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## Proton Pump Inhibitors (PPI)

Results achieved in prior matters are not meant to be a guarantee of success as the facts and legal circumstances vary from matter to matter.

The use of proton pump inhibitors (“PPIs”) has been linked to serious side effects, including kidney injuries, which may require hospitalization, and could result in death.

### What Are Proton Pump Inhibitors?

PPIs are a class of drugs used to reduce the production of acid in the stomach. They are available in both prescription and over-the-counter (OTC) formulations. Prescription PPIs are used to treat gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and inflammation of the esophagus. OTC PPIs are used to treat frequent heartburn. PPIs are the most widely prescribed and distributed class of pharmaceuticals in history.

PPIs were first approved by the FDA in 1989 and have been marketed by a number of pharmaceutical companies, including: Abbott (Prevacid), AstraZeneca (under the brand names Prilosec, Prilosec OTC, Nexium and Nexium 24HR), GlaxoSmithKline (Prevacid 24HR), Merck (Prilosec and Nexium), Novartis (Prevacid 24HR), Procter & Gamble (Prilosec OTC), Pfizer (Nexium OTC and Protonix), Takeda (Dexilant, Prevacid, Prevacid 24HR and Protonix), TAP Pharmaceutical (Prevacid), and Wyeth (Protonix).

The use of both prescription and OTC PPIs has been linked to severe kidney malfunction, including chronic kidney disease, acute kidney injury, renal failure, and acute interstitial nephritis. The complications associated with the use of PPIs often require hospitalization and complex treatments such as dialysis. In some cases, these complications may lead to death.

### Kidney-Related Side Effects and Complications

#### Chronic Kidney Disease (CKD)

The kidneys are responsible for filtering waste products from the bloodstream, which are then excreted through the urine. They also play an important role in blood pressure and fluid balance. Chronic Kidney Disease (also known as Chronic Renal Disease) refers to gradual damage to the kidneys resulting in reduced kidney function. As CKD progresses, it can lead to high blood pressure, anemia, weak bones and nerve damage. CKD also increases the risk of heart and vascular disease. Currently, there is no cure for advanced stage CKD.

If untreated, CKD can lead to kidney failure. Kidney failure refers to severe loss (85%-90%) of kidney function. When a patient experiences kidney failure, waste products and fluid can build up in the blood, causing multi-system symptoms. There is no cure for kidney failure, but it is possible to control its symptoms with dialysis or with a kidney transplant.

The following symptoms may indicate the presence of CKD:

- tiredness and loss of energy
- trouble concentrating
- poor appetite

- trouble sleeping
- muscle cramping at night
- swollen feet and ankles
- puffiness around your eyes, especially in the morning
- dry, itchy skin
- a need to urinate more often, especially at night

According to a February 2016 study that reviewed information of over 250,000 patients, those taking PPIs were 20% to 50% more likely to develop CKD than those who were not on these medications.

### **Acute Kidney Injury (AKI)**

Acute Kidney Injury (AKI) refers to sudden episodes of kidney injury or kidney failure, developing within hours or days. AKI causes the buildup of waste products in the blood and interferes with the proper balance of fluids. Recent studies have linked the use of PPIs to higher incidence of AKI, especially in older patients.

AKI can affect not only the kidneys, but other critical organs, including the brain, lungs and heart. Because of its systemic effects, AKI can lead to sudden death.

The following symptoms may indicate the onset of AKI:

- Too little urine leaving the body
- Swelling in legs, ankles and around the eyes
- Fatigue or tiredness
- Shortness of breath
- Confusion
- Nausea
- Seizures or coma in severe cases
- Chest pain or pressure

### **Acute Interstitial Nephritis (AIN)**

Acute interstitial nephritis refers to the internal swelling of the kidneys. The swelling can cause kidney damage. This condition often develops as an allergic reaction to medication, such as PPIs.

AIN is implicated in up to 15% of patients hospitalized with AKI, and symptoms of AIN are indistinguishable from those exhibited by AKI. There are no non-invasive tests that can diagnose AIN definitively. A kidney biopsy is the gold standard for diagnosing AIN.

### **FDA Safety Warnings**

Although PPIs have not been recalled and do remain on the market, the FDA has issued safety warnings about possible complications. In December 2014, the FDA required that the labels of prescription PPIs be updated to include a warning about the risk of developing AIN “at any point during PPI therapy.”

### **Lawsuits**

Hundreds of lawsuits have been filed in the United States against the manufacturers of PPIs. These lawsuits seek compensation for injuries suffered by patients taking PPIs, claiming that the defendants knew about the risks associated with PPIs, but continued to promote and sell these medications without additional warnings. If health care practitioners and patients had been warned about the increased risks, many would not have used PPIs.

### **How We Can Help**

If you have suffered serious health problems after taking a PPI, you may be entitled to reimbursement for medical expenses, lost wages, and other costs. Attorneys at Wilentz, Goldman & Spitzer P.A. may be able to help you recover compensation if you suffered serious injuries due to taking a PPI. As one of New Jersey's largest personal injury law firms, Wilentz is committed to helping clients with their cases.

For a free consultation or more information about your legal options, please call the number below. Or, if you prefer to complete our free case evaluation form, our client relations representative will contact you shortly.

**To speak with an attorney about your legal options, please call: 732-855-0375.**