**SUPREME COURT OF THE STATE OF NEW YORK**
**COUNTY OF NEW YORK**

THOMAS BIRD,

Plaintiff,

vs.

PFIZER, INC.,

Defendant.

**SUMMONS**

**JURY TRIAL DEMANDED**

**Date Index Number Purchased:**

**TO THE ABOVE NAMED DEFENDANT:**

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's attorney within 20 days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Pursuant to CPLR 503(c) venue is appropriate in this County because Defendant Pfizer, Inc.'s principal office is located in New York County.

Dated: New York, New York
October 24, 2012

/s/ Richard B. Brualdi

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**SUPREME COURT OF THE STATE OF NEW YORK**
**COUNTY OF NEW YORK**

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| THOMAS BIRD,<br>Plaintiff,<br>vs.<br>PFIZER, INC.,<br>Defendant. | **COMPLAINT**<br>**JURY TRIAL DEMANDED**<br>**Date Index Number Purchased:** |

Plaintiff THOMAS BIRD files his Complaint against Defendant PFIZER, INC., as follows:

## NATURE OF THE ACTION

1. This is an action to recover damages for severe, permanent personal injuries sustained by Plaintiff Thomas Bird ("Bird" or "Plaintiff"). Following his ingestion of Cleocin (sometimes referred to herein as "Clindamycin" or "Dalacin"), a drug designed, manufactured, packaged, marketed, labeled, distributed, promoted, tested, and sold by Defendant Pfizer, Inc. and related entities ("Pfizer), Plaintiff sustained severe, permanent and horrific injuries caused from an adverse drug reaction, Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). The SJS and TEN were the direct and proximate result of Defendant's wrongful conduct in connection with the design, manufacture, sale, testing, marketing, advertising, promotion, sale and/or distribution of the prescription drug Cleocin.

## PARTIES, JURISDICTION AND VENUE

2. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues,

or market capitalization.

3. At all times pertinent hereto Defendant was engaged in the business of the testing, manufacturing, packaging, marketing, labeling, adverse drug event reporting or non-reporting, distribution, promotion, and/or sale of Cleocinand placed the drug into the stream of commerce emanating from the State of New York, where the drug was compounded and distributed to Plaintiff by and through Pfizer's headquarters located in New York County, New York.

4. Plaintiff, at the times alleged herein, lived in Delaware.

5. Venue is proper in this Court because Defendant Pfizer's principal office is located in New York County. Jurisdiction over Pfizer is proper because it does business, and its principal office is located, in this and County.

## FACTUAL BACKGROUND

### PLAINTIFF'S INJURIES

6. Plaintiff, an immunocompromised patient, was prescribed and administered IV Cleocin on or about September 14, 2012. Plaintiff suffered a severe, near fatal adverse drug reaction called Stevens-Johnson syndrome ("SJS") that progressed into toxic epidermal necrolysis ("TEN"). The drug reaction was the direct result of Plaintiff's ingestion of Cleocin. SJS and TEN are severe, often fatal, mucocutaneous and skin conditions that are caused by pharmaceutical drugs. The mortality rate for SJS and TEN range from 30-80%. Most survivors of SJS and TEN are afflicted with permanent injuries, including permanent blindness, penile scarring, permanent lung injuries, psychiatric and cognitive brain damage, loss of hair, toenails and fingernails falling off, peripheral neuropathies, post-traumatic stress disorder, depression, esophageal strictures, liver and kidney failure or other multi-organ dysfunction. Plaintiff suffered many of these injuries.

7. Plaintiff was an immunocompromised patient due to his multiple myeloma when

he was prescribed Cleocin IV by his treating infectious disease physician in September 14, 2012. At the time of prescription, Plaintiff was receiving medical attention for a diabetic foot infection or cellulitis at Nanticoke Memorial Hospital located in Seaford, Delaware. Within hours of receiving the drug, Mr. Bird developed a maculopapular drug eruption that progressed into a severe, sloughing and desquamating loss of his skin resulting in 2nd and 3rd degree burns to his entire body, following which he was diagnosed with TEN. TEN is only caused by drugs, and resulted in 2nd and 3rd degree burns over 100% of Plaintiffs body, including the melting and sloughing of his eyelids and face, and the sloughing and obliteration and melting of his mucosal surfaces involving eyes, nose, lungs, GI tract, anus, penis, urethra, liver, kidney and heart. Mr. Bird had to be transferred to the closest available burn unit on or about September 19, 2012 because he was at a high risk of death. Plaintiff required specialized care at the Crozer Burn Unit located in Philadelphia, Pennsylvania, where he was hospitalized for nearly one month fighting for his life. Mr. Bird was subjected to hydrotub wound care dressings that required burn nurses to pick his dead skin off his body while he was conscious, and then having antibiotic and other therapies applied to his burned and exposed skin every day for weeks. Mr. Bird was diagnosed with acute renal failure from this TEN necessitating dialysis given through a perm-a-cath, a retroperitoneal hematoma, bilateral pleural effusions, followed by multiple blood transfusions. He also developed thrombocytopenia, and septic shock. He was hospitalized in critical condition for weeks where it was documented that he was in excruciating pain and received substantial amounts of pain medication and sedatives.

8. Plaintiff also suffered hypoxic-ischemic episodes, ICU delirium, and severe metabolic deficiencies that resulted in neuro-cognitive damage that is irreversible and permanent. The treating physicians at Nanticoke and Crozer diagnosed Plaintiff with SJS and TEN from Cleocin at least two dozen times. He was finally discharged from Crozer Burn Unit

to a rehabilitation facility on October 9, 2012. Mr. Bird could not care for himself and had to be trained on walking, talking, bathing, strength, endurance, pain control in order to begin to recover from his devastating injuries. Despite completing physical therapy, occupational therapy, mobility training, and other therapeutic interventions, Plaintiff remains permanently and irreversibly injured, and has substantial permanent scarring from his burn injuries.

9. As a result of the materially false and misleading claims made by Pfizer regarding the safety and effectiveness of Defendant's product Cleocin, Plaintiff suffered severe, painful and permanent injuries, including but not limited to erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous fixed drug eruption (FDE), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens Johnson Syndrome or Toxic Epidermal Necrolysis, or Lyell's Syndrome.

10. These conditions and the resulting injuries were the direct result of the administration of Defendant's product Cleocin.

11. Had Plaintiff been made aware of these known risks and dangers associated with Defendant's product Cleocin, or had Pfizer disclosed such information to Plaintiff, or Plaintiff's treating physicians, Mr. Bird and/or his physicians would not have taken Defendant's product Cleocin, and Bird would not have suffered the adverse reaction and its subsequent catastrophic complications.

12. Mr. Bird's hospital charges for his stay in the burn unit at Crozer were over $1 million dollars.

**DEFENDANT'S WRONGFUL CONDUCT AND KNOWING FAILURE TO DISCLOSE AND/OR WARN**

13. Cleocin products can and do cause severe cutaneous adverse reactions ("SCAR"), including SJS and TEN. Cleocin caused Plaintiff's severe TEN reaction, nearly killing him.

Defendant is and was aware of the risk of SJS and TEN that Cleocin presents to the public. Indeed, there is a significant amount of peer-reviewed epidemiological data involving case-control studies, case-series, and case report literature and good quality spontaneous reports that supports the scientific finding that Cleocin products can and do cause SJS and TEN in both adults and children.

14. In its package insert for Cleocin products Pfizer did not disclose this important safety information from its own dermatology expert consultant Dr. Roujeau, who confirmed in the early 90s, that a cause of TEN was Cleocin. Despite its awareness of the risk, Defendant failed to adequately warn regarding the risks of SJS and TEN. In fact, Defendant's own expert, Dr. Roujeau, stated in 1993 that "*Considering the severity of TEN, even a few cases attributed to one drug may have profound implications on the marketing of this drug*."(Correia, 1993)

15. Defendant committed various acts of negligence and fraud, misled and failed to adequately warn the users of the potential serious dangers which Defendant knew or should have known might result from being exposed to and consuming its product, Cleocin. Notably, at the time Bird was prescribed and administered Cleocin intravenously, Defendant was well aware that individuals who were immunocompromised, like Plaintiff, were at an increased risk for SJS and TEN if they were exposed to, or administered, Cleocin.

16. Defendant also manufactures, markets and sells vastly safer alternative antibiotic drugs, including Zyvox that are approved for the treatment of the same indications for which Cleocin was prescribed for Bird. Defendant has known or should have known about the risks of SJS and TEN associated with Cleocin for the last 30 years, and has known about patient populations that are even at higher risks of SJS and TEN. Defendant has blatantly and callously ignored the risks of SJS and TEN, and has never in the decades that Cleocin has been marketed, provided warnings in its physician package insert, or a Medication Guide or patient information

leaflet. Instead, Defendant deceptively hid the known risks from U.S. physicians and patients.

17. Moreover, Defendant defrauded various healthcare and regulatory entities by concealing the risks of these deadly drug-induced diseases. Defendant knew that the most vulnerable patients in our society, such as immunocompromised adults, including those who have malignancies such as HIV or AIDS, were at unacceptable risks of SJS and TEN.

18. In fact, Defendant's own experts reported in the literature as far back as the early 90s that clindamycin was being used frequently in the HIV/AIDS population (likewise immunocompromised) to treat pneumocystis carinii or toxoplasmosis, and that Cleocin was causing increased number of cases of TEN in this patient population. Despite this acute awareness, Defendant continued to ignore its own experts regarding the 1,000 times increased risk Cleocin presented to HIV/AIDS patients and elected not to warn about the risks in its prescribing information or labeling.

19. At all times material, Defendant was fully aware that certain populations, such as females and African-Americans were at higher risks of SJS and TEN from Cleocin, yet failed to provide warnings, precautions, or otherwise alert physicians and consumers regarding the early symptoms of SJS and TEN.

20. Prior to being prescribed Cleocin, Plaintiff was diagnosed with a condition called multiple myeloma, a cancer of the plasma cells - a type of white blood cell present in bone marrow. Plaintiff's myeloma was under control at the time he was prescribed Cleocin; however, he is considered to be an immunompromised patient due to this malignancy.

21. Defendant was aware that Cleocin would be prescribed to immunocompromised patients like Plaintiff. From 2006 to 2010, the incidence of multiple myeloma was 7.5 per 100,000 in men of all races in the U.S., and 4.5 per 100,000 in women of all races in the U.S. Despite knowing that there was a very large population with immunocompromised diseases that

would be exposed to Cleocin, Defendant failed to provide warnings for these individuals, like Plaintiff, who were at higher risks of SJS and TEN due to these immunocompromised conditions.

22. Defendant concealed safety and risk-benefit information from regulatory authorities, prescribing physicians and patients who use the Cleocin. For example, Pfizer received over 122 reports of SJS and TEN in the U.S. from 1969 to 2009, yet failed to conduct a comprehensive safety assessment of the risks of serious skin reactions associated with Cleocin, including SJS, TEN, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), fixed drug eruption (FDE), or other related cutaneous reactions associated with clindamycin. In fact, Pfizer's own experts reported in the public literature that its drug, Cleocin, had a statistically significant increased risk and reporting rate of SJS and TEN in the U.S. FDA database, even after controlling for confounding variables. Defendant ignored its own experts, and chose not to update its labeling to warn about this serious safety signal that was reported in a publicly available peer-reviewed literature.

23. The analyses, performed by Pfizer's dermatology expert, Dr. Maja Mockenhaupt, could have been conducted and provided to the FDA, prescribing physicians and patients as early as 2009. However, Pfizer elected not to do so - even though it had hired SCAR investigators for its drug Daypro as early as 1997. Pfizer's failure to research, report and warn did not meet the minimum standards set out by the FDA or the pharmaceutical industry with respect to performing reasonable and appropriate safety assessments Defendant failed to provide. Defendant's failure to warn regarding the risk Cleocin presented to Plaintiff and others on Cleocin is inexcusable given that Defendant provided (at least some form of limited) warnings for SJS and TEN in the prescribing information for several different Pfizer products, including Zithromax, Zosyn, Dilantin, Bextra, Advil and other Pfizer products.

24. As Defendant's own experts recognize in published literature, only 2-3 reports of SJS and TEN constitute a very strong safety signal for the adverse drug reaction. Despite its awareness and the known cases of SJS and TEN caused by Cleocin, Defendant failed to warn and continues to fail to warn, of this fatal drug reaction. Defendant's own dermatology experts/consultants reported an increased risk of SJS and TEN in patients with immunocomprised patients, like Plaintiff over 20 years ago. Defendant, however, continuously and consciously disregarded the safety of U.S. patients, including the most vulnerable patient populations, and concealed essential scientific information for the safe and effective use of Cleocin. This concealment includes misleading regulatory authorities, research centers and its IRBs, investigators, patients, pharmacy boards, insurance companies and its own shareholders. The fatal risk presented by SJS and TEN is so severe that Pfizer's drug Bextra was withdrawn from the worldwide market due to the risks of SJS and TEN.

25. Upon information and belief, as a result of the defective manufacturing and marketing Defendant's product Cleocin, Defendant still reaped huge profits, including sales of up to $300 million per year for Cleocin while concealing from the public, knowledge of the potentially very dangerous and hazardous drug reactions associated with the use or administration of Defendant's product Cleocin.

26. Defendant failed to perform adequate premarketing and postmarketing testing in that the adequate testing would have shown that Defendant's product Cleocin posed serious risks of serious skin reactions and other toxicities with respect to which Defendant should have taken appropriate measures to ensure that its defectively designed product would not be placed into the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects, along with measures to mitigate or completely eliminate these risks of these deadly diseases that can kill or severely

disable an otherwise healthy individual.

27. Prior to the manufacturing, sale and distribution of Defendant's product Cleocin to Plaintiff, Defendant, through its officers, directors and managing agents, had actual notice and convincing knowledge of these serious risks of SJS and TEN associated with Cleocin from several sources, including knowledge that the product presented substantial and unreasonable risks of harm to the consumer. As such, said consumers, including Bird, were unreasonably and unnecessarily subjected to risk of injury or death from the consumption of Defendant's product, Cleocin. Defendant knew that certain populations were at greater risks of serious injury or death from SJS and TEN, however, the Defendant blatantly failed to inform prescribers or patients about these unreasonable risks of serious harm, especially when the Defendant knew of a safer alternatives, and knew that adding warnings to the labeling could have been effective in eliminating or mitigating these risks substantially because Pfizer has advocated that warnings about SJS and TEN are important and paramount for patient safety.

28. Despite such knowledge and actual awareness of these risks, Defendant, through its officers, directors and managing agents, for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to adequately study or even make any attempt to remedy the known defects of Defendant's product Cleocin and failed to adequately warn the U.S. public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendant's product Cleocin. The U.S. FDA Adverse Event Reporting System (FAERS) database has reported that many deaths due to serious skin reactions associated with Cleocin products have been reported to Pfizer.

29. On or about May 26, 2010, one of the field offices for the U.S. FDA issued a notice of violations warning letter to the CEO of Pfizer at the timeregarding the findings of the FDA's inspection of Pfizer's Pharmacovigiliance Department during the period from June 29,

2009 through August 10, 2009. The FDA inspection was conducted by FDA investigators to determine Pfizer's compliance with the Postmarketing Adverse Drug Experience (PADE) reporting requirements of Section 505(k) of the Federal Food, Drug, and Cosmetic Act (the Act)) [21 U.S.C. § 355(k)], and Title 21, Code of Federal Regulations (21 CFR) 314.80 and 314.81.

30. The FDA noted that Section 505(k)(1) of the Act [21 U.S.C. § 355(k)(1)] and 21 CFR 314.80 and 314.81 require an applicant to establish and maintain records and to report data relating to clinical experience, along with other data or information, for drugs for which an approved application is in effect. The FDA noted that failure to comply with Section 505(k) is a prohibited act under Section 301(e) of the Act [21 U.S.C. § 331(e)]. The FDA inspectors found that Pfizer had violated or committed deviations from 21 CFR 314.80 and 21 CFR 314.81 to include the failure by Pfizer to submit Adverse Drug Experience (ADE) reports to FDA as required by 21 CFR 314.80(c). Specifically, Pfizer was found to have violated the reporting requirements of a serious, 15-day report involving Dalacin, which is the exact same drug as Cleocin, but is called Dalacin outside the U.S.

31. In the FDA's recent Enforcement report dated for the week of June 26, 2013, the FDA posted a notice of recall identified as Recall Number D-609-2013 for Cleocin Phosphate (clindamycin Injection), USP, a) 600 mg/4mL (150 mg/mL) ADD-Vantage Vial, b) 900 mg/6mL (150 mg/mL) ADD-Vantage Vial, Rx Only, For Intravenous Use Only, Use Only with the ADD-Vantage diluent container, Distributed by Pharmacia & Upjohn Co, Division of Pfizer Inc, NY, NY 10017, NDC a) 0009-3124-03 and b) 0009-3447-03.

32. This is the very same IV product that was used by Mr. Bird, just months before the recall. The total number of Cleocin IV products distributed were approximately 898,000 vials of Cleocin. The reason for the recall was due to a manufacturing defect that involved the presence of Particulate Matter: Firm is recalling a small number of vials with very small reflective flakes

consistent with delamination of the glass vial. (http://www.accessdata.fda.gov/scripts /enforcement/enforce_rpt-Product-tabs.cfm?action=select&recall_number=D-609-2013&w=062 62013&lang=eng) The recall was initiated on or about June 4, 2013.

33. Plaintiff contends that Cleocin IV was not manufactured pursuant to appropriate GMP Manufacturing practice and quality standards at the time the product was distributed in the stream of commerce when it was dispensed and used by Mr. Bird in 2012.

**ADDITIONAL SPECIFIC ALLEGATIONS OF FRAUD**

34. Pfizer has paid almost $3 billion in public agency fines since 2002 and entered into three corporate integrity agreements with the Department of Health and Human Services aimed at preventing future fraud. (See http://usatoday30.usatoday. com/news/washington/story/ 2012-03-05/health-drugmakers-fraud-fines) Some of Pfizer's historical acts of fraud are documented in the following press reports:

> 1) American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.
>
> Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.
>
> In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil

settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is $668,514,830 and the state Medicaid share of the civil settlement is $331,485,170. This is the largest civil fraud settlement in history against a pharmaceutical company.

As part of the settlement, Pfizer also has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter. (See http://www.hhs.gov/news/press/2009pres/09/20090902a.html)

2) The Securities and Exchange Commission today charged Pfizer Inc. with violating the Foreign Corrupt Practices Act (FCPA) when its subsidiaries bribed doctors and other health care professionals employed by foreign governments in order to win business.

The SEC alleges that employees and agents of Pfizer's subsidiaries in Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia made improper payments to foreign officials to obtain regulatory and formulary approvals, sales, and increased prescriptions for the company's pharmaceutical products. They tried to conceal the bribery by improperly recording the transactions in accounting records as legitimate expenses for promotional activities, marketing, training, travel and entertainment, clinical trials, freight, conferences, and advertising.

The SEC separately charged another pharmaceutical company that Pfizer acquired a few years ago – Wyeth LLC – with its own FCPA violations. Pfizer and Wyeth agreed to separate settlements in which they will pay more than $45 million combined to settle their respective charges. In a parallel action, the Department of Justice announced that Pfizer H.C.P. Corporation agreed to pay a $15 million penalty to resolve its investigation of FCPA violations.

According to the SEC's complaint against Pfizer filed in U.S. District Court for the District of Columbia, the misconduct dates back as far as 2001. Employees of Pfizer's subsidiaries authorized and made cash payments and provided other incentives to bribe government doctors to utilize Pfizer products. In China, for example, Pfizer employees invited "high-prescribing doctors" in the Chinese government to club-like meetings that included extensive recreational and entertainment activities to reward doctors' past product sales or prescriptions. Pfizer China also created various "point programs" under which government doctors could accumulate points based on the number of Pfizer prescriptions they wrote. The points were redeemed for various gifts ranging from medical books to cell phones, tea sets, and reading glasses. In Croatia, Pfizer employees created a "bonus program" for Croatian doctors who were employed in senior positions in Croatian government health care institutions. Once a doctor agreed to use Pfizer products, a percentage of the value purchased by a doctor's institution would be funneled back to the doctor in the form of cash, international travel, or free products.

3) In October of 2012, Pfizer's Wyeth pharmaceuticals unit and the Justice Department reached a tentative agreement for Pfizer to pay a total of $491 million to

resolve criminal and civil investigations of Wyeth's practices in marketing the organ transplant drug Rapamune. (http://www.northjersey.com/news/178976781_Pfizer_resolving _several_lawsuits_over_its_drugs.html)

4) Pfizer has agreed to plead guilty to a misdemeanor federal "misbranding offense" and to pay about $234 million to resolve criminal allegations and $257 million to resolve civil allegations. (http://www.northjersey.com/news/178976781_Pfizer_resolving_several_ lawsuits_over_its_drugs.html)

5) In another case, Pfizer reached an agreement in October to pay $164 million to end multiple potential class action lawsuits regarding its painkiller Celebrex, which generates well over $1 billion in annual year sales. The case originated in 2003, when several classaction complaints against Pfizer, its Pharmacia unit and certain former Pharmacia officers were filed in federal court in New Jersey. Pfizer had acquired Pharmacia, of Peapack, N.J., early in 2003, mainly to acquire the rights to Celebrex. (http://www.northjersey.com/news/178976781_Pfizer_resolving_several_lawsuits_over_its_drugs.html)

6) Attorney General J.B. Van Hollen of Wisconsin announced today that he and 32 other Attorneys General obtained a $42.9 million Consent Judgment with Pfizer Inc. to resolve allegations that Pfizer Inc. unlawfully promoted its drugs Zyvox® and Lyrica®. The Attorneys General allege that Pfizer Inc. engaged in misrepresentations in its promotion of Zyvox® by making misleading and unsubstantiated superiority claims that broadened the indications for Zyvox®, an antibacterial agent approved to treat certain types of infections, including among other approved indications, nosocomial pneumonia caused by methicillin-resistant *Staphylococcus aureus* (“MRSA”) and complicated skin and skin structure infections due to MRSA. Moreover, the Attorneys General allege that Pfizer Inc. engaged in untrue and deceptive representations in promoting Lyrica® for off-label uses.

“Making false claims about a drug's superiority not only violates our State's consumer protection laws, but it could put the public health at risk,” Van Hollen said. “For this reason, the State of Wisconsin will continue to be diligent in prosecuting pharmaceutical companies that misrepresent important characteristics of their drugs.” As part of the Consent Judgment, Pfizer Inc. is required to reform how it markets and promotes Zyvox® and Lyrica®. Under the Consent Judgment, Pfizer Inc. shall not:

- Make any false, misleading, or deceptive claims when comparing the efficacy or safety of Zyvox® to vancomycin;
- Promote any Pfizer product for off-label uses;
- Fail to design financial incentives that ensure that its marketing personnel are not motivated to engage in the improper marketing of Zyvox® or Lyrica®; or
- Fail to notify its sales force promptly of any warning letter received from the FDA that affects sales representatives in the promotion of Pfizer products.

> The investigation was led by the Attorney General of Texas with an Executive Committee consisting of the Attorneys General of Arizona, Illinois, Maryland, New Jersey, Pennsylvania, and South Carolina. Also participating in the settlement are Alabama, Arkansas, California, Colorado, Delaware, the District of Columbia, Florida, Hawaii, Idaho, Indiana, Kansas, Kentucky, Michigan, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Rhode Island, South Dakota, Tennessee, Vermont, Washington, Virginia, and Wisconsin. (See (http://www.doj.state.wi.us/media-center/2012-news-releases/december-12-2012)

35. In September of 2009, Pfizer entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General of the Department of the Health and Human Services that lasts through 2014. Plaintiff believes that Pfizer may have violated this agreement with respect to its conduct in the marketing, distribution and manufacturing of Cleocin. Further, Plaintiff contends that Pfizer may have committed acts of fraud, and violations of Securities & Exchange Commission (SEC) regulations involving bribery and corruption with the marketing and sales of Cleocin in the United Statesand throughout the world.

36. Defendant has in the past, and in this case, acted with conscious and wanton disregard of the health and safety of Plaintiff and others similarly situated. As a result, Plaintiff requests an award of additional damages for the sake of example and for the purpose of punishing such entities for their conduct, in an amount sufficiently large to be an example to others, and to deter Defendant and others from engaging in similar conduct in the future. The above-described wrongful conduct was done with knowledge, authorization, and ratification of officers, directors, and managing agents of Defendant.

37. As a direct and proximate result of Defendant's negligence as described herein, Plaintiff sustained harm, including months of painful adverse reactions to Defendant's product. These injuries caused Plaintiff extensive pain and suffering and severe emotional distress and economic damages through the expense of substantial sums of money for medical, hospital,

rehabilitative and related care. Plaintiff brings the claims below to recover these damages and to punish Defendant.

**FIRST CLAIM FOR RELIEF**
**STRICT PRODUCT LIABILITY - FAILURE TO WARN**

38. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

39. Defendant manufactured, marketed, distributed, and supplied Defendant's product Cleocin. As such, Defendant had a duty to warn the public including Plaintiff of the serious adverse health risks associated with using Defendant's product Cleocin.

40. Defendant's product Cleocin was under the exclusive control of Defendant, and was sold without any adequate warnings regarding the risk of serious skin reactions including, but not limited to, erythema multiforme exudativum, bullous fixed drug eruption, SCAR, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms exfoliative dermatitis, TEN, SJS and other risks associated with its use.

41. As a direct and proximate result of the defective condition of Defendant's product Cleocin, as manufactured and/or supplied by Defendant, and as a direct and proximate result of negligence, gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendant described herein, Plaintiff suffered injury, harm, decreased lifespan, and economic loss as alleged herein.

42. Defendant knew of the defective nature of Defendant's product Cleocin but continued to design, manufacture, market, and sell Defendant's product Cleocin so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Defendant's product Cleocin and in violation of its duty to provide any warnings, making its labeling inaccurate, misleading and

false in all regards to the risks of these fatal reactions concerning the use of Defendant's product Cleocin.

43. Defendant failed to adequately study the risks of serious skin reactions either in the premarketing or postmarketing phase of the marketing of Cleocin, and failed to inform or adequately warn the FDA, the public, Plaintiff or Plaintiff's prescribing physicians of the dangerous propensities of Defendant's product Cleocin, which dangers were known or should have been known to Defendant, as they were scientifically readily available to Defendant. Defendant failed to comply with basic and minimum risk-benefit assessments, including comprehensive safety assessments of Cleocin, and the submission of such data pursuant to its IND and to the NDA regulations pursuant to 314.50, and with FDA regulations governing the prescription labeling, including 21 C.F.R. 201.56, 201.57, 314.70. 314.80, 314.81 and 201.80. Further, Defendant since 1998 had the ability to request and obtain a patient Medication Guide that would have provided adequate warnings of the risks associated with SJS and TEN for Cleocin, but has never done so.

44. Defendant knew and intended that Defendant's product Cleocin would be prescribed by physicians and would be used by persons with a prescription, without any inspection for defects. Defendant also knew that physicians and users such as Plaintiff would rely upon the representations made by Defendant on the product labels and in other promotional and sales materials upon which the Plaintiff's prescribing physician did so rely.

45. As a direct and proximate result of the Defendant's sale of the product Cleocin without adequate warnings regarding the risk of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms exfoliative

dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other risks associated with its use, Plaintiff suffered injury and harm as previously alleged herein.

46. Defendant's conduct in the packaging, warning, marketing, advertising, promotion, distribution, and sale of Defendant's product Cleocin, was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter it from similar conduct in the future.

**SECOND CLAIM FOR RELIEF**
**STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN AND/OR MANUFACTURE**

47. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

48. Defendant was the manufacturer, seller, distributor, marketer, and/or supplier of Defendant's product Cleocin, which was defective and unreasonably dangerous to consumers.

49. Defendant's product Cleocin was sold, distributed, supplied, manufactured, marketed, and/or promoted by Defendant, and was expected to reach and did reach consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

50. The product Cleocin manufactured, supplied, and/or sold by Defendant was defective in design or formulation in that when it left the hands of the manufacturers and/or sellers and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation, the foreseeable risks exceeded the benefits associated with the designs or formulations of the product.

51. Upon information and belief, Defendant actually knew of the defective nature of Defendant's product Cleocin but continued to design, manufacture, market, and sell it so as to

maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Defendant's product Cleocin.

52. There were safer alternative methods and designs for the product.

53. At all times material, Cleocin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendant in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Bird, to risks which exceeded the benefits of the drug;

b. The drug was insufficiently tested;

c. The drug caused harmful side effects that outweighed any potential utility;

d. The drug was not accompanied by adequate labeling, instructions for use and/or earnings to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects associated with its use, thereby rendering Defendant liable to Plaintiff.

e. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Cleocin should not have been marketed in that condition.

54. At all times material, the drug Cleocin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach,

users and/or consumers of the drug across the United Sates, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold.

55. At all times, Plaintiff used Cleocin for its intended or reasonably foreseeable purpose. As a direct, legal proximate and producing result of the defective and unreasonably dangerous condition of Cleocin, Plaintiff has sustained harm, including severe permanent injuries, among other things, for which Plaintiff is entitled to damages. These injuries have caused extensive pain and suffering, severe emotional distress to Plaintiff and his family, and caused Plaintiff, to expend substantial sums of money for medical, hospital, rehabilitative and related care.

56. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Cleocin, Plaintiff was injured in health, strength and activity and has suffered physical injuries as well as mental anguish. All of these injuries caused Plaintiff intense anxiety, distress, fear, pain and suffering secondary to physical injury and damages, for which Plaintiff is entitled to damages.

57. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition, Plaintiff required reasonable and necessary health care treatment and services and incurred expenses for which Plaintiff is entitled to damages.

58. As a direct and proximate result of the design and manufacturing defects of Defendant's product Cleocin, Plaintiff has suffered injury and harm as previously alleged herein, including ascertainable economic loss, including the purchase price of Defendant's product Cleocin, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Plaintiff's use or administration of this harmful and defective product, as well as extreme pain and suffering, loss of enjoyment of life, and other injuries.

59. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff and others, including Defendant's knowingly withholding and/or misrepresenting information to the public including Plaintiff, which information was material and relevant to the harm in question, punitive damages in an amount to be determined at trial that are appropriate to punish Defendant and deter it from similar conduct in the future.

**THIRD CLAIM FOR RELIEF**
**NEGLIGENT MISREPRESENTATION AND FRAUD AND/OR FRAUDULENT CONCEALMENT**

60. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

61. At all material times, Defendant was engaged in the business of manufacturing, marketing, distributing, promoting, and selling Defendant's product Cleocin. Defendant made misrepresentations of material facts to, and omitted and/or concealed material facts from Plaintiff's prescribing physician in the advertising, marketing, distribution and sale of Defendant's product Cleocin regarding its safety and use. Prior to Plaintiffs' first dose of Cleocin, and during the period in which he was administered Cleocin, Defendant misrepresented that Cleocin IV (IV clindamycin) was a safe and effective means of treating certain infections.

62. Defendant deliberately and intentionally misrepresented to, and omitted and/or concealed material facts from, consumers, including Plaintiff, and prescribing physicians, that Defendant's product Cleocin was safe when used as intended. Such misrepresentations, omissions, and concealments of facts include, but are not limited to:

a. Failing to disclose, and/or intentionally concealing, the results of tests showing the potential risks of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous

pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other injuries associated with the use of Defendant's product Cleocin;

b. Failing to include adequate warnings with Defendant's product Cleocin about the potential and actual risks and the nature, scope, severity, and duration of serious adverse effects of Defendant's product Cleocin;

c. Concealing and/or providing false or inaccurate information regarding the known risks of serious skin reactions, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other risks associated with Defendant's product Cleocin; and

d. Concealing the known incidents of serious skin reactions, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other injuries, as previously alleged herein.

63. Defendant intentionally concealed facts known to it, as alleged herein, in order to ensure increased sales of Defendant's product Cleocin.

64. Defendant had a duty to disclose the foregoing risks and failed to do so, despite possession of information concerning those risks. Defendant's representations that Defendant's product Cleocin was safe for its intended purpose were false, as Defendant's product Cleocin was, in fact, dangerous to Bird's health. Moreover, Defendant knew that its statements were false, knew of incidents of serious injuries, such as serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome, and knew that their omissions rendered its statements false or misleading.

65. Further, Defendant failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Defendant's product Cleocin, and failed to disclose that Defendant's product Cleocin caused serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome, among other serious adverse effects. Defendant also failed to exercise reasonable care in communicating the information concerning Defendant's product Cleocin to Plaintiff, and/or concealed facts that were known to Defendant.

66. Plaintiff was not aware of the falsity of the foregoing representations, nor was Plaintiff aware that material facts concerning the safety of Defendant's product Cleocin had been concealed or omitted. In reliance upon Defendant's misrepresentations (and the absence of disclosure of the serious health risks), Plaintiff was administered Defendant's product Cleocin. Had Plaintiff known the true facts concerning the risks associated with Defendant's product Cleocin, he would not have taken it.

67. The reliance by Plaintiff upon Defendant's misrepresentations was justified because said misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning Defendant's product Cleocin. Plaintiff was not in a position to know the true facts because Defendant aggressively promoted the use of Defendant's product Cleocin and concealed the risks associated with its use, thereby inducing Plaintiff and his prescribing physician to use Defendant's product Cleocin.

68. As a direct and proximate result of Defendant's misrepresentations, and/or concealment, Plaintiff suffered conscious pain and suffering, and suffered injury and harm as previously alleged.

69. Defendant's conduct in concealing material facts and making the foregoing misrepresentations, as alleged herein, was committed with conscious or reckless disregard of the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter it from similar conduct in the future. In no way is Plaintiff alleging any cause of action of fraud on the FDA. Defendant's conduct, as described above, was extreme and outrageous. Defendant risked the lives of the consumers and users of its products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendant made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's outrageous conduct warrants an award of punitive damages.

**FOURTH CLAIM FOR RELIEF**
**BREACH OF WARRANTY**

70. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

71. Defendant manufactured, marketed, sold, and distributed Defendant's product Cleocin. At the time Defendant marketed, sold, and distributed Defendant's product Cleocin for use by Plaintiff, Defendant knew of the purpose for which Defendant's product Cleocin was intended and impliedly warranted Defendant's product Cleocin to be of merchantable quality and safe and fit for such use.

72. Plaintiff's prescribing physician reasonably relied on the skill, superior knowledge, and judgment of Defendant as to whether Defendant's product Cleocin was of merchantable quality and safe and fit for its intended use.

73. Plaintiff used Defendant's product Cleocin which was provided to Plaintiff's prescribing physician by the Defendant. Due to Defendant's wrongful conduct as alleged

herein, Plaintiff could not have known about the risks and side effects associated with Defendant's product Cleocin until after Plaintiff developed SJS and TEN from Cleocin, which was too late.

74. Contrary to such implied warranty, Defendant's product Cleocin was not of merchantable quality and was not safe or fit for its intended use.

75. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff suffered conscious pain and suffering and suffered injury and harm as previously alleged herein.

76. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter it from similar conduct in the future.

**FIFTH CLAIM FOR RELIEF**
**BREACH OF EXPRESS WARRANTY**

77. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

78. Defendant expressly warranted that Cleocin was safe and well accepted by patients and was safe for most, if not all patients, without any regard to specific subpopulations.

79. Cleocin does not conform to these express representations because Cleocin is not safe and has high levels of serious, life-threatening side effects.

80. As a direct and proximate result of the breach of said warranties, Plaintiff has been damaged, and is therefore entitled to damages as described herein.

## SIXTH CLAIM FOR RELIEF
## NEGLIGENCE

81. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

82. Defendant owed a duty to consumers of Defendant's product Cleocin, including Plaintiff, to use reasonable care in designing, testing, labeling, manufacturing, marketing, supplying, distribution and selling Defendant's product Cleocin, including a duty to ensure that Defendant's Product Cleocin did not cause users to suffer from unreasonable, unknown, and/or dangerous side effects.

83. Defendant failed to exercise reasonable care in the warning about, designing, testing, labeling, manufacture, marketing, sale, and/or distribution of Defendant's product Cleocin and breached its duties to Plaintiff in that, and not by way of limitation, it did not warn of the known risks associated with the use of Defendant's product Cleocin and did not exercise an acceptable standard of care, *i.e.*, what a reasonably prudent manufacturer or seller would have known and warned about. Moreover, the product lacked sufficient warnings of the hazards and dangers to users of said product, and failed to provide safeguards to prevent the injuries sustained by Plaintiff. Defendant failed to properly test Defendant's product Cleocin prior to its sale, and as a result subjected users to an unreasonable risk of injury when those products was used as directed and recommended.

84. Defendant additionally breached its duty and was negligent in its actions, misrepresentations, and omissions toward Plaintiff, in part, in the following ways:

a. Failed to exercise due care in designing, developing, and manufacturing Defendant's Product Cleocin so as to avoid the aforementioned risks to individuals, and specific individuals with higher risks of SJS and TEN that would be using these products;

b. Failed to include adequate warnings, precautions, information for patients,

Medication Guides, patient information leaflets, or other risk-benefit communications with Defendant's product Cleocin that would alert prescribers, Plaintiff and other users or consumers to its potential risks and serious side effects;

c. Failed to adequately and properly test Defendant's product Cleocin before and after placing it on the market;

d. Failed to conduct sufficient testing or safety analyses on Defendant's product Cleocin, which if properly performed, would have shown that Defendant's Product Cleocin had serious side effects, including, but not limited to, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other serious skin reactions; and that certain subpopulations would be at greater risks, that the risk-benefit profile was significantly affected by the increased risks of these diseases to patients that would be exposed to treat various infections; that the frequency was greater than disclosed; that the reporting rate of SJS and TEN associated with Cleocin was greater than ever expected or disclosed by Defendant; that the risks is highest during the first 2-8 weeks of therapy; that no Dear Healthcare professional letter were ever sent to prescribers to warn about the risks, but should have been sent by Defendant;

e. Failed to adequately warn Plaintiff and physicians that use of Defendant's product Cleocin carried a risk of serious skin reactions; erythema multiformeexudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other serious side effects and the potential for death, blindness, urogenital injury, pulmonary injury, brain damage, disfiguring scarring of the body; damage to other organs;

f. Failed to provide adequate post-marketing warnings or instructions after Defendant knew, or should have known, of the significant risks of reactions from the use of Defendant's product Cleocin; and failed to adequately perform Pharmacovigilance activities to evaluate safety signals and actions to take to eliminated or mitigate the risks of SJS and TEN associated with Cleocin or clindamycin products;

g. Placed an unsafe product into the stream of commerce;

h. Negligently engaged, and continues to engage in false and misleading statements and data regarding its safety information, or lack thereof, with

respect to the risks of SJS and TEN, and other serious skin reactions (DRESS, AGEP) associated with its products, Cleocin;

i. Failed to disclose critical epidemiological data, incidence data, risk factors data, and additional safety information related to increased frequency/risks to certain subpopulations, along with the failure to require proper warnings for Cleocin/clindamycin in efforts to mitigate or reduce the risks of serious skin reactions associated with its Cleocin/clindamycin products;

j. Failed to disclose and warn prescribers and patients about how certain subpop- ulations were at increased risks of serious skin reactions, death and disability associated with Cleocin/clindamycin therapy compared to its lack of benefits for most patients;

k. Failed to warn prescribers or patients that certain predictors or risk factors increase the risk of serious rash, and that these risk factors have been proven to be associated with Cleocin/clindamycin, to increase therisks of serious rash, and death and disability. Some of these proven risk factors, include females, immunocompromised, HIV/AIDS patients, African-Americans, all of this is not adequately disclosed in all forms of labeling for Cleocin/clindamycin, including package insert, Medication Guides or Dear Doctor Letters the various increased risks of SJS and TEN associated with these products;

l. Failed to implement its own consultants' recommendations from the SCAR and EuroSCAR group regarding how warnings about the risks of SJS and TEN are very important to mitigate fatalities and disability associated with SJS and TEN, DRESS and AGEP;

m. Failed to timely and adequately amend its labeling to reflect the publicly available scientific literature reporting on the increasing reporting of serious cutaneous reactions, the strong safety signal between SJS/TEN and Cleocin, and the reporting of unique and distinct adverse events that are included in serious skin reactions and fatalities, including DRESS and AGEP that were associated with Cleocin products;

n. Failed to state in the labeling for Cleocin products definitively that Cleocin can and does cause SJS and TEN. Instead it makes a very inaccurate and misleading statement that "*Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome…*" have occurred with clindamycin. The label does not list TEN in the labeling. Instead, Pfizer describes something that might look like SJS, but is not definite, leaving the prescriber to think that the association or risk from its product is ambiguous, or that it does not cause TEN. Even though the literature and Pfizer's own experts have published that it is not only causal, but that certain patients (HIV/AIDS) have up to 1000 times higher

risks of SJS and TEN (Roujeau and Revuz, "Toxic epidermal necrolysis: An expanding field of knowledge," J Am Acad Dermatol 31:301-2, 1994);

o. Failed to conduct, implement and report on very detailed safety surveillance regarding all of these safety factors related to serious skin reactions, even when its own experts and consultants were recommending further surveillance of Cleocin was needed, especially if larger populations are likely to use this medication;

p. Failed to provide critical safety information in the INFORMATION FOR PATIENTS SECTION, or the Medication Guide regarding the risk factors for serious skin reactions involving, SJS, TEN, DRESS and AGEP, including (females, immunocompromised, HIV/AIDS, early withdrawal important) associated with Cleocin, and information on how its use should be restricted in certain subpopulations, or how the risks of serious cutaneous reactions associated with Cleocin/clindamycin, could be reduced through other risk mitigation measures.

q. Was otherwise careless or negligent.

85. Defendant knew, or should have known, that Defendant's product Cleocin caused unreasonably dangerous risks and serious side effects of which Plaintiff would not be aware. Defendant nevertheless advertised, marketed, sold and/or distributed Defendant's product Cleocin knowing of its unreasonable risks of injury.

86. Defendant knew or should have known that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

87. Upon information and belief, Defendant knew or should have known of the defective nature of Defendant's product Cleocin, as set forth herein, but continued to design, manufacture, market, and sell Defendant's product Cleocin so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Defendant's product Cleocin.

88. Defendant failed to disclose to prescribers, Plaintiff and the general public facts known or available to it, as alleged herein, in order to ensure continued and increased sales of Defendant's product Cleocin. This failure to disclose deprived Plaintiff of the information

necessary for his to weigh the true risks of taking Defendant's product Cleocin against the benefits.

89. As a direct and proximate result of Plaintiff's use of Defendant's product Cleocin, Plaintiff suffered serious bodily injury, including, but not limited to, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson Syndrome, a severe adverse reaction, and skin disorder.

90. By virtue of Defendant's negligence, Defendant has directly, foreseeable and proximately caused Bird to suffer serious bodily injury, loss of lifespan, and significantly decreased enjoyment of the end period of his life. As a result, the imposition of punitive damages against Defendant is warranted.

91. As a direct and proximate result of Defendant's negligence, Plaintiff has suffered conscious pain and suffering and suffered injury and harm as previously alleged herein.

**SEVENTH CLAIM FOR RELIEF**
**MANUFACTURING DEFECT**

92. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

93. At all pertinent times, Defendant was engaged in the business of designing, manufacturing, marketing, testing, labeling, selling, distributing, and placing Cleocin products into the stream of commerce, including the Cleocin IV that was used by Plaintiff just prior to the time of his developing TEN.

94. When it left the control of Defendant, defects in the manufacture of the Cleocin IV rendered it defective and unreasonably dangerous in that it was prone to expose patients to clindamycin and excipients that are known to induce serious skin reactions, such as SJS and TEN

in animals and humans. Pfizer had to recall numerous lots and vials of its Cleocin IV formulation due to manufacturing quality defects, and the production of which did not meet GMP standards and the Cleocin products did not meet the quality and purity characteristics that it purported or is represented to possess at the time it was distributed and used by Plaintiff.

95. Plaintiffs contend that Pfizer failed to comply with Good Manufacturing Practices for Finished pharmaceutical products, and specifically, violated 21 C.FR. 211.22-211.180, and these violations contributed to the adulterated or defective vials of Cleocin.

96. Plaintiff used the Cleocin IV for its intended and foreseeable purpose.

97. The defective manufacture of Defendant's Cleocin IV products directly and proximately caused Plaintiff's SJS and TEN reaction, and his related injuries and Plaintiff's damages.

**EIGHT CLAIM FOR RELIEF**
**GROSS NEGLIGENCE**

98. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

99. Defendant had a duty to exercise reasonable care in warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product Cleocin, including a duty to ensure that Defendant's product Cleocin did not cause users to suffer from unreasonable and dangerous side effects.

100. Defendant failed to exercise reasonable care in warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's Product Cleocin, in that Defendant knew or should have known that taking Defendant's Product Cleocin caused unreasonable and life-threatening injuries, and death as alleged herein.

101. Defendant is grossly negligent in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product Cleocin as recited the in statement of facts above and the negligence count above.

102. Although Defendant knew, or recklessly disregarded, the fact that Defendant's product Cleocin caused potentially lethal side effects, Defendant continued to market Defendant's product Cleocin to consumers, including Plaintiff, without disclosing these side effects.

103. Defendant knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

104. Defendant knew of, or recklessly disregarded the defective nature of Defendant's product Cleocin, as set forth herein, but continued to design, manufacture, market, and sell Defendant's Product Cleocin so as to maximize sales and profits at the expense of the health and safety of the public, including Bird, in conscious and/or reckless disregard of the foreseeable harm caused by Defendant's product Cleocin.

105. As a direct and proximate result of the gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendant described herein, which constitute a deliberate act or omission with knowledge of a high degree probability of harm and reckless indifference to the consequences, Plaintiff suffered conscious pain and suffering, and suffered injury and harm as previously alleged herein. In addition, Plaintiff was rendered sick, blistered and scarred, both internally and externally. All of said injuries have caused Plaintiff, and continue to cause Plaintiff, intense anxiety, distress, fear, pain, suffering, and distress secondary to the physical injury and damages.

106. As a direct and proximate result of the gross negligence, willful and wanton

misconduct, or other wrongdoing and actions of Defendant, which constitute a deliberate act or omission with knowledge of a high degree probability of harm and reckless indifference to the consequences, Plaintiff incurred unnecessary medical and/or hospital bills.

107. Defendant's aforementioned conduct was committed with knowing, conscious, and/or deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendant and deter it from similar conduct in the future.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff prays for relief as follows:

a. Awarding actual and compensatory, and any ancillary damages to Plaintiff incidental to Plaintiff's ingestion of, and subsequent severe adverse reaction to, Defendant's product Cleocin and or associated products in an amount to be determined at trial;

b. Awarding punitive damages to Plaintiff;

c. Awarding pre-judgment and post-judgment interest to Plaintiff;

d. Awarding the costs and expenses of this litigation to Plaintiff;

e. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

f. For such further relief as this Court deems necessary, just, and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all issues so triable in this civil action.

Dated: New York, New York
October 24, 2013

/s/ Richard B. Brualdi

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