2013 Consumer Safety Update: FDA Recalls

Throughout the year, the U.S. Food and Drug Administration issues recalls, alerts and warnings for products and devices whose safety and integrity have come into question. PHP takes immediate action to inform members and providers when claims analysis indicates these issues directly or potentially affect the Plan member. These are reviewed at the Plan Pharmacy & Therapeutics Committee. The most recent FDA recall communications are provided here for reference in your practice. More information here: http://www.fda.gov/ .

November 28, 2013

FreeStyle and FreeStyle Lite Blood Glucose Test Strips by Abbott. Recall - Erroneously Low Blood Glucose Results

ISSUE: Abbott is initiating a voluntary recall of 20 lots of FreeStyle and FreeStyle Lite Blood Glucose Test Strips in the United States. These lots of test strips may produce erroneously low blood glucose results when used with both "FreeStyle Blood Glucose Meter" and "FreeStyle Flash Blood Glucose Meter" [neither of which have been in production since 2010], as well as the OmniPod Insulin Management System. When the test strips are used with the newer FreeStyle brand meters including FreeStyle Freedom Blood Glucose Meter, FreeStyle Lite Blood Glucose Meter and FreeStyle Freedom Lite Blood Glucose Meter, the blood glucose test results are not affected. Testing with the FreeStyle InsuLinx Blood Glucose Meter is not affected by this action, as FreeStyle InsuLinx Blood Glucose Meter uses FreeStyle InsuLinx test strips.

RECOMMENDATION: The company is notifying healthcare professionals, pharmacies, distributors and customers about the recall; customers affected by this action are instructed to call Abbott's diabetes care customer service at 1-888- 736-9869 for a replacement of the affected test strips at no charge.

Plan Action – Letter patients (~20 affected)

November 27, 2013

Nitroglycerin in 5% Dextrose Injection by Baxter. Recall - Particulate Matter

ISSUE: Baxter International Inc has initiated a voluntary recall of one lot of Nitroglycerin in 5% Dextrose Injection due to particulate matter found in one vial. If infused, particulate matter could lead to potential venous and/or arterial thromboembolism (blockage of blood vessels). Other adverse events associated with injection of particulate matter include inflammation due to foreign material, particularly in the lungs, and local irritation of blood vessels. - The affected product code is 1A0694, and the affected lot number is G105197.

RECOMMENDATION: Customers should locate and remove all affected product from their facility

No Plan Action – Hospital

November 16, 2013

Nature's Pharmacy and Compounding Center Sterile Compounded Products. Recall - Lack of Sterility Assurance

ISSUE: Nature's Pharmacy and Compounding Center of Asheville, NC is voluntarily recalling all lots of sterile products compounded by the pharmacy that are not expired to the consumer level. The product will be in the form of an injectable drug or an eye drop. The recall is being initiated due to concerns associated with quality

control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.

BACKGROUND: This recall is being conducted as a result of an inspection conducted by the North Carolina Board of Pharmacy. These products were supplied to the offices of licensed medical professionals and to patients by prescription within the pharmacy's local market area in North Carolina. They were distributed from January 1, 2013 to present. Out of abundance of caution and in the interest of the pharmacy's patients, Nature's Pharmacy has decided to voluntarily proceed with this recall process and to cease production of all sterile products.

RECOMMENDATION: Medical professionals, clinics, or patients who have these products should stop its use and return them to the place of purchase. Clinics should contact any patient that has received treatment using any of these sterile products.

No Plan Action – North Carolina only

November 10, 2013

OxyElite Pro Dietary Supplements by USP Labs. Recall - Products Linked to Liver Illnesses

ISSUE: The U.S. Food and Drug Administration announced today that USPlabs LLC, of Dallas, Texas, is recalling certain OxyElite Pro dietary supplement products that the company markets. The company took this action after receiving a letter from the FDA stating that the products have been linked to liver illnesses and that there is a reasonable probability that the products are adulterated. In a review of 46 medical records submitted to the FDA by the Hawaii Department of Health, the records indicated that 27 patients, or 58 percent, had taken a dietary supplement labeled as OxyElite Pro prior to becoming ill. Seventeen of the 27 patients (or 63 percent) reported that OxyElite Pro was the only dietary supplement they were taking. One death has occurred among these patients, another patient has required a liver transplant, and others await liver transplants.

10/08/2013 - OxyElite Pro: Health Advisory - Acute Hepatitis Illness Cases Linked to Product Use
11/12/2013 - Drug Information Update- USPlabs LLC recalls OxyElite Pro dietary supplements; products linked to liver illnesses

No Plan Action - OTC

November 2, 2013

Perrigo Acetaminophen Infant Suspension Liquid. Recall - Potential Defect with Co-packaged Oral Syringe

ISSUE: The Perrigo Company announced that it has initiated a voluntary, nationwide product recall to the retail level of 18 batches of its acetaminophen infant suspension liquid, 160 mg/5 mL, sold in 2 oz. and 4 oz. bottles with syringes in a box under store brand products. (Refer to the Firm Press Release for full list of affected brand names and products). *Perrigo's Chairman, President and CEO Joseph C. Papa stated, "There are no issues or concerns with respect to the safety or efficacy of the product, only the potential that the oral dosing device in a relatively small number of packages could be unmarked. Out of an abundance of caution, we are taking this measure to maintain the highest possible product quality standards for our retail customers and consumers.*

RECOMMENDATION: If the oral dosing device contained in the package has dose markings (for 1.25 mL, 2.5 mL, 3.75 mL, and 5 mL), no action is required, and the consumer can continue to use the product consistent with the label instructions. If the package contains an oral dosing device that does not have dose markings, the consumer should not use the product and should call Perrigo's Consumer Affairs Department, toll free, 1-800-719-9260.

No Plan Action - OTC

October 21, 2013

Specialty Medicine Compounding Pharmacy Certain Unexpired Compounded Sterile Products. Recall - Particulate Matter Found in Vials

ISSUE: Specialty Medicine Compounding Pharmacy is voluntarily recalling all lots of certain unexpired human and veterinary sterile products to the consumer level due to particulate matter found in vials of a compounded dextrose injection product dispensed to a local hospital

BACKGROUND: The recalled products were distributed to hospitals and consumers located only within Michigan from July 1, 2013, through October 19, 2013. No products were distributed out of state. Refer to the Firm Press Release for a detailed list of affected products

October 17, 2013

Albuterol Sulfate Inhalation Solution, 0.083 percent (Nephron Pharmaceuticals). Recall - Aseptic Processing Simulation Results

ISSUE: Nephron Pharmaceuticals initiated a voluntary recall, at the retail level, of ten lots of product due to results from an internal monitoring process. NPC performs aseptic process simulation as part of an internal processes to assure product quality. All of the lots listed above met and passed NPC's quality specifications at the time of manufacture. In accordance with published guidance regarding aseptic processing simulation from the FDA, NPC has initiated this recall as a precautionary measure.

RECOMMENDATION: NPC is asking retailers to remove the affected lots from store shelves and is asking consumers to discontinue use and dispose of any product they may have that is included in this recall.

October 15, 2013

Cefepime For Injection, USP And Dextrose Injection, USP By B. Braun Medical Inc. Recall - Visible Particulate Matter

ISSUE: B. Braun Medical Inc. is voluntarily recalling one lot of 1g Cefepime for Injection USP and Dextrose Injection USP (Lot H3A744, catalog 3193-11) to the consumer level. The 1g Cefepime for Injection USP and Dextrose Injection USP lot has been found to contain visible organic particulate matter in a reserve sample unit.

October 4, 2013

1% Lidocaine HCL Injection By Hospira

Recall - Presence Of Dark Particulate

ISSUE: Hospira, Inc. announced it has initiated a voluntary nationwide recall of one lot of 1% Lidocaine HCI Injection, USP, 10 mg/mL, 20 mL Multiple-dose Fliptop Vial, NDC 0409-4276-01 Lot 25-090-DK (the lot number may be followed by 01 or 02). This action is due to one confirmed customer report of visible particulate, identified in the primary container, in the form of dark red/black particles. The particulate was identified as oxidized stainless steel. Depending on the particle size, if undetected, it could block administration of the drug to the patient, causing a delay in therapy. Impact to the patient would depend on the time it would take to obtain a new vial, the condition being treated and the patient's status.

BACKGROUND: The recall is being conducted as a precautionary measure. The root cause has not been determined and is under investigation. Hospira informed customers of the issue in a letter dated Sept. 16, 2013. This lot was distributed March 2013 through June 2013.

October 2, 2013

Metoclopramide Injection And Ondansetron Injection by Hospira. Recall - Glass Strand Particulates Caused By Glass Supplier Defect

ISSUE: Hospira, Inc. announced it initiated a voluntary nationwide recall of one lot of Metoclopramide Injection, USP, 10 mg/2 mL (5 mg/mL)and two lots of Ondansetron Injection, USP, 4 mg/2 mL, (2 mg/mL). This action is due to a confirmed vial defect where glass particulate matter (glass strands) were identified as being affixed to the inside of the vial walls. There is potential for the glass particulates to dislodge into the solution. To date, Hospira has not received reports of any adverse events associated with this issue for these lots.

September 9, 2013

Bupivacaine HCL Injection 0.25% (2.5 MG/ML) and Bupivacaine HCL 0.75% (7.5 MG/ML), 30 ML Single-Dose Vials by Hospira, Inc. Recall- Presence of Particulate Matter

Hospira, Inc. on July 12, 2013, initiated a voluntary nationwide recall to the user level for one lot of 0.25% Bupivacaine HCl Injection, USP (2.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1159-02). An expanded recall was issued on August 29, 2013 for one lot of 0.75 Bupivacaine HCl Injection, USP (7.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1165-02). Both recalls are due to confirmed customer reports of particulate floating and/or embedded in the glass vial. The particulate was identified as stainless steel ranging in size from 542 microns to 1700 microns in lot 18-136-DK (0.25% bupivacaine) and as iron oxide with an average size of 2000 microns in lot 23-338-DK (0.75% bupivacaine). Bupivacaine is indicated for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. Anyone with an existing inventory should immediately quarantine any affected product and return the product to Stericycle.

Plan Action: ***One medical claim in Florida – Holy Cross Hospital***

September 12, 2013

Leiter's Compounding Pharmacy. Recall - Concerns of Sterility Assurance

Leiter's Compounding Pharmacy is voluntarily recalling 3 lots of its sterile products due to concerns of sterility assurance with Front Range Laboratories, Leiter's Compounding Pharmacy's independent testing laboratory. FDA investigators observed that methods used by the independent laboratory to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. The FDA has concerns that results obtained from the laboratory are not reliable.

Bevacizumab Lot No. 08052013@1, expiry 11/03/13

Bevacizumab Lot No. 08052013@4, expiry 11/03/13

Lidocaine/phenylephrine Lot No. 07302013@6, expiry 10/28/13

These products were dispensed to health care providers between 8/05/13 to 9/02/13 nationwide throughout the United States.

No Plan Action

September 10, 2013

Park Compounding Sterile Medication. Recall – Concerns of Sterility Assurance

Park Compounding is voluntarily recalling one lot of sterile medication Testoserone Cypionate (Sesame Oil) 200mg/ml Lot #05072013@1 Exp: 11/3/2013 for injection in 10ml amber vials, to the consumer level. In a recent inspection, FDA investigators observed that methods used by Front Range Laboratories to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. The prescription preparations were sold during May and June of 2013, in the following states: California and Indiana. The products would have been sold directly to customers (pick up and by mail) and to physician offices by prescription (pick up and by mail).

No Plan Action

09/09/2013

Avella Specialty Pharmacy Sterile Medications. Recall - Concerns Of Sterility Assurance At Testing Vendor
Avella Specialty Pharmacy is voluntarily recalling two compounded sterile medications, Bevacizumab 1.25 mg/0.05 mL PF and Vancomycin PF (BSS) 1%. The recall is a result of concerns of sterility assurance with the specialty pharmacy's independent testing laboratory, Front Range Laboratories. To date, Avella has not received any reports of adverse events related to the recall. Avella was notified that in a recent inspection of Front Range Labs, FDA investigators observed methods used to assess sterility and other qualities (e.g. strength and stability) which may have resulted in Avella receiving inaccurate laboratory test results on the specified lots. FDA has raised concerns that test results obtained from Front Range Labs may not be reliable.
No Plan Action

September 8, 2013
Altaire Pharmaceuticals Carboxymethylcellulose Sodium 0.5 Percent Ophthalmic Solution Sold Under Wal-Mart, CVS, and Target Brands. Recall - Preservative May Not Be Effective Through Expiry
Altaire Pharmaceuticals, Inc., announced that it is voluntarily recalling a total of nine (9) lots of Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution, 30 mL, to the consumer level. Due to complaints of mold found in the 30 mL bottles after use, concerns regarding the effectiveness of the preservative after use and handling of the product by consumers have prompted the recall. A product whose preservative may not be effective could lead to the use of a contaminated product which creates a potential risk for eye infection. Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution is a non-prescription (OTC) drug product used to relieve dryness of the eye and packaged in a plastic bottle inside a unit box.
No Plan Action – OTC retail brands

September 8, 2013
MOTRIN Infants Drops Original Berry Flavor 1/2 fl oz. Recall - Particles Identified
McNeil Consumer Healthcare is voluntarily recalling at the retail level three lots, approximately 200,000 bottles, of Concentrated MOTRIN Infants' Drops Original Berry Flavor 1/2 fl oz bottles distributed in the United States (refer to Firm Press Release for full product list). After releasing these three lots of Concentrated MOTRIN Infants' Drops Original Berry Flavor 1/2 fl oz into the market, tiny plastic particles (approximately 1 mm in size or about the size of a poppy seed) were identified in a different product lot during manufacturing. This lot was not released to the market.
No Plan Action-OTC

September 8, 2013
University Compounding Pharmacy Injection Products. Recall - Lack of Sterility Assurance
University Compounding Pharmacy is voluntarily recalling products, including Testosterone Cypionate (Sesame Oil), Testosterone Cypionate/Testosterone Proprionate, and PGE-1 NS, for injection, to the consumer level (refer to Recall Notice for a detailed product list with affected lot numbers and expiry dates). In a recent inspection, FDA investigators observed that methods used by the Independent Third Party laboratory to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. The prescription preparations were distributed nationwide from May 9th, 2013 to September 7th, 2013.The preparations would have been sold, directly to customers by pick up and by mail.
No Plan Action

September 5, 2013
Medaus Pharmacy Sterile Compounded Products. Recall: Inability to Confirm Sterility

Medaus Pharmacy is voluntarily recalling certain sterile compounded consumer products (see table in press release) due to inability to confirm that the quality control testing performed on these specific lots by an independent, third party laboratory was conducted in a manner consistent with standards. Medaus is notifying its customers by telephone and email, and is arranging for return of affected products. Health care facilities and customers that have products which are being recalled should stop using the product and call Medaus at 800-526-9183 for instructions on returning the product for a full refund.
No Plan Action

August 29, 2013
Cubicin (daptomycin for injection). Recall - Glass Particulate Matter Present in Four Lots
Cubist has notified customers by letter and phone of the voluntary recall of four lots of Cubicin (daptomycin for injection) due to the presence of particulate matter found in a number of vials from four lots shipped from May 2011 to March 2013. The administration of glass particulate, if present in an intravenous drug, poses a potential safety risk to patients. Case reports suggest that sequelae of thromboembolism, some life-threatening (such as pulmonary emboli), may occur

August 27, 2013
Wellness Pharmacy, Inc. Products. Recall - Laboratory Results Indicating Microbial Contamination
Wellness Pharmacy, Inc. issues nationwide voluntary recall of certain sterile products due to laboratory results indicating microbial contamination. If there is microbial contamination in medications intended to be sterile, patients are at risk of serious infections which may be life threatening. To date Wellness Pharmacy has not received any reports of adverse events related to this recall. This recall was initiated after Wellness Pharmacy was notified that in a recent inspection of Front Range Labs, FDA investigators observed methods used by Front Range Labs to assess sterility and other qualities (e.g.,strength and stability) may have resulted in Wellness Pharmacy receiving inaccurate sterility test results on products. Recalled medications were distributed to individual patients and to physician offices nationwide
No Plan action – no claims

August 27, 2013
Compounded Sterile Preparations By Park Pharmacy & Compounding Center. Recall - Lack of Sterility Assurance
Park Pharmacy & Compounding Center is voluntarily recalling two lots of products Methylcobalamin 5mg/ml 30ml Amber Vials Lot #06132013@1 Exp: 12/10/2013 and Multitrace-5 Concentrate 10ml Amber Vials Lot #05212013@20 Exp: 11/17/2013 for injection, to the consumer level. In a recent inspection, FDA investigators observed that methods used by the laboratory to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. FDA has concerns that results obtained from the laboratory are not reliable. The prescription preparations were sold during June and July of 2013, in California, Florida, New Mexico and Indiana. The products would have been sold directly to customers (pick up and by mail) and to physician offices by prescription (pick up and by mail).
No Plan action – no claims

August 17, 2013
Aidapak Services LLC, Selected Repackaged Pharmaceuticals by Aidapack. Recall - Potential Incorrect Labeling
Aidapak Services LLC, is conducting a voluntary recall of specific unit dose repackaged products sent to 25 hospital inpatient pharmacies in the States of Washington, Oregon, California, and Arizona for products listed

on the company's website. The Firm voluntarily recalled these products to the hospital/user level after learning of possible incorrect labeling which could involve OTC, prescription, and dietary supplement products
No Plan action – no claims

August 16, 2013
All Sterile Drug Products Made and Distributed By NuVision Pharmacy Dallas Facility Update. Recall - Lack Of Sterility Assurance
FDA is reminding health care providers about safety concerns with all sterile drug products made and distributed by NuVision Pharmacy of Dallas, Texas. Health care providers should not administer any NuVision Pharmacy sterile products to patients because the products' sterility is not assured. NuVision Pharmacy has repeatedly declined to recall its sterile products. The FDA cannot require NuVision to undertake such a recall. Therefore the agency reminds health care providers not to use any sterile products from NuVision.
No Plan action – no claims

August 10. 2013
Specialty Compounding Sterile Products Update. FDA Alert - Bacterial Infections
Specialty Compounding, LLC has announced a voluntary nationwide recall of all lots of unexpired sterile products. The recall applies to all unexpired sterile compounded products dispensed since May 9, 2013, including all strengths and dosage forms. The recall was initiated after reports of bacterial infection affecting 15 patients at two Texas hospitals, Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area, whose treatment included IV infusions of calcium gluconate from Specialty Compounding. There is a potential association between the infections and the medication at this time. Recalled products were distributed directly to hospitals and physician offices in Texas. Recalled products were also sent directly to patients located nationwide with the exception of North Carolina. Specialty Compounding is notifying its customers by telephone, fax, electronic mail and/or regular mail of this recall. Users or recipients of these products should immediately discontinue use and return the recalled unexpired products to Specialty Compounding.
No Plan action – no claims

August 1, 2013
Healthy Life Chemistry By Purity First B-50 Update. FDA Health Risk Warning - Undeclared Ingredients
Purity First Health Products is recalling two lots of Healthy Life Chemistry B-50 (100 capsules), one lot of Healthy Life Chemistry Multi-Mineral (200 capsules) and all lot numbers for Healthy Life Chemistry Vitamin C (200 capsules). The B-50 capsules were found on testing by FDA to contain Methasterone (a schedule III controlled substance) and Dimethazine. Testing of the Multi-Mineral and Vitamin C capsules appear to indicate the presence of Dimethyltestosterone
No Plan action – no claims

August 1, 2013
Beacon Hill Medical Pharmacy/Rxtra Solutions, Recall - Lack of Sterility Assurance
Beacon Hill Medical Pharmacy and FDA is notifying health professionals and consumers of the recall of all lots of certain sterile products. FDA has raised a question of sterility assurance for the affected products.The products were distributed nationwide to outlets including hospitals, clinics, and patients who have received orders by directly placing phone calls or faxed prescriptions to the Beacon Hill Medical pharmacy facility in Southfield,Michigan

Beacon Hill began notifying its customers on July 26th 2013 via telephone, and will begin initiating recall mailers including formal letters, and will continue to call its patients and providers, and schedule office visits to discuss with physicians further. List of products located at: http://www.fda.gov/Safety/Recalls/ucm363284.htm
No Plan action – no claims

May 30, 2013
Olympia Pharmacy Sterile Compounded Products: Recall - Concerns About Sterility
Lowlite Investments d/b/a Olympia Pharmacy ("Lowlite") notified the public of a voluntary multi-state recall of all sterile drug products compounded by the pharmacy that have not reached the expiration date listed on the product. The recall is being initiated due to concerns associated with prior quality control procedures that impacted sterility assurance. In the event a sterile product is compromised patients are at risk for serious and possible life threatening infections.
The recall includes all sterile products that Olympia Pharmacy supplied to patients and offices of licensed medical professionals with a use by date of 09/25/2013 or earlier.
Olympia Pharmacy will be notifying customers by phone, fax, or mail to return the products to the pharmacy

May 29, 2013
Magnesium Sulfate Injection by Fresenius Kabi USA: Recall - Glass Particles in Vials
Fresenius Kabi USA notified health professionals of a voluntary recall of one lot – Lot 6103882 – of Magnesium Sulfate Injection, USP due to the potential presence of glass particles in the vials. The recalled product is labeled with Product Code 6450 and packaged as 500mg/mL strength in 50mL glass vials (25 vials per tray). The product was shipped in the United States between May 30, 2012 and June 6, 2012 and has an expiration date of October 31, 2014.
All customers who received the recalled vials are being notified and instructed to return any unused product to their supplier.

May 24, 2013
Main Street Family Pharmacy in Tennessee: FDA Alerts Health Care Providers of Adverse Reactions Associated with Steroid Injections
The U.S. Food and Drug Administration is working closely with the Centers for Disease Control and Prevention and Tennessee Board of Pharmacy to investigate reports of seven adverse events (in the form of skin abscesses, one of which appears to be fungal in nature) associated with steroid injections compounded by Main Street Family Pharmacy, LLC (Main Street) of Newbern, Tenn. The reports of adverse events are all from patients who received preservative free methylprednisolone acetate (80 mg/mL) by injection. To date, the FDA has received seven reports. Clinical information about these patients is pending; at least one of these infections appears to be fungal in nature.
No action by Plan – no utilization

May 21, 2013
Methotrexate Sodium, USP Injectable Vials by Sandoz US: Recall - Particulate Matter In Vials
Parenteral injection of drug from the affected lots can lead to microembolisation in areas where the particles lodge. Clinical symptoms are not to be expected from these microemboli and Sandoz is not aware of any reports of related adverse events.
No action by Plan – no utilization

May 20, 2013
Medical Device Recalls: Abbott Diabetes Care, FreeStyle InsuLinx Blood Glucose Meters
Abbott initiated a voluntary recall of FreeStyle Insulinx Blood Glucose Meters in the United States. At extremely high blood glucose levels of 1024 mg/dL and above, the FreeStyle InsuLinx Blood Glucose Meter will display and store in memory an incorrect test result that is 1024 mg/dL below the measured result. **On April 15, 2013, Abbott Diabetes Care sent an Urgent Product Recall letter to all its affected customers**

May 18, 2013
All Sterile Drug Products Made and Distributed By NuVision Pharmacy Dallas Facility: Recall - Lack Of Sterility Assurance
FDA is alerting health care providers of concerns about a lack of sterility assurance of all sterile drug products made and distributed by NuVision Pharmacy of Dallas, Texas. The FDA is basing this expanded alert on a recent inspection of the NuVision Dallas facility, during which FDA investigators observed poor sterile production practices that raise concerns about a lack of sterility assurance of the company's sterile drug products. The agency is not aware of any additional adverse event reports associated with other sterile products from NuVision.
No action by Plan – no utilization

May 17, 2013
Compounded Prescription Therapies By Pentec Health Inc.: Recall - Lack Of Sterility Assurance
Pentec Health, Inc. initiated a limited, voluntary recall of in-date nutritional prescriptions for renal patients due to lack of sterility assurance associated with one of its laminar flow hoods used in compounding. These renal therapies were supplied to renal dialysis centers and directly to patients. **Pentec Health is directly notifying each dialysis center and in-home dialysis patient of the recall.**

May 1, 2013
Piperacillin and Tazobactam for Injection, USP 40.5 grams: Recall - Precipitation or Crystallization in IV Bag or IV Line Upon Reconstitution
No action by Plan – no utilization

April 23, 2013
LifeScan, Inc. OneTouch Verio IQ Blood Glucose Meter: Recall- Failure to provide a warning at extremely high blood glucose levels
ISSUE: At extremely high blood glucose levels of 1024 mg/dL and above, the OneTouch Verio IQ Meter will turn off instead of displaying the message "EXTREME HIGH GLUCOSE above 600 mg/dL" as intended. When turned back on, the meter enters the "Set-Up" mode and requires the user to confirm the date and time settings before being able to test again. However, if the glucose level is still measuring1024 mg/dL or above when testing, the meter will shut down again
Investigating claim history

April 23, 2013
All Sterile Compounded Products by Nora Apothecary And Alternative Therapies: Recall - Lack of Sterility Assurance
All Sterile Compounded Products by Nora Apothecary And Alternative Therapies: Recall - Lack of Sterility Assurance
No action by Plan – zero claims

April 5, 2013
BIVIGAM Immune Globulin Intravenous (Human), 10 Percent Liquid, 100 mL Sterile Vial: Recall - Visible Particles Observed
BACKGROUND: BIVIGAM is indicated for the treatment of patients with primary humoral immunodeficiency (PI).
No action by Plan – zero claims

April 5, 2013
Animas Corporation 2020 Insulin Infusion Pump: Recall - False Alarm or Warning Sound Medical Device Recalls
Animas Corporation 2020 Insulin Infusion Pump: Class I
No action by Plan – zero claims