these already expensive medicines by tens of millions of dollars for all hospitals, including those in the safety net,” the Safety Net Hospitals for Pharmaceutical Access, a Washington group representing 340B hospitals, said in a statement to The Cancer Letter.

“Providers that serve high percentages of the nation's needy run on thin margins and can least afford this dramatic cost increase. The change financially benefits stakeholders in Genentech's specialty distribution channel at the expense of healthcare providers.”

Andrew Crawford, manager of the University of Illinois oncology pharmacy, said he isn't especially worried.

“It may, in a small way, impact our wholesaler rebates,” said Crawford, whose institution buys drugs through 340B and the Medicaid program.

So far, the shift has meant moving the purchasing of three Genentech drugs from one part of McKesson Corp. to another, Crawford said to The Cancer Letter.

Responding to the letter from the Hematology/Oncology Pharmacy Association, Genentech officials [pointed out](#) that the company's recently-launched products are supplied through specialty distribution channels.

“We have experienced firsthand the benefits of the specialty distribution model with our recent oncology launches, and we are confident in the ability of these authorized specialty distributors to successfully serve their customers,” the Genentech letter states. “We also understand that many of your members have been using this model to purchase other specialty medicines.”

Three of Genentech's most recently approved infused cancer drugs—Perjeta (pertuzumab), Kadcyla (ado-trastuzumab emtansine), and Gazyva (obinutuzumab)—were launched into specialty distribution channels.

Other cancer drugs sold through specialty

distributors include Dendreon's Provenge (sipuleucel-T), Bristol-Myers Squibb's Yervoy (ipilimumab), Merck's Keytruda (pembrolizumab), Gilead's Zydrelig (idelalisib), Onyx's Kyprolis (carfilzomib), Eisai's Halaven (eribulin mesylate), and Seattle Genetics's Adcetris (brentuximab vedotin).

Echoes of 2006?

In 2006, Genentech announced a similar plan to move these three drugs to specialty distribution, causing an outcry from the cancer centers that make up the National Comprehensive Cancer Network.

The distribution plan threatened to alter the "business model" of academic cancer centers, then NCCN CEO William McGivney wrote to Genentech.

"In view of the fact that we represent twenty preeminent cancer centers across the country, we do believe that we have a unique role to play in resolving what has clearly become a very intense issue between Genentech and our member institutions," McGivney wrote in a letter dated April 13, 2006. "Many of our member institutions have expressed a strong desire to work with Genentech on developing a future-oriented distribution model that would address some of their concerns while allowing Genentech to achieve its goals of increased efficiency, control and security for distribution of Avastin, Herceptin and Rituxan."

McGivney offered to act as a "convener and facilitator of a dialogue" between pharmacists at NCCN institutions and Genentech's top leadership. The letter is posted [on The Cancer Letter website](#).

At that time, change was announced in April, but the switchover to the new distribution system was to start in June. NCCN said it's concerned about the recent change.

"We are especially concerned because of the vital role that these three agents play in the treatment of patients with cancer, and the significant barriers and burdens that the new policy produces to providing optimal oncology care," the statement said.

"We appreciate Genentech's stated goal of improving patient safety, integrity of the medicines, and ensuring access. However, the NCCN Member Institutions are concerned that this change will have a strongly negative impact on business processes, facility demands, patient access, and financial demands on patients."

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Conversation with The Cancer Letter **Soefje: Genentech Decision an "Unbudgeted Price Increase"**

(Continued from page 1)

Soefje, who is also president-elect of the Hematology/Oncology Pharmacy Association, spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *Genentech is talking about drug integrity issues here, and referring—by name and not by name—to the Turkish Avastin caper [See Story on page 1]. Is it relevant here?*

Scott Soefje: Drug counterfeiting is something we are always concerned about. Congress has enacted a pedigree law, the Drug Supply Chain Security Act, that goes into effect in January, in which the manufacturers and the wholesalers would have to provide to the ultimate users the documentation that the supply chain was secure and that this drug is actually what it says it is.

PG: *However, community practices were buying drugs through specialty distributors for years. And the Turkish Avastin case was a way to circumvent those channels. Do you know anybody in any hospital who was in any way involved in this? How does this connect? I've gone through every one of those cases, and I don't see a single hospital pharmacy involved here.*

SS: And it's not. It's smaller practices who are getting squeezed by reimbursement, looking for a way to reduce costs. I used to get cold calls on a daily basis from people going, "I can help you save money. Would you be interested in buying drugs from us?"

And you have to do your diligence. Most hospitals, because we have contracts with the big, reputable companies, don't face these issues on a regular basis.

PG: *Does this switch to specialty distributors have anything to do with the Turkish Avastin?*

SS: I can't speak to why Genentech chose to do this. I do believe that in their heart and mind they believe that this is going to improve their supply chain and their ability to supply drugs.

But reality of the world is, there has never been a shortage, and we have never had an issue in the hospital setting with counterfeit drugs at this point in time. We are in a situation where, yes, they may believe it, but the general belief among hospital pharmacists is this is coming down to a financial decision.

PG: *How does that financial decision hurt you? Are you not going to get the discounts you have been getting? How large are those discounts and rebates?*

SS: It all depends upon the contract that you've

negotiated with your wholesaler. Every hospital negotiates with their wholesaler and gets what's called a cost-minus discount. So they give a discount based upon the cost of the drug. In most institutions, it will run somewhere between 2 and 5 percent.

And then you also get discounts based upon volume purchases, and there are other incentives that can be built in. Every hospital has a different contracting system. We can't sit here and say that across the board, this is going to hurt X percent.

What we are hearing from the group purchasing organizations who negotiate these contracts is that nationally it's probably going to be a half-a-billion-dollar impact on the system.

PG: *What about your institution? What do you expect to lose?*

SS: Actually, my particular institution isn't going to be heavily hit, because we have a lot of indigent patients, and we tap heavily into patient drug assistance programs. Our network—we are part of the Ascension Network—is estimating a \$30 million hit.

PG: *Since we are talking about 340B, do you expect 340B to be impacted in any way at all?*

SS: I lose again. The 340B discounts will be less, but it will be impacted by 2 or 3 percent.

PG: *But on a smaller base, because of the 340B discount.*

SS: Exactly.

PG: *These are among the biggest drugs in oncology; right?*

SS: They are probably—in most cancer hospitals—three of the top ten drugs they dispense. In most institutions, Avastin is either the No. 1 or No. 2 drug. Rutuxan is usually in there, pretty high. It depends on your breast cancer population whether your Herceptin is pretty high or not. So it's probably No. 2—or 4 or 6, or something like that.

PG: *In recent years, Genentech's new drugs have been going to specialty distributors.*

SS: And I think that's why Genentech thought that this wouldn't be a big deal, because their last two launches went into specialty distribution.

PG: *What can you do then? Anything?*

SS: Unless they choose to change it, there is nothing I can do.

These are life-saving drugs. I am not going to stop treating patients; right? So what happens is I am going to end up eating whatever loss I have. It basically becomes an unbudgeted price increase for me. And, at some point in time, because we can't afford to go bankrupt, we are going to start passing on the increased costs to patients.

And ultimately, whether Genentech believes this or not, the long-term impact of this is to harm patients. They are the ones who will individually end up paying for this, because their copays are percentage copays.

A number of institutions—and my institution is one of them—have banned the Genentech sales force from our facilities, as a protest basically.

Our big concern is, if Genentech gets away with it, who is to stop Amgen, and Pfizer, Lilly, and Merck from doing the same thing?

PG: *Is there anything we missed?*

SS: The hidden costs. Our clinic opens at 7:30 a.m. Our normal wholesaler delivery arrives at 6 a.m. So if I am short of a drug, I can order it by 5 p.m. the day before, and I can have it ready in the clinic, ready to treat a patient at 7 a.m. the next morning.

Now, it comes by FedEx. I don't get the FedEx delivery till 10 a.m. All FedEx packages go to the loading dock, whereas my McKesson delivery goes straight to the pharmacy. So I have a 30 to 45-minute delay by the time the loading dock processes it and gets it delivered to me.

So now I can't schedule patients early in the morning if I am concerned about running out of a drug. Or—and this is what's going to end up happening to most institutions—you end up increasing your on-hand quantity, and so you end up having inventory costs and carrying costs that you normally wouldn't have.

PG: *These can be large amounts of money, no?*

SS: It depends on the size of your institution. For an institution that uses millions and millions of dollars of these drugs, a half-percent change is a huge amount of money. And we are talking about these guys losing five, six, seven percent off their adjustment, plus additional inventory costs, and FedEx sends everything in a refrigerated shipping box, which now we have to throw away. It goes into waste management stream, which adds to our cost of waste management. All these are little hidden costs, but by the time you get done with it, it's a significant problem.

PG: *Do we actually know what happens in the black box of a relationship between a pharma company and a specialty distributor?*

SS: No.

PG: *Are drug companies making more money? They could be making less money for all we know. Do we know?*

SS: I would seriously doubt they are doing something that's making less money.

PG: *But we really don't know.*

SS: We do know a lot of the discounts that the

wholesalers give us for stocking and providing drugs are passed on from discounts that the manufacturers give the wholesaler. If Avastin is a more than \$2 billion drug, if you don't have to pass through even 1 percent, that's a lot of money. And when you multiply that times three, it adds up pretty quickly.

PG: *How does this change affect wholesalers? Are they different from specialty distributors?*

SS: The specialty distributors that are going to be able to dispense the drugs are in general subsidiaries of the major wholesalers.

So the wholesaler corporations don't lose any money. Their individual divisions might, but it's just shifting money around in that corporation's big buckets.

PG: *And the only people who are affected are...*

SS: The hospitals and patients.

Counterfeit Avastin Bypassed Specialty Distribution Channels

(Continued from page 1)

After this discovery and a subsequent investigation, FDA notified over 150 doctors across 33 states that cancer drugs they had purchased at strikingly low prices had been mislabeled, and thus considered unapproved and counterfeit.

The drugs, discounted by as much as 50 percent compared to U.S. market prices, might have been expected to raise suspicion.

The packaging—some marked in foreign languages, with versions of the drugs not approved for sale in the U.S.—might have triggered skepticism as well. Avastin, for example, was purchased by American oncologists under its Turkish brand name: Altuzan.

Less obvious was the fact that the Altuzan in question contained no trace of bevacizumab, and that some of the drugs brought in by these importers were improperly stored. Some doctors had been buying these drugs since 2007, documents show.

U.S. prosecutors say that many of the oncology practices had knowingly purchased these illegal drugs and administered them to patients. The practices then submitted reimbursement claims for the full price of the drugs—and pocketed the difference.

On Aug. 15, two years after discovery of the global scheme, FDA announced that a key supplier of the drugs, Sabahaddin Akman pled guilty to smuggling some of the counterfeits into the U.S.

The case against Akman, owner of Turkish drug wholesaler Ozay Pharmaceuticals, illustrated the complexity of one breach in the U.S. drug supply chain.

Court documents examined by The Cancer Letter reconstruct the scope of the investigation—showing how federal prosecutors pursued Akman, his associates, and the American oncologists and practice managers who, prosecutors contend, either knew or should have known that the drugs they were administering to cancer patients were mislabeled.

“Gifts” Came in Small Packages

According to the FDA Office of Criminal Investigations, Akman was arrested after his company was identified as the source of the counterfeit Altuzan.

Akman used his firm to procure the drugs and conceal them for shipment to the U.S., FDA said.

“Akman, along with his employee, Ozkan Semizoglu, obtained the illicit drugs and then used shipping labels to conceal the illegal nature of the shipments, including customs declarations falsely describing the contents as gifts,” the agency said in a statement. “They also broke large drug shipments into several smaller packages to reduce the likelihood of seizures by U.S. Customs and Border Protection authorities.

“Some cancer chemotherapy prescription drugs sent by defendant to the United States from Turkey had different lot numbers on the exterior packaging of the drugs than the lot numbers found on the actual vials of the drug inside the packages.

“Additionally, Akman shipped some prescription drugs that needed constant cold temperatures to maintain their stability and effectiveness in shipping boxes without insulation or any temperature protection whatsoever.”

Semizoglu has also pled guilty. The investigations of Ozay Pharmaceuticals and Akman involved law enforcement agencies from around the world, FDA officials said.

“These criminals exploited our most vulnerable patients when they arranged for their illicit drugs to be brought into the United States and used to treat cancer patients,” said Philip Walsky, acting director of the FDA Office of Criminal Investigations.

“We will continue to investigate and bring to justice those who prey on our ill, susceptible patients. We commend our colleagues—international, national, state, and local—whose contributions helped bring this case to a successful conclusion.”

Akman, was arrested in Puerto Rico in January, and faces fines of up to \$150,000, a \$150,000 forfeiture, and up to 20 years in prison. He is scheduled to be sentenced in November.

Prosecuting Oncologists In the Supply Chain

In September 2012, [FDA warned oncologists](#) about the counterfeit drugs and the legal consequences of having administered them to patients.

One version of the FDA letter to oncologists read:

“The U.S. Food and Drug Administration... has received information indicating that your medical practice purchased multiple medications from a foreign distributor named Clinical Care, Quality Specialty Products (QSP), Montana Healthcare Solutions, or Bridgewater Medical. Most, if not all, of the products sold and distributed by this distributor have not been approved by the FDA and may include counterfeit versions of Avastin or Altuzan.”

Many doctors were buying the counterfeit drugs as early as 2007—five years before FDA discovered them in 2012.

“These medical practices are putting patients at risk of exposure to medications that may be unapproved, counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous,” the agency’s letter said. “To minimize the chance of patients receiving an unapproved, counterfeit, unsafe, or ineffective medication, FDA is requesting that the medical practices stop administering drugs purchased from any foreign or unlicensed source.”

According to a statement by Genentech, the sponsor of bevacizumab, the counterfeit versions of the drug contained no active ingredients.

“According to the FDA, lab tests conducted by the FDA confirmed that at least one batch of the counterfeit version of Altuzan 400 mg/mL contains no active ingredient,” the company [said in an April 12 press release](#).

“FDA has advised that packaging or vials found in the United States that claim to be Roche’s Altuzan with batch numbers B6022B01 and B6024B01 should be considered counterfeit. The only Avastin (bevacizumab) that is FDA-approved for use to treat certain cancers in the United States is Avastin that is manufactured by Genentech. Even authentic Altuzan is only approved for use in Turkey and not approved for use in the United States.”

The Department of Justice initiated prosecution of several physicians, alleging that they had knowingly bought the unapproved drugs and administered them to patients—and sent the bills to Medicare and other payers.

In July, Hematology and Oncology Center of Somerset, Ky., and its former office manager, Natarajan Murugesan, pled guilty to introducing the mislabeled and unapproved drugs into interstate commerce.

The Cancer Letter found that at least five doctors

faced prosecution and had either been convicted or entered guilty pleas in cases that appear to be related.

According to court documents in the Kentucky case, over a period from January 2010 to July 2011, Murugesan bought large quantities of counterfeit versions of Avastin from Quality Specialty Products at a price that was substantially lower than the going U.S. price.

“On or about July 1, 2010, the defendant ordered a version of the prescription drug marketed in the United States as Avastin, an injectable prescription drug used in the treatment of cancer, from Quality Specialty Products,” court documents read.

In a separate civil case, which was concluded in January, Murugesan, the clinic, and N. Mullai, an oncologist there, agreed to pay \$2 million plus interest to resolve allegations that they had violated the False Claims Act by submitting bills to Medicare.

An investigation by the Kentucky Medical Board is underway, Bertha Wallen, the open records custodian at the state board, said in an email to The Cancer Letter.

Several of the doctors and clinics now facing prosecution purchased drugs from Montana Healthcare Solutions, also known as Quality Specialty Products, a firm whose former owner Paul Bottomly, pled guilty in 2013 to importing mislabeled and counterfeit drugs into the U.S., including the counterfeit versions of Turkish Avastin ([The Cancer Letter, July 25, 2013](#)).

At the time, [The Wall Street Journal reported](#) that the counterfeit Avastin originated in Turkey and traveled through a complicated chain of middlemen before arriving in England, where it was uncovered by British authorities.

Murugesan was buying large quantities of the mislabeled and counterfeit versions of Avastin from QSP between January 2010 and July 2011, documents state. QSP was selling counterfeit 400-milligram vials of Avastin for \$1,995, about \$400 below the market-value price of \$2,400.

After knowingly buying the counterfeit drugs, the company submitted reimbursement claims for the going price of the drug to Medicare, a violation of the False Claims Act.

Lawyers for Murugesan did not respond to requests for comments.

Many of the cases follow a similar pattern. Doctors or managers ordered their medicine from Quality Specialty Products or other distributors, rather than an FDA-approved source. They then submitted reimbursement claims to Medicare, Medicaid, and other health care benefit programs, the court documents said.

There have been at least four resolved cases relating to Quality Specialty Products:

- Though he was not on the list of doctors warned by FDA, Eduardo Miranda, a Laredo, Texas, oncologist, began ordering mislabeled chemotherapy drugs from QSP in 2007. He pled guilty to ordering five different drugs: Kytril, Taxotere, Zometa, Eloxatin, and Gemzar.

According to court documents, “These drugs were not approved for distribution or use in the U.S. and were misbranded as (1) the labels did not bear the ‘Rx Only’ language as required by the Good and Drug Administration; (2) the labels did not bear National Drug Code numbers that FDA-approved versions bear; and (3) some of them had instructions/labeling in other languages, such as French, contrary to FDA-approved versions.”

Miranda pled guilty to buying over \$745,600 dollars worth of the mislabeled drugs. Like the situation with McLeod Center, he mixed the drugs with approved versions and filed reimbursement claims with Medicare, Medicaid, and private insurance companies. He was sentenced to probation for five years and to pay full restitution for the unentitled reimbursement.

- In two related cases, Michael Dean Combs and William Kincaid, of McLeod Cancer and Blood Center in Tennessee, both pled guilty to knowingly buying the mislabeled and unapproved drugs, including counterfeit versions of Rituximab, which came labeled as MabThera.

According to court documents, the drugs purchased by McLeod originated in Switzerland and traveled through both India and the U.K. before being shipped into the U.S.

Starting in 2007, “Dr. Lamb [a doctor at McLeod] received a fax mailer from QSP which offered for sale certain prescription drugs, including chemotherapy drugs, along with price information for the drugs, the prices being less than what McLeod Cancer had been paying to purchase the drugs from FDA-approved sources in the U.S.

“A decision was made by Drs. Kincaid, Lamb, and Famoyin to have Combs begin ordering drugs from QSP, and QSP began shipping misbranded unapproved drugs to McLeod Cancer, to include the drugs listed above, were the drugs were administered to patients and claims for reimbursement were submitted to Medicare, TennCare, and other health benefits programs,” court documents said.

After nurses began raising concern in late 2007 that the drugs being purchased were from unlicensed foreign distributors, the McLeod Center stopped.

Combs and Kincaid resumed buying the drugs from QSP in 2009 after the two had QSP ship the counterfeit drugs directly to a third-party storage business, where Kincaid was part owner. The drugs were then brought to the office and stored with FDA-approved medication.

From 2007 on, McLeod Cancer and Blood Center purchased over \$2 million in counterfeit drugs. Kincaid was sentenced to two years imprisonment and a \$10,000 dollar fine, and Combs was sentenced to probation for three years and a \$4,000 dollar fine.

- In another recent case, Anindya and Patricia Sen, of the East Tennessee Cancer and Blood Center, were found guilty of knowingly buying over \$3 million of counterfeit drugs from a drug distributor in Canada named Clinical Care, which, like QSP, sold unapproved drugs to health care providers throughout the U.S.

“In April 2009, the defendants began ordering drugs from Clinical Care, and Clinical Care began shipping misbranded unapproved drugs to [East Tennessee Cancer and Blood Center]...where the drugs were administered to patients and claims for reimbursement for the drugs were submitted to Medicare, TennCare, and other health benefits programs,” the federal indictment read.

“The drugs provided by Clinical Care...were drugs from foreign sources that were not inspected and approved by the FDA, to include drugs which had been distributed in Turkey, India, the European Union, and elsewhere...”

“When nurses and other staff raised concerns that packaging for chemotherapy drugs... bore labeling in foreign languages, establishing that the drugs were not approved for use in the United States, defendant Patricia Posey Sen told the staff that there were no problems with the drugs, or words to that effect.”

Since the couple began buying the drugs in 2009, they billed Medicare, TennCare, and other benefit programs for over \$3.2 million.

They were sentenced June 10, according to a Department of Justice press release. Anindya Sen was sentenced to three years probation and a fine of \$100,000 and Patricia Sen was sentenced to probation for four years and a fine of \$200,000.

Court documents cited in this story are available on [The Cancer Letter website](#).

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Gonzalez-Angulo To Serve 10 Years In Poisoning Case

By Leonard Zwelling

Ana Maria Gonzalez-Angulo, a 43-year-old oncologist at MD Anderson Cancer Center, was sentenced to 10 years in prison for poisoning her lover and colleague George Blumenschein.

The sentence, issued Sept. 29, makes Gonzalez-Angulo ineligible for probation, but under Texas law, she will be eligible for parole in 5 years.

A jury at the Harris County 248th District Court found Gonzalez-Angulo guilty of aggravated assault Sept. 26, a charge that could have landed her in prison for 99 years. Blumenschein remains employed by MD Anderson.

At the press conference following the trial, Gonzalez-Angulo's lawyers said they would appeal, and expressed disappointment in the severity of the verdict and penalty.

Other than cross-examining the 22 prosecution witnesses and making their opening and closing arguments, Gonzalez-Angulo's lawyers did not present any witnesses, presumably relying instead on the hope that the jury would believe the prosecution had not made its case beyond a reasonable doubt.

During the jury's deliberation on the penalty, a former colleague said Gonzalez-Angulo knew that ethylene glycol was used in Blumenschein's poisoning before his doctors did.

According to testimony, Gonzalez-Angulo also said she hired bodyguards, claimed that she was attacked outside her home some six weeks before the poisoning occurred, and claimed to have had people killed in her native Colombia.

"You can't fix evil," said Assistant District Attorney Justin Keiter in his closing statements, alluding to Gonzalez-Angulo's premeditated assault.

Blumenschein reportedly lost nearly 60 percent of his renal function in the incident, reducing his life expectancy, and severely limiting his diet as well as his ability to metabolize certain medicines.

Blumenschein may also have to deal with other social and professional consequences.

Testimony showed that he lied to his supervisor about the affair and led a double life—one with his live-in girlfriend in Houston, and another on the road at scientific meetings with Gonzalez-Angulo.

The author, a former physician-scientist and administrator at MD Anderson, covered the trial on his blog, lenzwelling.blogspot.com.

Matthew Bin Han Ong contributed to this story.

FDA Publishes Two Guidances For Lab-Developed Tests

By Matthew Bin Han Ong

FDA published two draft guidance documents Oct. 3 for regulatory oversight, notification and medical device reporting for laboratory developed tests.

LDTs are a category of assays that has escaped scrutiny because of loopholes in the regulatory process—laboratories can get around FDA measures of analytic validity, clinical validity and clinical utility using LDTs.

FDA has been phasing in regulation of LDTs, starting with assays that may lead patients to select one treatment option over others (The Cancer Letter, [Aug. 1](#)).

According to the new draft guidances, the FDA oversight framework would require notifying FDA of all LDTs manufactured by a laboratory. All clinical laboratories manufacturing LDTs for clinical use would be required as medical device manufacturers to submit reports to the FDA if malfunctions or adverse events occur.

FDA also intends to continue exercising enforcement discretion with respect to applicable premarket review requirements and quality system requirements for Class I devices, which present the lowest risk.

The Federal Register notices for these draft guidances are currently available [here](#) and [here](#).

"As a general matter, FDA proposes a risk-based, phased-in approach, in combination with continued exercise of enforcement discretion for certain regulatory requirements and certain types of LDTs," the agency wrote in the regulatory oversight draft guidance.

"First, FDA believes that the health risks associated with LDTs, as with all [in vitro diagnostic devices], vary with each type of device and the Agency's regulatory activities should, accordingly, be implemented based on risk.

"Second, a phased-in implementation period is meant to mitigate any unintended and unpredictable consequences of immediately enforcing all applicable requirements, such as potential shortages in the availability of these devices for clinical testing.

"The Agency may continue to exercise its discretion by not actively enforcing FDA requirements for longer periods of time than described in this guidance when there are shortages of medically necessary devices or for other compelling reasons."

Public comment on these draft guidances will be

open for 120 days.

The loophole for LDTs exists because FDA chose not to actively regulate LDTs, the American Associate for Cancer Research [said in an article published Sept. 9](#) in Clinical Cancer Research (The Cancer Letter, [Sept. 12](#)).

As it stands, the many assays currently utilized in clinical practice don't have to demonstrate safety and efficacy, and are largely billed in such a way that Medicare and private insurers cannot identify what is being tested, and why (The Cancer Letter, [Aug. 8](#)).

Groups Push For CMS Coverage For LDCT Lung Screening

By Matthew Bin Han Ong

A coalition of patient advocacy and medical organizations urged the Centers for Medicare & Medicaid Services to cover low-dose computed tomography for Medicare patients at high risk for lung cancer.

More than 60 organizations—including the American Society of Clinical Oncology, the American Cancer Society and several cancer centers—signed a [43-page joint letter](#) to CMS recommending unrestricted national coverage for annual screening.

“The American Cancer Society carefully considered the evidence supporting screening for lung cancer with low dose CT scans and issued a guideline recommending screening for people at high risk based on age and smoking history,” Richard Wender, ACS chief cancer control officer, said in a statement. “This vital new screening tool is required by law to be available to most individuals with commercial insurance, but not those covered by Medicare.

“It's time to extend coverage to all who may benefit from screening. We look forward to working with other interested parties to encourage Medicare to cover lung cancer screening and ensure that the exams are delivered in a high quality manner.”

Consistent with U.S. Preventive Services Task Force recommendations, the coalition wrote that CMS should cover screening for adults ages 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit with the past 15 years.

The task force gave a B rating to the procedure last fall—Medicare has the authority, but not the obligation, to cover preventive services if the USPSTF gives them an A or a B recommendation (The Cancer Letter, [March 21](#)).

CMS expects to release a decision memo in November, with a final coverage determination by February 2015.

At an advisory hearing April 30, members of the Medicare Evidence Development & Coverage Advisory Committee expressed low confidence in LDCT as a method for screening for lung cancer in the Medicare population, saying evidence is inadequate to ensure that benefits of the procedure would outweigh harms (The Cancer Letter, [May 9](#)).

It's unclear how CMS will interpret MEDCAC's recommendation, which is largely based on results from the NCI-funded National Lung Screening Trial, a \$256 million randomized trial that accrued over 53,000 participants.

The trial documented a 20 percent decrease in lung cancer specific mortality (95% CI, 6.8 to 26.7; p=0.004) for patients between the ages of 55 and 75.

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Several MEDCAC members at the hearing were concerned that, without stringent reporting requirements and mandatory accreditation procedures for screening centers, there would be no way to predict whether medical practitioners would limit availability of the procedure to the cohorts that match the NLST population or meet the USPSTF criteria.

Coalition advocates disagree, saying that screening would be consistent and safe.

“The infrastructure is in place to help ensure the quality, safety and consistency of these exams,” Douglas Wood, immediate past president of the Society of Thoracic Surgeons said in a statement. “Medicare just needs to provide coverage to support these efforts and help physicians save lives.”

In Brief

Platanias Appointed Director Of Lurie Cancer Center

LEONIDAS PLATANIAS was appointed director of the **Robert H. Lurie Comprehensive Cancer Center of Northwestern University**, a position he has served in interim since January.

Platanias joined Northwestern University Feinberg School of Medicine in 2002, as the Lurie Cancer Center’s first deputy director and the Jesse, Sara, Andrew, Abigail, Benjamin and Elizabeth Lurie Professor of Oncology in Medicine-Hematology/Oncology.

He will oversee both the clinical operations in the Lurie Cancer Center and the basic science research programs, including programs to translate basic and clinical research into personalized medicine.

Before arriving at Feinberg, Platanias was the chief of the Division of Hematology/Oncology at the University of Illinois at Chicago.

Platanias’s research focuses on signaling pathways in cancer cells and developing therapies that target those pathways to treat malignancies. He is well known for his work involving cytokines.

He received the Seymour & Vivian Milstein Award for Excellence in Interferon and Cytokine Research in 2013. Platanias served as president of the International Society for Interferon and Cytokine Research in 2010-2011, and currently serves on the board of directors of the International Cytokine Society.

He is currently an associate editor of *Leukemia and Lymphoma* and the *Journal of Interferon and Cytokine Research*, and he sits on the editorial board of the *Journal of Biological Chemistry*.

THE BARBARA ANN KARMANOS CANCER INSTITUTE and **Wayne State University** reaffirmed their affiliation agreement, which has spanned 20 years.

The affiliation agreement contains a commitment to provide for more funds for research, support a more integrated governance structure. Recently approved by the KCI Board of Directors and the WSU Board of Governors, the agreement became effective Oct. 1.

The new agreement builds upon one signed in 2009. Karmanos and WSU have held an affiliation since 1994. Karmanos includes 167 members who are among the faculty at Wayne State. The new agreement will last three years and will automatically extend on a year-by-year basis.

Karmanos will continue to operate and manage on WSU’s behalf the cancer center’s NCI support grant, which is up for renewal in 2015. The KCI president will serve as the cancer center director and principal investigator of the support grant.

The KCI president/cancer center director also will serve as chair of the WSU Department of Oncology, which includes all oncology-related areas. With this new agreement, the Department of Radiation Oncology and the Division of Gynecologic Oncology join the Department of Oncology.

ROBERT MILLER was named medical director of the **Institute for Quality of the American Society of Clinical Oncology**.

Miller is assistant professor of oncology and oncology medical information officer at the Sidney Kimmel Comprehensive Cancer Center at The Johns Hopkins University. A long-time ASCO member and volunteer, he will begin his new position Dec. 3.

He will lead a team of more than 30 individuals working to advance iQ’s quality initiatives, including: The Quality Oncology Practice Initiative; QOPI Certification Program; practice guidelines; performance measures and practice improvement; and CancerLinQ.

Miller has served on the Board of Directors; the Quality of Care Committee; the Clinical Practice Committee; the Cancer Education Committee; the Integrated Media and Technology Committee; and the Health Information Technology Workgroup.

He currently serves as editor-in-chief of *Cancer. Net* and on the editorial board for the *Journal of Oncology Practice*. ASCO awarded him a Fellow of the American Society of Clinical Oncology Award in 2011. He is also past recipient of an ASCO Travel Award from the Conquer Cancer Foundation.

MD ANDERSON CANCER CENTER received a \$10 million grant from **ExxonMobil** for the center's Moon Shots program.

ExxonMobil chairman and CEO Rex Tillerson shared the news at a press conference preceding the Greater Houston Partnership's State of Energy luncheon. He also announced an additional \$3 million for Texas Children's Hospital and \$5 million for the Texas Heart Institute.

The MD Anderson grant supports the Healthy Community Initiative, developed by leaders of the Moon Shots program's cancer prevention and control platform. MD Anderson will designate a targeted population in the Houston area and collaborate with schools, workplaces, clinics, social service agencies, faith-based organizations and neighborhood centers.

JANEBERTS was appointed CEO of **Agendia Inc.**

Egberts served most recently as CEO of OctoPlus, which was acquired in 2013 by India-based Dr. Reddy's Laboratories Ltd. He has held business development and general management positions at McKinsey & Co., Merck, Johnson & Johnson and Mölnlycke Health Care, and served as CEO of Novadel Pharmaceuticals Inc.

MEMORIAL SLOAN KETTERING Cancer Center's new, largest suburban location, **MSK West Harrison**, is set to see patients Oct. 6.

The 114,000-square-foot outpatient cancer facility will include more than 30 cancer doctors with expertise in medical and radiation oncology, radiology, surgery, and dermatology, as well as programs for genetic counseling, high-risk cancer screening and surveillance, cancer survivorship, social work, and consultations with certified dietitian-nutritionists. Patients will also find an on-site pharmacy, a café, and outdoor spaces.

The center also announced a partnership with Mount Kisco Medical Group. MKMG physicians with appointments to the MSK medical staff will be based on-site at MSK West Harrison to provide clinical services including cardiology, gastroenterology, gynecology, infectious disease, and internal medicine to MSK patients.

Upon check-in, patients visiting MSK West Harrison will be given special tags to carry while waiting for their appointment or test result.

Using GPS technology, the tags will enable staff to find where a patient is sitting, whether it's in a common area, a waiting room, or a bench in the gardens

outside. "Instead of announcing a patient's name, our staff will be able to find and greet the patient and their caregivers wherever they might be," said Margaret Burke, MSK's senior vice president of ambulatory care and hospital operations.

Approximately 13 percent of MSK's current patient population lives in the Hudson Valley and Western Connecticut region. In addition, more than 70 percent of MSK patients living in the Westchester area travel to New York City facilities for treatment.

CANCERCARE received a \$1.5 million grant from **Susan G. Komen For the Cure**.

The grant will support Linking A.R.M.S., a CancerCare program in partnership with Komen, which provides financial assistance for breast cancer patients for hormonal and oral chemotherapy, pain and anti-nausea medication, child care, transportation, lymphedema care and durable medical equipment.

Funding Opportunity **NYC-Based Research Alliance Offering \$200,000 Per Year For Young Investigators**

THE PERSHING SQUARE SOHN CANCER RESEARCH ALLIANCE is taking applications for its **Prize for Young Investigators in Cancer Research**.

The prize of \$200,000 per year for up to three years is awarded annually to five New York City-based scientists. Each prize winner is given a mentor in the pharmaceutical industry and the opportunity to present his or her work to scientific and business audiences.

In May 2014, the alliance awarded the inaugural prize to six winners: Emily Bernstein, of the Icahn School of Medicine at Mount Sinai; Adolfo Ferrando, of Columbia University Medical Center; Ross Levine, of Memorial Sloan Kettering Cancer Center; Agata Smogorzewska, of The Rockefeller University; Lloyd Trotman, of Cold Spring Harbor Laboratory; and Sihong Wang, of CUNY City College.

Applicants must have between two to eight years of experience running their own laboratories and must have a PhD, MD or MD-PhD or equivalent. The deadline to submit a Letter of Intent is November 12. More details are available at www.psscra.org.