NOTICE TO THE BAR

MASS TORTS – APPLICATION FOR MASS TORT DESIGNATION OF NEW JERSEY STATE-COURT LITIGATION INVOLVING THE DRUG PLAVIX®

Pursuant to Directive #7-09, "Revised Mass Tort Guidelines," an application has been made to the Supreme Court, through the Acting Administrative Director of the Courts, requesting designation of all New Jersey state-court litigation involving the drug Plavix® as a mass tort. The application includes a suggestion that the litigation, if designated as a mass tort, be assigned to Bergen County for centralized management.

Anyone wishing to comment on or object to this application should provide such comments or objections, with relevant supporting documentation, to the Acting Administrative Director of the Courts, P.O. Box 037, Trenton, NJ 08625-0037, by **May 27, 2011.**

A copy of the application is posted with this Notice and is also available on the Judiciary's Internet Website at (www.njcourts.com.) in the Mass Tort Information Center (http://www.judiciary.state.nj.us/mass-tort/index.htm).

/s/ Glenn A. Grant

Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts

Dated: April 15, 2011

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April 4, 2011

Civil Practice Division

APR 08 2011

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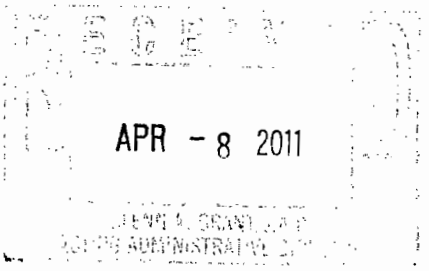

VIA FIRST-CLASS MAIL

Hon. Glenn A. Grant, J.A.D.
Acting Administrative Director
of the New Jersey Courts
Richard J. Hughes Justice Complex
25 Market Street
P.O. Box 037
Trenton, NJ 08625

Re: ***Application for Mass Tort Designation of Cases Involving Plavix®***

Dear Judge Grant:

Pursuant to Rule 4:38A and Revised Mass Tort Administrative Directive #7-09, Defendants Bristol-Myers Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (together "Sanofi") (collectively "Defendants") respectfully request mass tort treatment for pending and future personal injury litigation involving the drug Plavix®. More than forty plaintiffs have filed cases that are now pending in state and federal courts around the country, including five recently filed in Atlantic County, New Jersey (the "New Jersey State Actions"). Additional cases may be filed in New Jersey and other venues in the near future.

Coordination of the New Jersey State Actions will avoid duplicative discovery and motion practice, as well as the danger of inconsistent rulings. It will also allow this State's courts to coordinate with other judicial systems handling multiple Plavix® cases. Defendants

urge the Court to order coordination ***now***, to ensure that all pending and future New Jersey Plavix® cases proceed in an orderly and efficient fashion from the beginning.

Defendants further respectfully suggest that the cases be coordinated in Bergen County because it is the least congested of New Jersey's mass tort venues, as well as the most convenient to the parties, witnesses, and defense counsel. If Bergen County is unavailable, Defendants request coordination in Middlesex County. Atlantic County is the least appropriate choice for coordination because of its congestion and its geographic inconvenience for the parties, counsel, and witnesses.

Background

Plavix® has been approved by the U.S. Food & Drug Administration for treating certain cardiovascular and cerebrovascular conditions caused by blood clots. With U.S. sales exceeding $6.5 billion in 2010, Plavix® is one of the nation's most prescribed drugs.

Plavix® is marketed in the United States by BMS and Sanofi. BMS is a Delaware company with headquarters in New York City. It has five facilities in central New Jersey (Mercer County and Middlesex County). The Sanofi defendants are also Delaware companies, with headquarters in central New Jersey (Somerset County).

Plaintiffs around the country have sued BMS and Sanofi, asserting strict liability, negligence, and fraud claims for injuries they allege were caused by Plavix®. In 2006 and 2007, twenty-three such cases alleging substantially identical legal claims were filed in the U.S. District Court for the District of New Jersey. Pretrial proceedings in those cases (of which twenty-two are remaining) are being coordinated by Judge Freda Wolfson and Magistrate Judge

Tonianne Bongiovanni. The lawyers representing these twenty-two plaintiffs have also entered into a tolling agreement with Defendants that contains potential claimants. In October 2010, eleven additional plaintiffs filed a lawsuit with almost identical allegations in Illinois state court. Defendants removed that case to the Southern District of Illinois and have moved to transfer it to the District of New Jersey. Additional plaintiffs have filed individual cases in other jurisdictions.

Most recently, five out-of-state plaintiffs ("Plaintiffs") filed nearly identical complaints in Atlantic County, New Jersey based on alleged Plavix®-related injuries. These new cases, filed in February and March 2011, increase the number of Plavix® plaintiffs in state or federal court to more than forty.

Argument

The Plavix® cases easily qualify for mass tort designation. *See* Revised Mass Tort Administrative Directive #7-09. The Court should, accordingly, assign the cases for coordination in Bergen County.

A. The Plavix® Cases Qualify for Mass Tort Treatment

1. Large Numbers of Parties

The number of current and potential Plavix® suits plainly justifies mass tort designation. More than forty Plavix® plaintiffs have filed cases in state and federal courts around the country, including five such cases in New Jersey state court. Additional potential plaintiffs have tolled the statute of limitations and may file suit at any time. At least thirty-eight law firms in New Jersey and throughout the country are currently advertising for more Plavix® claimants. *See* Plaintiff Advertising Chart (Ex. A).

2. *Commonality and Relatedness*

Each of the New Jersey State Actions asserts identical strict products liability, negligence, and consumer fraud causes of action against the same Defendants. The complaints recite identical allegations about Defendants' purported conduct. Moreover, Plaintiffs seek the same damages: actual, compensatory, treble, and punitive damages, as well as interest, attorneys' fees, and the costs of litigation.

Plaintiffs' complaints are virtually identical (in large part, verbatim) to the complaints filed in New Jersey federal court and in Illinois. *Compare* First Am. Compl., *Adkins v. Bristol-Myers Squibb Co.* (Ex. B), *with* Compl., *Davidson v. Bristol-Myers Squibb Co.*(Ex. C), *and* Compl., *Brooks v. Bristol-Myers Squibb Co.* (Ex. D). The common pattern of these existing suits suggests that future complaints will involve the very same claims.

The striking similarity of the pending cases also confirms the "value interdependence" of the existing and future Plavix® cases. Because the cases rely on almost identical legal theories and seek the same types of damages, the rulings in each case will impact the perceived strength or weakness of all these matters.

3. *Dispersion of the Parties and Counsel*

Plaintiffs and Defendants in these cases are geographically dispersed. While Plaintiffs' counsel maintains offices in Atlantic County,[1] their five clients reside in other states (Michigan, Florida, California, Tennessee, and Oklahoma). The Sanofi defendants are headquartered in

[1] On their website, Plaintiffs' counsel represent themselves as Philadelphia lawyers with two offices in Atlantic County and another in Burlington County. *See* http://www.roberskine.com/perskie/about.html.

Somerset County. BMS is headquartered in New York City and has facilities in Mercer and Middlesex Counties. The office of the undersigned firm, serving as local counsel for Defendants, is in Essex County in northern New Jersey. National counsel for Defendants is located in New York City and in Washington, D.C.

4. Fairness and Danger of Prejudice

Centralized management will be fair to the parties and to their counsel because it will prevent the delay and expense of duplicative motion practice and discovery. It will also eliminate the risk of inconsistent rulings on pretrial and trial motions. The fairness of consolidation is especially assured here, because the New Jersey State Actions are in their earliest stages. Defendants have not yet responded to the complaints, and the parties have not yet initiated discovery. There is accordingly no risk of undue delay, increased expense, or prejudice to any party.

The benefit of centralized management is well-illustrated by the twenty-two separate Plavix® cases all currently pending before Judge Wolfson in the District of New Jersey. Those cases are proceeding expeditiously and efficiently. Discovery is well underway. The court has ruled on motions to dismiss, entered a confidentiality order, ruled on the appropriate scope of *ex parte* contacts with non-party treating doctors, and ruled on the temporal scope of the document production. In addition, both the plaintiffs and Defendants have developed, served, and answered detailed fact sheets tailored to the litigation, and have exchanged written document requests and responses.

5. Convenience of the Court, Parties, Witnesses, and Counsel

Centralized management will be convenient to the parties, witnesses, and counsel. Absent centralized management, Defendants will surely face duplicative demands for document production and for the depositions of current and former executives and sales representatives. Because of the similarity in the injuries asserted in the various cases, the New Jersey State Actions will have expert issues in common. Coordination and management of both fact and expert depositions by a single judge who oversees all current and future Plavix® cases in New Jersey state court will avoid duplicative and burdensome discovery, and will prevent potentially inconsistent rulings.

6. Coordination with Other Jurisdictions

Centralized management will also facilitate coordination between the New Jersey mass tort judge and other jurisdictions with pending Plavix® cases. In particular, the mass tort judge will be able to coordinate discovery and other pretrial issues with the District of New Jersey and other jurisdictions with multiple Plavix®-related cases.

B. Bergen County Is the Most Appropriate Venue

This Court determines the venue for a mass tort proceeding based on (1) issues of fairness, (2) geographical location of parties and attorneys, and (3) the existing civil and mass tort caseload in the venue. *See* Revised Mass Tort Administrative Directive #7-09. Each factor favors Bergen County as the most appropriate venue for the New Jersey State Actions. Defendants thus respectfully request that the Plavix® cases be centrally managed before the mass tort judge for Bergen County.

1. Bergen County Is the Most Appropriate Venue Based on Relative Court Congestion As Well As Convenience for the Parties, Counsel, and Witnesses

Court Congestion. This paramount consideration strongly favors coordination in Bergen County, which is, by far, the least congested of the three mass tort vicinages in New Jersey. According to 2011 Court Management statistics, Bergen County has 1,194 active pending mass tort cases, in contrast to Atlantic County's 5,215 active pending mass tort cases and 4,500 in Middlesex County. *See* New Jersey Judiciary, Court Management January 2011, at 8, 10, 30, *available at* http://www.judiciary.state.nj.us/quant/cman1101.pdf ("N.J. 2011 Statistics"). Bergen County's lack of congestion is actually more pronounced than these statistics indicate. Several of the mass torts and centrally managed cases listed as pending in that county are in fact substantially complete.[2]

Over the past five years, more mass tort cases were filed in Atlantic and Middlesex Counties than in Bergen County. *See* New Jersey Judiciary, Superior Court Caseload Reference

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[2] In accordance with the federal MDL schedule, discovery was to have been completed in Digitek in December 2010. *See* Order, *In re Digitek Litig.*, No. 283 (N.J. Super. Ct. Law Div. May 12, 2010). Judge Martinotti, the mass tort judge for Bergen County, has ordered any party who intends to participate in the MDL settlement to comply with deadlines established by the MDL court, *see* Order, *In re Digitek Litig.*, No. 283, BER-L-917-09 MT (N.J. Super. Ct. Law Div. Sept. 24, 2010), and only twenty-seven cases remain in the mass tort in New Jersey state court. The Mahwah Toxic Dump Site, Prudential, and Zelnorm mass tort and centrally managed litigations have nearly resolved in settlement negotiations. *See* Order, *In re Alleged Mahwah Toxic Dump Site Litig.*, No. BER-L-489-08 (N.J. Super. Ct. Law Div. Sept. 3, 2009) (noting that the case has been "substantially resolved"); Notice to the Bar, "Mass Torts -- Proposed Termination of Mass Tort Designation and Centralized Management of the Mahwah Toxic Dump Site Litigation," Mar. 8, 2011 (notice to the bar regarding Judge Martinotti's proposed termination of mass tort designation), *available at* http://www.judiciary.state.nj.us/notices/2011/n110310c.pdf; Order, *In re Prudential Life Ins. Co. of Am. Litig.*, No. 288, BER-L-2251-10 (N.J. Super. Ct. Law Div. Nov. 15, 2010) (noting that the litigation was mediated and the parties agreed to settle); Order, *In re Zelnorm Litig.*, No. 280 (N.J. Super. Ct. Law Div. May 26, 2010) (noting that the parties agreed in principle to the resolution of the majority of the cases).

Guide 2006-2010, at 79, *available at* http://www.judiciary.state.nj.us/quant/fiveyear.pdf ("N.J. Five-Year Statistics") (showing that between 2006 and 2010, the total number of mass tort filings was 2,142 in Bergen County; 18,848 in Atlantic County; and 5,972 in Middlesex County).

The number of backlogged cases also demonstrates that Bergen County is in the best position to manage the New Jersey State Actions in a timely and efficient manner. As of January 2011, only 5% of mass tort cases were considered backlogged in Bergen County, whereas the Atlantic County number (15%) and Middlesex County number (78%) were much higher.[3] *See* N.J. 2011 Statistics, at 8, 10, 30; *see also* N.J. Five-Year Statistics, at 82 (showing an increasing backlog in Atlantic and Middlesex Counties over the past five years, but a decreasing backlog in Bergen County).

Fairness and Geographic Location. Bergen County will provide a convenient venue to out-of-state parties, witnesses, and counsel traveling to New Jersey, given the county's proximity to the state's only major airport, Newark Liberty International, and to Newark Penn Station. The Bergen County courthouse is just 20 miles from Newark Liberty International Airport, and 18 miles from LaGuardia Airport. For those traveling by train, it is 16 miles from Newark Penn Station and 13 miles from New York Penn Station. By contrast, the Atlantic County courthouse is situated more than 115 miles from Newark Liberty International Airport and more than 66

[3] The dockets in the three vicinages for non-mass tort civil cases are comparable. The clearance percentages are nearly equal: Atlantic County (100%), Bergen County (105%), and Middlesex County (100%). *See* N.J. 2011 Statistics, at 8, 10, 30. The same is true of non-mass tort cases in backlog: Atlantic County (18%), Bergen County (11%), Middlesex County (17%). *See id.*

miles from the nearest major airport in Philadelphia. Bergen County is located much closer to Defendants' facilities in central New Jersey and in New York City than is Atlantic County.

2. Middlesex County Is the Second-Most Appropriate Venue

Defendants believe these cases should be coordinated in Bergen County. If the Court does not wish to choose that forum, however, the next best choice is Middlesex County. That venue ranks just behind Bergen County in terms of active pending mass tort proceedings. It is also the second-best venue from a geographic perspective. The Middlesex County courthouse is located some 24 miles from Newark Liberty International Airport, 47 miles from LaGuardia Airport, 27 miles from Newark Penn Station, and 37 miles from New York Penn Station. Moreover, Middlesex County is conveniently close to Defendants' facilities in central New Jersey (and to the witnesses and documents located in those facilities).

3. Atlantic County Is the Least Appropriate Venue in Terms of Both Congestion and Geographic Convenience

Atlantic County is the least appropriate court to coordinate these particular cases. The county has, by far, the greatest number of active mass tort proceedings, many of which are new or young litigations. Atlantic County currently has four mass tort proceedings (Accutane, Bristol-Myers Squibb Environmental, Fosamax, and Levaquin) and three centrally managed litigations (Pelvic Mesh, Stryker Implant, and Reglan). Additionally, Judge Higbee recently

requested that the Isotretinoin (generic Accutane) cases be designated as part of the Accutane litigation in Atlantic County.[4]

The Accutane, Levaquin, and Reglan cases are all very large, with 3,104, 1,581, and 969 cases respectively. Four of the seven mass torts in Atlantic County were designated within the last two years and are in their infancy. *See* Order, *In re Levaquin Litig.*, No. 286 (N.J. Super. Ct. Law Div. Dec. 20, 2010) (order regarding the exchange of fact sheets); Orders, *In re Bard Litig. (Pelvic Mesh)*, No. 292 (N.J. Super. Ct. Law Div. Sept. 27, 2010) (initial case management order) and *In re Pelvic Mesh/Gynecare Litig.*, No. 291 CT, 6341-10 (N.J. Super. Ct. Law Div. Mar. 14, 2011) (order regarding electronic service); Order, *In re Reglan Litig.*, No. 289 (N.J. Super. Ct. Law Div. Jan. 11, 2011) (protocol governing the production of documents); Order, *In re Stryker Trident Hip Implant Litig.*, No. 285 (N.J. Super. Ct. Law Div. Sept. 11, 2009) (order setting forth initial discovery protocol).

Atlantic County also is geographically inconvenient for out-of-state parties, witnesses, and counsel, as well as for the witnesses and documents located at Defendants' central New Jersey facilities. Although Plaintiffs' counsel in the five New Jersey State Actions are located in Atlantic County, this factor is offset by the fact that Atlantic County is the least convenient forum for their clients -- out-of-state Plaintiffs for whom travel to Bergen or Middlesex County will be far more convenient compared to Atlantic County.

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[4] *See* Notice to the Bar, "Mass Torts -- Proposed Designation of Isotretinoin (Generic Accutane) Litigation as Part of the Accutane Litigation," Mar. 14, 2011, *available at* http://www.judiciary.state.nj.us/notices/2011/n110328c.pdf.

Defendants acknowledge that Plaintiffs in the New Jersey State Actions filed in Atlantic County. But Plaintiffs' initial filing choice is ***not*** one of the factors this Court has identified as relevant to the choice of proper forum for mass tort coordination. *See* Revised Mass Tort Administrative Directive #7-09; New Jersey Mass Tort (Non-Asbestos) Resource Book, at 3 (3d ed. 2007).

Required Notification

Pursuant to Revised Mass Tort Administrative Directive #7-09, all involved parties are hereby notified that this application will be sent by the Acting Administrative Director of New Jersey Courts to all Assignment Judges and Civil Presiding Judges, advising that the application has been made and that a Notice to the Bar will appear in the legal newspapers and in the Mass Tort Information Center on the Judiciary's Internet website providing information on where and within what time period comments on and objections to the application may be made.

Respectfully submitted,

LOWENSTEIN SANDLER

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Of Counsel

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04/04/11 17164593.1

cc: Robert T. Fendt, Esq.
Perskie & Fendt P.C.
450 Tilton Road, Suite 260
Northfield, NJ 08225

Counsel for Plaintiffs

Plavix Internet Advertising by Plaintiffs' Firms *

Firm Name	Location	Home Page	Advertising for Plavix
Aylstock, Witkin, Kreis & Overholtz	Pensacola, FL	http://www.awkolaw.com	http://www.awkolaw.com/blog/uncategorized/plavix-linked-to-increased-risk-of-heart-attack-in-some-patients/ http://www.defectivedrug.com/plavix.php
Beasley Allen	Montgomery, AL	http://www.beasleyallen.com	http://www.beasleyallen.com/news/FDA-places-black-box-warning-on-Plavix/
Bernstein Liebhard	New York, NY	http://www.bernlieb.com/	http://www.consumerinjurylawyers.com/legal-news/plavix-nexium-side-effects/index.html
The Joel Bieber Firm	Richmond, VA Virginia Beach, VA Greenville, SC	http://www.joelbieber.com	http://www.joelbieber.com/plavix.php
Carey, Danis & Lowe	Louis, MO Belleville, IL	http://www.jefflowepc.com/index.html	http://www.druginjuryattorneyblog.com/2010/03/fda_adds_black_box_warning_abo.html
Colling, Gilbert, Wright & Carter	Orlando, FL	http://www.thefloridafirm.com	http://www.thefloridafirm.com/2010/03/fda-puts-black-box-warning-on-plavix.html
James O. Cunningham	Orlando, FL	http://www.cunninghampilaw.com	http://www.cunninghampilaw.com/blog/product-liability/fda-says-heartburn-drugs-may-interfere-with-plavix/#more-145
Edgar Law Firm	Santa Rosa, CA	http://www.classattorneys.com/	http://www.classattorneys.com/plavix.html
Ennis & Ennis, P.A.	Washington, DC Miami, FL Fort Lauderdale, FL	http://www.ennislaw.com/	http://www.the-plavix-lawyer.com/ http://www.ennislaw.com/plavix-side-effects-lawsuit-lawyer-attorney.html
Finz & Finz	Mineola, NY	http://www.finzfirm.com/	http://www.finzfirm.com/drugs/Plavix_Injury_Lawyer

* All websites last visited on 3/29/11

Plavix Internet Advertising by Plaintiffs' Firms *

Hersh & Hersh	San Francisco, CA	http://www.hershlaw.com	http://www.californiainjuryattorneysblog.com/professional-liability-and-mal/ http://www.hershlaw.com/lawyer-attorney-1427242.html http://www.californiainjuryattorneysblog.com/2010/07/earlier-this-year-the-fda.html
Hurley, McKenna & Mertz	Chicago, IL	http://www.hurley-law.com/	http://www.chicagoinjurylawyerblog.com/2010/03/
Iannella & Mummolo	Boston, MA	http://www.iannellamummolo.com	http://www.iannellamummolo.com/dangerous_drugs/plavix.htm
Lopez McHugh LLP	Newport Beach, CA Moorestown, NJ Philadelphia, PA	http://www.lopezmchugh.com/	http://www.lopezmchugh.com/practice-areas/pharmaceutical-litigation/plavix-clopidigrel
The Lyon Firm	Cincinnati, OH	http://www.thelyonfirm.com/	http://www.thelyonfirm.com/cases/plavix/
Mark & Associates	Uniondale, NY Boston, MA	http://www.youhaverights.com	http://www.youhaverights.com/legal_updates/read/fda-adds-new-warning-to-plavix-label/ http://www.youhaverights.com/dangerous-drugs/plavix/
The Miller Firm	Orange, VA McComb, MO Washington, DC Bala Cynwyd, PA	http://www.millerfirmllc.com	http://www.plavixhelp.com/ http://www.millerfirmllc.com/current-case-updates/plavix-update.html
Miller & Zois	Maryland	http://www.millerandzois.com	http://www.accidentinjurylawyerblog.com/2010/03/plavix_lawsuit.html
Nash & Associates	Washington, DC Baltimore, MD	http://www.nashandassociates.com	http://nashandassociates.wordpress.com/2010/03/13/st-joseph-medical-center-stent-patients-now-face-another-risk-the-fda-requires-a-black-box-warning-on-anti-clotting-drug-plavix/

* All websites last visited on 3/29/11

Plavix Internet Advertising by Plaintiffs' Firms *

Newsome Lawfirm	Orlando, FL	http://www.newsomelaw.com/	http://www.newsomelaw.com/blog/2010/03/29/plavix-side-effects-lead-debate-over-test-subjects http://www.newsomelaw.com/blog/2010/03/24/plavix-blood-clotting-issues-leads-black-box-warning
Parker Waichman Alonso LLP	New York, NY Great Neck, NY Bonita Springs, FL Edison, NJ	http://www.yourlawyer.com	http://www.yourlawyer.com/topics/overview/plavix
Phillips Webster, PLLC	Seattle, WA	http://www.phillipswebster.com/	http://www.phillipswebster.com/blog/2010/04/plavix-european-plavix-recall-on-heels-of-fda-black-box-warnings/
Pintas & Mullins Law Firm	Chicago, IL	http://www.pintasattorney.com/index.html	http://www.pintasattorney.com/attorney-lawyer-1567383.html
Pogust Braslow Millrood	Conshohocken, PA	http://www.druginjurylawyerblog.com	http://www.druginjurylawyerblog.com/2010/03/plavix_doesnt_work_for_everyon_1.html
J. Neal Rodgers PLLC	Charlotte, NC	http://www.recalls-drugs.com/	http://www.recalls-drugs.com/Dangerous-Drugs-Medical-Devices/Plavix.shtml
James Rolshouse & Associates	Burnsville, MN	http://rolshouselaw.com	http://www.rolshouselaw.com/personal-injury-topics/plavix.html
The Ronan Law Firm	Overland Park, KS	http://theronanlawfirm.com	http://theronanlawfirm.wordpress.com/2010/03/12/new-black-box-warning-for-plavix/
The Law Firm of Allen L. Rothenberg	New York, NY Philadelphia, PA Cherry Hill, NJ Hackensack, NJ Lakewood, NJ	http://injurylawyer.com	http://www.plavixinjurylawyer.com http://www.injurylawyer.com/default.asp?p=dd_plavix
Saiontz & Kirk	Baltimore, MD	http://www.youhavealawyer.com	http://www.youhavealawyer.com/blog/2010/03/15/plavix-black-box/ http://www.youhavealawyer.com/plavix/index.html

* All websites last visited on 3/29/11

Plavix Internet Advertising by Plaintiffs' Firms *

The Schmidt Law Firm, LLP	Dallas, TX	http://www.schmidtlaw.com	http://www.schmidtlaw.com/plavix#{height:750,id:57312}
Schmidt & Clark	Washington, DC	http://www.schmidtandclark.com	http://www.schmidtandclark.com/plavix#{height:449,id:43778}
Schwartzapfel & Partners	New York, NY	http://www.fightingforyou.com	http://www.fightingforyou.com/plavix-lawsuits
Sheller, P.C.	Philadelphia, PA Medford, NJ	http://www.sheller.com	http://philadelphia.injuryboard.com/fda-and-prescription-drugs/fda-blackbox-warning-for-plavix.aspx?googleid=279476
Silverman Thompson Slutkin White	Baltimore, MD Washington, DC New York, NY	http://www.mdmalpracticeattorney.com	http://www.mdmalpracticeattorney.com/lawyer-attorney-1497377.html
Edgar Snyder & Associates	Pennsylvania	http://www.edgarsnyder.com	http://www.edgarsnyder.com/news/drugs/plavix-concerns.html?ref=http%3A//www.google.com/search%3Fhl%3Den%26source%3Dhp%26q%3Dedgar+snyder+plavix%26aq%3Df%26aqi%3D%26aql%3D%26oq%3D%26gs_rfai%3D
Sokolove Law	Wellesley, MA	http://www.sokolovelaw.com	http://www.sokolovelaw.com/case-types/plavix.html
Summers & Johnson, P.C.	Weston, MO Lenexa, KS	http://www.summersandjohnson.com	http://www.summersandjohnson.com/plavix.html
Robert S. Waldman & Associates, P.C.	Philadelphia, PA	http://www.lawonyourside.net/index.html	http://www.lawonyourside.net/html/drugs.html

* All websites last visited on 3/29/11

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAMES ADKINS, Plaintiff, vs. BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS SANOFI-SYNTHELABO, INC. Defendants.	CIVIL ACTION NO. **3:07-cv-901 (FLW-TJB)** **FIRST AMENDED COMPLAINT AND JURY DEMAND**

COMES NOW, the Plaintiff, James Adkins, bringing this action for injuries and damages suffered as a result of ingesting the drug Plavix. In support, Plaintiff alleges as the following.

I. PARTIES

1. Plaintiff, James Adkins, is a natural person currently residing, and at all times material to this complaint, residing at 3506 Knox Lane, Knoxville, Tennessee 37917.

2. Defendant, Bristol-Myers Squibb Company (hereinafter referred to as "BMS") is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.) to manufacture and market Plavix in the United States. Bristol-Myers Squibb Company has

its headquarters at 345 Park Avenue, New York, New York 10154-0037.

3. Defendant, Sanofi-Aventis U.S. L.L.C. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.

4. Defendant, Sanofi-Aventis U.S., Inc. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S., Inc. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.

5. Defendant, Sanofi-Synthelabo, Inc. is a Delaware corporation with its commercial headquarters at 90 Park Avenue, New York, New York 10016. Sanofi-Synthelabo Inc. did business as Sanofi Pharmaceuticals, Inc. and was the sponsor for the drug application for Plavix. Sanofi-Synthelabo, Inc. is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc. that was instrumental in bringing Plavix to market.

6. The three Sanofi Defendants—Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S., Inc. and Sanofi-Synthelabo, Inc.—will be collectively referred to as "Sanofi" in this Complaint.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction pursuant to 28 United States Code § 1332, because of the diversity of citizenship among the parties and because the amount in

controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

8. Venue in this action properly lies in the District of New Jersey in that the Sanofi Defendants reside in this district.

9. This action is brought under the Tennessee Products Liability Act, Tenn. Code Ann. §29-28-101, *et seq.* ("Products Liability Act"), Tennessee Consumer Protections Act, Tenn.Code.Ann §47-18-101, *et seq.* ("Consumer Protection Act"), and the common law of the State of Tennessee to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees to compensate the Plaintiff for injuries the Plaintiff has sustained as a result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix.

III. FACTS

10. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Plavix.

11. At all material times, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants.

12. The Sanofi Defendants and BMS co-developed Plavix, applying in April 1997 for a rare, priority regulatory review by the FDA (Food and Drug Administration), which cleared the way for the Defendants to bring Plavix to market in November 1997.

13. The rush to obtain FDA approval of Plavix is indicative of the Defendants' emphasis on marketing and profit making over patient safety.

14. Plavix was heavily marketed directly to consumers through television, magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin. Those assertions have proven to be false.

15. The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies, should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking Plavix, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death far outweigh any potential benefit.

16. Still, BMS and Sanofi continued to exaggerate the results of their own studies and to make false statements in their advertising and promotional materials for the purpose of increasing their profit from Plavix sales.

17. The profit at stake for the Defendants is enormous. By way of illustration, in 2005, Plavix, was the sixth top selling drug in the United States and the Defendants enjoy annual sales of Plavix totaling $3,800,000,000.00 (3.8 Billion Dollars).

18. BMS and the Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about the drug they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promoting practices.

19. As examples, in 1998, the FDA requested the Defendants stop promoting Plavix for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were the Defendants marketing Plavix to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA-approved dosage nearly four (4) times that of other applications be given.

20. That same FDA warning criticized the Defendants' attempts at over-promotion of Plavix for unapproved use for lacking fair balance and failing to disclose any of the risks associated with its use. In particular, the FDA criticized that the Defendants were claiming to physicians, in their promotional letter, that Plavix was safe for use with other drugs. This, said the FDA, was overstating the safety profile of Plavix. In particular, its safety when combined with aspirin (known as "dual therapy") had not been established, yet Defendants were making a claim that the dual combination therapy of aspirin plus Plavix was safe. This claim has now been proven to be untrue in a recent study called CHARISMA (the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial), which was reported on in *The New England Journal of Medicine*, April 20, 2006.

21. Again in 1998, the FDA issued a letter demanding the Defendants immediately cease distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.

22. Undaunted, the Defendants were back in the business of hiding bad facts about their drug and fabricating more favorable information so they could sell large quantities of Plavix and make giant corporate profits. In 2001, the FDA was again forced

to order Defendants to immediately cease distribution of promotional material that made unsubstantiated claims about Plavix and was misleading. Specifically, the Defendants' promotional material misled consumers about their own study, called CAPRIE, (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events). While the Defendants' trumped-up promotional material claimed that Plavix was 19.2% better than Aspirin, the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin—providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given aspirin. Defendants again claimed that the use of Plavix combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.

23. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved.

24. Defendants, through their drug representatives, and their promotional efforts, have encouraged physicians to prescribe Plavix to a broad population of people who would receive the same therapeutic benefit from aspirin alone, (without risking death) and to use Plavix for unapproved applications.

25. The result is that physicians are prescribing Plavix to people who could be cheaply and effectively protected against ischemic events by a simple aspirin, to pay approximately four dollars ($4.00) a day for a dose of Plavix.

26. Defendants' nearly eight-year run of lying to physicians and the public about the safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal that not only is Plavix not worth its high price—it is dangerous.

27. The Chan study, written about in *The New England Journal of Medicine* and named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertions that Plavix is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin.

28. The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than paying for a four- dollar ($4.00) a-day Plavix pill that greatly increases the risk of stomach bleeding.

29. Most recently, the CHARISMA trial uncovered another truth about Plavix. It found that Plavix plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), Plavix plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other

words, in those patients without ACS or PAD, dual therapy with aspirin and Plavix does more harm than good.

30. Despite the growing body of scientific knowledge that the four-dollar ($4.00) Plavix pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.

31. Plaintiff James Adkins was prescribed Plavix, to be taken in combination with aspirin (known as "dual therapy") on or about May 19, 1999 in connection with stent placement. On or around June 18, 1999 he suffered a subdural hematoma. A craniotomy evacuated the blood requiring an extended hospital stay. He continues to have health problems as a result of taking Plavix.

COUNT I

PRODUCT LIABILITY ACT-DEFECTIVE DESIGN
(Tenn. Code Ann. §29-28-101, *et seq.*)

32. Plaintiff incorporates by reference paragraphs 1 through 31 above, as though fully set forth herein.

33. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Plavix.

34. Plavix is defective and unreasonably dangerous to consumers.

35. Plavix is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

36. At all times material to this action, Plavix was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including the Plaintiff herein, without substantial change in the condition in which it was sold.

37. At all times material to this action, PLAVIX was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective, unreasonably dangerous condition, at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, Plavix contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks that exceeded the benefits of Plavix, including but not limited to the risks of heart attacks, strokes, blood disorders, abnormal bleeding and even death in an unacceptably high number of its users;

b. When placed in the stream of commerce, Plavix was defective in design and formulation, making the use of Plavix more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other similar drugs on the market including Aspirin, such that a reasonably prudent manufacturer would not place Plavix in the market because of its dangerous conditions;

c. Plavix's design defects existed before it left the control of the Defendants;

d. Plavix was insufficiently tested;

e. Plavix's design defects were such that they were not open and obvious, but were hidden from consumers, including the Plaintiff's decedent;

f. Plavix caused harmful side effects that outweighed any potential utility; and

g. Plavix was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the

risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.

38. In addition, at the time that Plavix left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Plavix's utility.

39. As a direct and proximate result of Plavix's defective design, the Plaintiff suffered severe and permanent physical injuries, including but not limited to those described in paragraph No. 31.

40. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

41. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

42. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, James Adkins, demands judgment against Defendants for compensatory, and punitive damages, together with interest, costs of suit, attorney's fees, expert witness's fees, and all such other relief as the Court deems proper.

COUNT II

PRODUCT LIABILITY ACT-MANUFACTURING DEFECT (Tenn. Code Ann. §29-28-101, *et seq.*)

43. Plaintiff incorporates by reference paragraphs 1 through 42 above, as though fully set forth herein.

44. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Plavix.

45. At all times material to this action, Plavix was expected to reach and did reach consumers in the State of New Jersey and throughout the United States, including the Plaintiff herein without substantial change in the condition from which it was sold.

46. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Plavix contained manufacturing defects which rendered the product unreasonably dangerous;

b. Plavix's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. Plavix was not made in accordance with the Defendants' specifications, safety standards, or performance standards;

d. Plavix's manufacturing defects existed before it left the control of the Defendants;

47. As a direct and proximate result of Plavix's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries, including but not limited to those described in paragraph No. 31.

48. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

49. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

50. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, James Adkins, demands judgment against Defendants for compensatory, and punitive damages, together with interest, costs of suit, attorney's fees, expert witness's fees, and all such other relief as the Court deems proper.

COUNT III

PRODUCT LIABILITY ACT-FAILURE TO WARN
(Tenn. Code Ann. §29-28-101, *et seq.*)

51. Plaintiff incorporates by reference paragraphs 1 through 50 as though fully set forth herein.

52. Plavix was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff herein, of the dangerous risks and reactions associated with Plavix, including but not limited to its propensity to cause strokes, heart attacks, abnormal bleeding and other serious injuries and side effects notwithstanding the Defendants' knowledge of an increased risk of these injuries over other similar drugs such as Aspirin.

53. The Plaintiff was prescribed and used the subject product for its intended purpose.

54. The Plaintiff could not have discovered any defect in Plavix through the exercise of reasonable care.

55. The Defendants, as manufactures and/or distributors of Plavix are held to the level of knowledge of an expert in the field.

56. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

57. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of stroke, heart attack, and other serious injuries and side effects.

58. The warnings that were given by the Defendants failed to properly warn consumers of the increased risks of stroke, heart attack, and other serious injuries and side effects.

59. The Plaintiff, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

60. The Defendants withheld information and/or misrepresented to the FDA required information that was material and relevant to the performance of the product and was causally related to Plaintiff's injuries.

61. The Defendants promoted and/or advertised Plavix for an indication not approved by the FDA.

62. The Defendants had a continuing duty to warn the Plaintiff of the dangers associated with Plavix.

63. Had the Plaintiff received adequate warnings regarding the risks of Plavix, he would not have used it.

64. As a direct and proximate result of Plavix's defective and inappropriate warnings, the Plaintiff suffered severe and permanent physical injuries, including but not limited to those described in paragraph No. 31.

65. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

66. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

67. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, James Adkins, demands judgment against Defendants for compensatory, and punitive damages, together with interest, costs of suit, attorney's fees, expert witness's fees, and all such other relief as the Court deems proper.

COUNT IV

PRODUCT LIABILITY ACT-NEGLIGENCE
(Tenn. Code Ann. §29-28-101, *et seq.*)

68. Plaintiff incorporates by reference paragraphs 1 through 67 above, as though fully set forth herein.

69. At all times material hereto, the Defendants, and each of them individually, had a duty to exercise reasonable care to consumers, including the Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Plavix.

70. The Defendants, and each of them individually, breached their duty of reasonable care to the Plaintiff in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold Plavix.

71. The Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of the Defendants as follows:

a. In its design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of Plavix;

b. In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of Plavix, including Plaintiff herein, of Plavix's dangerous and defective characteristics;

c. In its design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Plavix;

d. In its promotion of Plavix in any overly aggressive, deceitful and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;

e. In representing that Plavix was safe for its intended use when, in fact, Plavix was unsafe for its intended use;

f. In failing to perform appropriate pre-market testing of Plavix;

h. In failing to perform appropriate post-market testing of Plavix; and

i. In failing to perform appropriate post-market surveillance of Plavix.

72. The Defendants knew or should have known that consumers such as the Plaintiff herein would foreseeably suffer injury as a result of the Defendants' failure to exercise reasonable and ordinary care.

73. In addition, at the time that Plavix left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Plavix's utility.

74. As a direct and proximate result of Defendants' misrepresentations, carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries, including but not limited to those described in paragraph No. 31.

75. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

76. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

77. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, James Adkins, demands judgment against Defendants for compensatory, and punitive damages, together with interest, costs of suit, attorney's fees, expert witness's fees, and all such other relief as the Court deems proper.

COUNT V

PRODUCT LIABILITY ACT-NEGLIGNET MISREPRESENTATION (Tenn. Code Ann. §29-28-101, *et seq.*)

78. Plaintiff incorporates by reference paragraphs 1 through 77 as though fully set forth herein.

79. Defendants having undertaken the manufacturing, marketing, distribution, and/or promotion of Plavix owed a duty to provide accurate and complete information regarding Plavix.

80. Defendants falsely represented to Plaintiff in direct to consumer advertising and indirectly through misrepresentation to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff's health.

81. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and his prescribing physician information about the

propensity of Plavix to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Plavix despite the lack of information regarding same.

82. The aforementioned misrepresentations were made by Defendants with the intent to induce Plaintiff to use Plavix to Plaintiff's detriment.

83. At the time of Defendants' misrepresentations and omissions, Plaintiff and his physician were ignorant of the falsity of these statements and reasonably believed them to be true.

84. Defendants represented and marketed Plavix as being safe and effective. After Defendants became aware of the risk of ingesting Plavix, however, Defendants failed to communicate to Plaintiff and/or the general public that the ingestion of this drug could cause a person serious and potentially fatal bodily injury.

85. Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

a. Plaintiff incorporates all facts and allegations previously stated in this Complaint;

b. Defendants failed to warn Plaintiff and other consumers of the defective condition of Plavix as manufactured and/or supplied by Defendants;

c. Defendants individually and through its agents, representatives, distributors, and/or employees negligently misrepresented material facts about Plavix in that they made such representations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

d. The above misrepresentations were made to Plaintiff, as well as the general public;

e. Plaintiff and his healthcare provider justifiably relied on Defendants' misrepresentations; and

f. Consequently, Plaintiff's ingestion of Plavix was to his detriment. Defendants' misrepresentations proximately caused Plaintiff's injuries and monetary losses.

86. As a direct and proximate result of Defendants' carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries, including but not limited to those described in paragraph No. 31.

87. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

88. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

89. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, James Adkins, demands judgment against Defendants for compensatory, and punitive damages, together with interest, costs of suit, attorney's fees, expert witness's fees, and all such other relief as the Court deems proper.

COUNT VI

VIOLATIONS OF TENNESSEE CONSUMER PROTECTIONS ACT, (Tenn.Code.Ann §47-18-101, *et seq.*)

90. Plaintiff incorporates by reference paragraphs 1 through 89 above, as though fully set forth herein.

91. Plavix is considered "goods" as that term is defined by Tenn.Code.Ann §47-18-103(5).

92. Plaintiff is a "consumer" as that term is defined by Tenn.Code.Ann §47-18-103(2).

93. The Defendants are designers, manufacturers, promoters, marketers, developers, sellers and/or distributors of Plavix.

94. The Defendants knew or should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects.

95. Notwithstanding the foregoing, the Defendants omitted material facts in the disclosures it made to the public, the medical community and to consumers, including the Plaintiff herein, concerning the use and safety of Plavix.

96. The Defendants have violated the Consumer Protections Act for the following reasons:

a. Defendants' business practices caused likelihood of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;

b. Defendants' business practices caused likelihood of confusion or misunderstanding as to affiliation, connection, or association with, or certification by another;

c. Defendants' represented that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has sponsorship, approval, status, affiliation, or connection which it does not

d. Defendants' represented that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;

e. Defendants engaged in business practices which were deceptive to the consumer and other persons.

97. The Defendants have violated the Tennessee Consumer Protections Act, in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff herein, concerning the use and safety of Plavix.

98. The Defendants' practices relating to their promotion of Plavix created and/or reinforced a false impression as to its safety.

99. The Defendants' practice of promoting Plavix placed and continues to place all consumers of Plavix at risk for serious injury and potentially lethal side effects.

100. The Defendants' statements and omissions were made with the intent that the Plaintiff herein, and his prescribing physician, would rely on such statements and omissions.

101. The Plaintiff purchased and used Plavix for personal, family or household purposes and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

102. The aforesaid promotion, statements and/or omissions concerning Plavix by the Defendants constitute an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by Defendants, in violation of the Consumer Protections Act.

103. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff has suffered ascertainable loss-economic loss that includes the purchases of Plavix and additional out-of-pocket healthcare related costs, for which the Defendants are liable to the Plaintiff for treble and his actual damages.

104. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff further suffered severe and permanent physical injuries, including but not limited to those described in paragraph No. 31.

105. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

106. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

107. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, James Adkins, demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees, expert witness's fees, and all such other relief as the Court deems proper.

COUNT VII

PUNITIVE DAMAGES UNDER COMMON LAW

108. Plaintiff incorporates by reference paragraphs 1 through 107 above, as though fully set forth herein.

109. At all times material hereto, the Defendants knew or should have known that Plavix was inherently more dangerous than aspirin with respect to the risk of bleeding injuries, heart attacks, stroke and death.

110. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Plavix.

111. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety of Plavix.

112. At all times material hereto, the Defendants knew and recklessly disregarded the fact that Plavix causes debilitating and potentially lethal side effects with greater frequency than safer alternative drugs, such as Aspirin.

113. Notwithstanding the foregoing, the Defendants continued to aggressively market Plavix to consumers, including Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternatives such as Aspirin.

114. The Defendants knew of Plavix's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Plavix.

115. Defendants intentionally concealed and/or recklessly failed to disclose to the public, including the Plaintiff herein, the potentially life threatening side effects of Plavix in order to ensure continued and increased sales.

116. The Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff of necessary information to enable him to weigh the true risks of using Plavix against its benefits.

117. Plaintiff is entitled to punitive damages because the Defendants' failure to warn was reckless and without regard for the public's safety and welfare. The Defendants misled both the medical community and the public at large, including the Plaintiff herein, by making false representations about the safety of Plavix. Defendants downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Plavix despite available information demonstrating that Plavix was likely to cause serious and even

fatal side effects to users. Defendants' actions and/or inactions were willful and wanton.

118. Defendants were or should have been in possession of evidence demonstrating that Plavix caused serious side effects. Nevertheless, Defendants continued to market Plavix by providing false and misleading information with regard to safety and efficacy.

119. Defendants failed to provide warnings that would have dissuaded physicians from prescribing Plavix and consumers from purchasing and consuming Plavix, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Plavix.

120. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, the Plaintiff suffered severe and permanent physical injuries, including but not limited to those described in paragraph No. 31.

121. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

122. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

123. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

124. The aforesaid conduct of the Defendants was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff, James Adkins, demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees, expert witness's fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against each of the Defendants as follows:

a. Awarding actual damages to the Plaintiff James Adkins incidental to his purchase and use of Plavix in an amount to be determined at trial;

b. Awarding Plaintiff compensatory damages against Defendants in an amount sufficient to fairly and completely compensate him for all damages;

c. Awarding Plaintiff treble damages against Defendants so as to fairly and completely compensate him for all damages, and to deter similar wrongful conduct in the future;

d. Awarding Plaintiff punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter similar wrongful conduct in the future;

e. Awarding pre-judgment and post-judgment interest to the Plaintiff;

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

g. Awarding reasonable attorney's fees and costs to the Plaintiff as provided by law; and

h. Granting all such other relief as the Court deems necessary, just and proper.

Respectfully submitted,

THE MILLER FIRM, LLC

BY: Michele A DiMartino
Michele A. DiMartino

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

Michele A. DiMartino
Michele A. DiMartino, Esquire

Dated: May 1, 2009

CERTIFICATION PURSUANT TO LOCAL RULE 11.2

The undersigned attorney for the Plaintiff certifies that the matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration or administrative proceeding.

I certify that the foregoing statement made by me is true to the best of my knowledge, information and belief. I am aware that if the foregoing statement made by me is willfully false, I am subject to punishment.

Michele A DiMartino
Michele A. DiMartino, Esquire

Dated: May 1, 2009

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A., 56:8-20, Plaintiff is mailing a copy of this Complaint and

Jury Demand to the Office of Attorney General, Cn-006, Trenton, New Jersey, within (10) days of the filing of this Complaint and Jury Demand.

Michele A. DiMartino, Esquire

Dated: May 1, 2009

MICHAEL J. MILLER, ESQ.*
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IN THE CIRCUIT COURT
TWENTIETH JUDICIAL DISTRICT
ST. CLAIR COUNTY, ILLINOIS

RICHARD DAVIDSON, DAVID BUTLER, PATRICK HAHNE, OVEZ JAPANWALLA, MARYLOU MOFFETT, REBECCA ARNOLD, MARVIDA BLACKMON, RONNIE BURNS, JOE CAPPO, TROY CODDARD, CONNIE YEAGER, Plaintiffs,	)	Case No. 10L544
v.	)	
BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., and SANOFI-SYNTHELABO, INC. Defendants.	)	

FILED
ST. CLAIR COUNTY
OCT 15 2010
Barbara F. Kelly
CIRCUIT CLERK

COMPLAINT

COMES NOW the Plaintiffs, by and through their undersigned attorney, for their Complaint against Defendants, state and allege as follows:

1. Plaintiffs bring this action for injuries and damages suffered as a result of ingesting Plavix. In support, Plaintiffs allege the following:

PARTIES

PLAINTIFFS

2. Plaintiff, Richard Davidson, a natural person, is a citizen and resident of St. Clair County. Currently, and at all times material to this complaint, Richard Davidson resides at 9625 Fairmont Road, Fairview Heights, Illinois. Richard Davidson was sold Plavix in St. Clair County, and was treated in St. Clair for his injuries arising from the ingestion of Plavix.

3. Richard Davidson's injuries were caused by his usage of Plavix. As more particularly pled below, Richard Davidson maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

4. Plaintiff, David Butler, a natural person, is a citizen and resident of the State of Illinois. Currently, at all times material to this complaint, David Butler resides at 530 North 35th Street, East St. Louis, Illinois.

5. David Butler's injuries were caused by his usage of Plavix. As more particularly pled below, David Butler maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

6. Plaintiff, Patrick Hahne, a natural person is a citizen and resident of the State of New York.

7. Patrick Hahne's injuries were caused by his usage of Plavix. As more particularly pled below, Patrick Hahne maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

8. Plaintiff, Ovez Japanwalla, is a natural citizen and resident of the State of New York. Ovez Japanwalla currently, and at all times material to this complaint, resides at 50 Kalda Lane, Plainview, New York 11803.

9. Ovez Japanwalla's injuries were caused by the usage of Plavix.

10. As more particularly pled below, aforementioned Plaintiff, Ovez Japanwalla maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

11. Plaintiff, Marylou Moffett, is a natural citizen and resident of the State of Virginia. Marylou Moffett currently, and at all times material to this complaint, resides at 1344 Stringfellow Court, Virginia Beach, Virginia 23464.

12. Marylou Moffett's injuries were caused by the usage of Plavix.

13. As more particularly plead below, Marylou Moffett maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

14. Plaintiff, Rebecca Arnold, is a natural citizen and resident of the State of Alabama. Rebecca Arnold currently, and at all times material to this complaint, resides at 51204 Alphine Drive, Weaver, Alabama 36277.

15. Rebecca Arnold's injuries were caused by the usage of Plavix.

16. As more particularly pled below, aforementioned Plaintiff, Rebecca Arnold maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

17. Plaintiff, Marvida Blackmon, is a natural citizen and resident of the State of Iowa. Marvida Blackmon currently, and at all times material to this complaint, resides at 421 Oak Ave. Apt. 302, Waterloo, Iowa 50703.

18. Marvida Blackmon's injuries were caused by the usage of Plavix.

19. As more particularly pled below, aforementioned Plaintiff, Marvida Blackmon maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

20. Plaintiff, Ronnie Burns, is a natural citizen and resident of the State of Kentucky. Ronnie Burns currently, and at all times material to this complaint, resides at 329 Byrum Street, Providence, Kentucky 42450.

21. Ronnie Burns's injuries were caused by the usage of Plavix.

22. As more particularly pled below, aforementioned Plaintiff, Ronnie Burns maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

23. Plaintiff, Joe Cappo, is a natural citizen and resident of the State of Louisiana. Joe Cappo currently, and at all times material to this complaint, resides at 107 Union Avenue, West Monroe, Louisiana 71291.

24. Joe Cappo's injuries were caused by the usage of Plavix.

25. As more particularly pled below, aforementioned Plaintiff, Joe Cappo maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

26. Plaintiff, Troy Coddard, is a natural citizen and resident of the State of Ohio. Troy Coddard currently, and at all times material to this complaint, resides at 4615 Refugee Road, Apt. 2C, Columbus Ohio 43232.

27. Troy Coddard's injuries were caused by the usage of Plavix.

28. As more particularly pled below, aforementioned Plaintiff, Troy Coddard maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

29. Plaintiff, Connie Yeager, is a natural citizen and resident of the State of New Jersey. Connie Yeager currently, and at all times material to this complaint, resides at 227 Knollcrest Ct., Sommerset, New Jersey 08873.

30. Connie Yeager's injuries were caused by the usage of Plavix.

31. As more particularly pled below, aforementioned Plaintiff, Connie Yeager maintains that Plavix is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

DEFENDANTS

32. Defendant, Bristol-Myers Squibb Company (hereinafter referred to as "BMS") is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.) to manufacture and market Plavix in the United States. The headquarters for Bristol-Myers Squibb Company is located at 345 Park Avenue, New York, New York, 10145-0037.

33. Defendant, Sanofi-Aventis U.S. L.L.C. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey 08807-0912.

34. Defendant, Sanofi-Aventis U.S., Inc., is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S., Inc., is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.

35. Defendant, Sanofi-Synthelabo, Inc., is a Delaware corporation with its commercial headquarters at 90 Park Avenue, New York, New York, 10016. Sanofi-Synthelabo, Inc., did business as Sanofi Pharmaceuticals, Inc., and was the sponsor for Plavix application for Plavix. Sanofi-Synthelabo, Inc., is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., that was instrumental in bringing Plavix to market.

36. The three Sanofi Defendants—Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo, Inc., will be collectively referred to as "Sanofi" in this complaint.

JURISDICTION AND VENUE

37. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over the Defendants, because Defendants are present in the State of Illinois such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

38. This Court has personal jurisdiction over the Defendants, pursuant to, and consistent with, Illinois' long-arm statute (735 ILCS 5/2-209) and the Constitutional requirements of Due Process in that the Defendants acting through agents or apparent agents, committed one or more of the following:

a. Defendants transacted business in the State of Illinois, 735 ILCS 5/2-209(a)(1);

b. Defendants owned, used or possessed real estate situated in the State of Illinois, 735 ILCS 5/2-209(a)(3);

c. Defendants made or performed a contract or promise substantially connected within this state, 735 ILCS 5/2-209(a)(7);

d. Defendants do business in and within Illinois, 735 ILCS 5/2-209(b)(4); and;

e. Requiring Defendants to litigate this claim in Illinois does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

39. Defendants marketed, promoted, and sold Plavix throughout the United States, including St. Clair County, Illinois. Additionally, the Plaintiffs herein suffered injury from Plavix in St. Clair County, Illinois. Accordingly venue is proper under 735 ILCS 5/1-108 and 2-101 of the Illinois Code of Civil Procedure.

40. This action is brought under the common law of the State of Illinois and the Illinois Consumer Fraud and Deceptive Trade Practices Act, to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, to compensate the Plaintiffs for injuries they sustained as a result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix.

STATEMENT OF FACTS

41. This is an action for damages suffered by Plaintiffs as a direct and proximate result of the Defendants' negligence and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of Plavix.

42. At all material times, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants.

43. The Sanofi Defendants and BMS co-developed Plavix, applying in April 1997, for a rare *priority regulatory review*, by the U.S. Food and Drug Administration (FDA), which cleared the way for the Defendants to bring Plavix to market in November 1997.

44. The rush to obtain FDA approval of Plavix is indicative of Defendants' emphasis on marketing and profit making over patient safety.

45. Plavix was heavily marketed directly to consumers through television, magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin while being safer and easier on a person's stomach than aspirin. Those assertions have proven to be false.

46. The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies, should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking Plavix, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death far outweigh any potential benefit.

47. Still, BMS and Sanofi continued to exaggerate the results of their own studies and made false statements in their advertising and promotional materials for the purpose of increasing their profits from Plavix sales.

48. The profit at stake for the Defendants is enormous. By way of illustration, in 2005, Plavix, was the sixth top selling drug in the United States and the Defendants enjoy annual sales of Plavix totaling $3,800,000,000.00 (3.8 billion dollars).

49. BMS and Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about Plavix they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promotional practices.

50. As examples, in 1998, the FDA requested the Defendants stop promoting Plavix for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were the Defendants' marketing Plavix to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA approved dosage nearly four (4) times that of other applications be given.

51. That same FDA warning criticized the Defendants' attempts at over-promotion of Plavix for unapproved use for lacking fair balance and failing to disclose any of the risks associated with its use. In particular, the FDA criticized that the Defendants were claiming to physicians, in their promotional letter, that Plavix was safe for use with other drugs. This, said the FDA, was overstating the safety profile of Plavix. In particular, its safety when combined with aspirin (known as "dual therapy") had not been established, yet Defendants were making a claim that the dual combination therapy of aspirin plus Plavix was safe. This claim has now been proven to be untrue in a recent study called CHARISMA (the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance Trial), which was reported in *The New England Journal of Medicine*, April 20, 2006.

52. Again in 1998, the FDA issued a letter demanding the Defendants immediately cease distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.

53. Undaunted, the Defendants were back in the business of hiding bad facts about their drug and fabricating more favorable information so they could sell large quantities of Plavix and make giant corporate profits. In 2001, the FDA was again forced to order Defendants to immediately cease distribution of promotional materials that made unsubstantiated claims about Plavix and was misleading. Specifically, the Defendants' promotional materials mislead consumers about their own study, called CAPRIE (Clopidogrel versus Aspirin in Patients at Rick of Ischemic Events). While the Defendants' trumped-up promotional material claimed that Plavix was 19.2% better than aspirin, the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin-providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given aspirin. Defendants again claimed that the use of Plavix combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.

54. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved.

55. Defendants, through, their drug representatives, and their promotional efforts, have encouraged physicians to prescribe Plavix to a broad population of people who would receive the same therapeutic benefit from aspirin alone, (without risking death) and to use Plavix for unapproved applications.

56. The result is that physicians are prescribing Plavix to people who could be cheaply and effectively protected against ischemic events by a simple aspirin, to pay approximately four dollars ($4.00) a day for a dose of Plavix.

57. Defendants' nearly eight-year run of lying to physicians and to the public about the safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal that not only is Plavix not worth its high price—it is dangerous.

58. The Chan study, written about in *The New England Journal of Medicine*, and named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertion that Plavix is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that the patients would not erroneously believe that Plavix is safer on the stomach than aspirin.

59. The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like

Prilosec) is far more cost effective for the consumer than paying for a four-dollar ($4.00) a day Plavix pill that greatly increases the risk of stomach bleeding.

60. Most recently, the CHARISMA trial uncovered another truth about Plavix. It found that Plavix plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), Plavix plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other words, in those patients without ACS or PAD, dual therapy with aspirin and Plavix does more harm than good.

61. Despite the growing body of scientific knowledge that the four-dollar ($4.00) Plavix pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.

62. Plaintiff, Richard Davidson, was prescribed Plavix on or about November 20, 2007, and continued on Plavix until June 2009. On or about June 2009 until November 5, 2009, Richard Davidson suffered a heart attack, suffered excessive bleeding, requiring blood transfusions, placement of a pacemaker and stents and hospitalization all resulting from his ingestion of Plavix.

63. Plaintiff, David Butler, was prescribed Plavix on or about September 21, 2009, and continued on Plavix until on or about March 13, 2010. On March 13, 2010, David Butler suffered a heart attack, excessive bleeding which necessitated a blood transfusion and hospitalization, all resulting from his ingestion of Plavix.

64. Plaintiff, Patrick Hahne, was prescribed Plavix on or about August 26, 2004, and continued on Plavix until on or about October 8, 2009. On or about October 8, 2009, resulting from his ingestion of Plavix, Patrick Hahne suffered two strokes and required hospitalization.

65. Plaintiff, Ovez Japanwalla, was prescribed Plavix on or about May 1, 2007, and continued on Plavix until December 1, 2007. On or about December 1, 2007, as a result of the ingestion of Plavix, Ovez Japanwalla suffered a stroke and excessive bleeding which necessitated a blood transfusion and hospitalization.

66. Plaintiff, Marylou Moffett, was prescribed Plavix on or about September 2009, and continued on Plavix until on or about February 15, 2010. On or about February 15, 2010, Marylou Moffett, as a result of her ingestion of Plavix, was hospitalized and suffered from thrombotic thrombocytopenic purpura and stent placements.

67. Plaintiff, Rebecca Arnold, was prescribed Plavix on or about January 1, 2001, and continued on Plavix thereafter. On or about December 15, 2008, Rebecca Arnold, as a result of her ingestion of Plavix, suffered a stroke and a heart attack and was hospitalized.

68. Plaintiff, Marvida Blackmon, was prescribed Plavix on or about November 1, 2006 and continued thereafter. On or about November 1, 2008, Marvida Blackmon, underwent a colonoscopy, as a result of her ingestion of Plavix, suffered excessive bleeding, required a stent placement and required hospitalization.

69. Plaintiff, Ronnie Burns was prescribed Plavix on or about October 8, 2008, and continued on Plavix until on or about December 12, 2009. On or about

December 12, 2009, Ronnie Burns, as a result of his ingestion of Plavix, suffered a heart attack, excessive bleeding, and required a stent placement and hospitalization.

70. Plaintiff, Joe Cappo, was prescribed Plavix on or about May 1, 2007, and continued on Plavix thereafter. On or about December 3, 2009, Joe Cappo, as a result of his ingestion of Plavix, suffered a heart attack and was hospitalized.

71. Plaintiff, Troy Coddard, was prescribed Plavix on or about November 1, 2005, and continued on Plavix thereafter. On or about December 22, 2008, Troy Coddard, as a result of his ingestion of Plavix, suffered a heart attack and was hospitalized.

72. Plaintiff, Connie Yeager was prescribed Plavix on or about December 28, 2008, and continued on Plavix thereafter. On or after December 28, 2008, Connie Yeager, as a result of her ingestion of Plavix, suffered a stroke and was hospitalized.

73. The label for Plavix drug products, known as the "Package Insert" was developed by the Defendants and accompanied all Plavix prescription drug products and/or samples and was published in the Physician's Desk Reference.

74. Drug labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, efficacy, contraindications, warnings, precautions and side effects.

75. Defendants failed to fully, truthfully and accurately communicate the safety and efficacy of Plavix drug products and intentionally and fraudulently mislead the medical community, physicians, Plaintiffs' physicians and Plaintiffs about the risks associated with Plavix.

76. Defendants fraudulently and aggressively promoted Plavix drug products to physicians for use in patients, such as Plaintiffs, through medical journal advertisements, use of mass mailings, and direct communications, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures, leaflets and hand outs as these materials downplayed the significance of the adverse effects of Plavix.

77. At all relevant times hereto, Defendants did not investigate the accuracy of the Plavix drug product labeling.

78. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of the true effects described above to the FDA, healthcare providers and patients, including Plaintiffs.

79. Defendants were required to report literature, papers; and, to undertake action to reflect truthful and accurate information in its labeling and promotional materials and failed to do so.

80. Defendants are under a duty to ensure that their Plavix drug product labels are accurate.

81. Defendants failed to ensure its Plavix warnings to the medical community were accurate and adequate and breached this duty.

82. Defendants have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Plavix drug products, the medical community, Plaintiffs' physician, Plaintiffs and other foreseeable users and failed to fulfill this duty.

83. Defendants breached their duty to the medical community, Plaintiffs' physicians, Plaintiffs, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Plavix, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of their Plavix drug products.

84. Defendants breached their duty to the medical community, Plaintiffs' physicians, Plaintiffs, and other foreseeable users similarly situated because Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Plavix drug products to said persons and other foreseeable users.

85. Defendants breached their duty to the medical community, Plaintiffs' physicians, Plaintiffs, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report significant data concerning the lack of efficacy and side effects associated with Plavix.

86. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in Plavix drug product labels and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiffs, plaintiffs' physicians and other foreseeable users.

87. At all times material hereto, Defendants were aware of the serious side effects described herein which were caused by Plavix drug products and failed to fulfill the obligation to report and divulge said side effects, and in doing so, mislead the medical

community, physicians, Plaintiffs' physicians, Plaintiffs and other foreseeable users about the safety and efficacy of Plavix drug products.

88. At all times material hereto, Defendants knew or should have known that physicians and plaintiffs were unaware of or did not fully appreciate the seriousness of the risks associated with use of Plavix drug products and the lack of benefit

89. At the time Defendants made the above-described representations, Plaintiffs and Plaintiffs' physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

90. Plaintiffs' serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Plavix.

91. In doing the acts alleged in this Complaint, Defendants acted with oppression, fraud, and malice and Plaintiffs are therefore entitled to punitive damages to deter Defendants and others from engaging in similar conduct in the future.

92. As a proximate result of the fraud and deceit of Defendants, Plaintiffs sustained the injuries and damages as described in this Complaint.

93. Defendants have an absolute duty to disclose the true facts regarding the safety of Plavix drug products to the medical community, to physicians and their patients, which they negligently and/or intentionally failed to do.

94. Defendants have a duty to ensure that they had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of Plavix were accurate which it negligently and/or intentionally failed to do.

95. Plaintiffs would not have suffered Plaintiffs' injuries but for the above misrepresentations or omissions of Defendants.

96. Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiffs' damages.

97. A reasonably competent physician who prescribed Plavix and a reasonably competent Plaintiff who consumed Plavix would not realize its dangerous condition.

98. The reasonably foreseeable use of Plavix drug products involved substantial dangers not readily recognizable by Plaintiffs' physicians, who acted as ordinary, reasonable and prudent physicians would, when prescribing Plavix to ordinary, reasonable and prudent patients, like Plaintiffs.

99. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, Plaintiffs, have:

(a) Suffered severe and permanent injuries, which they will be forced to endure for the remainder of their lives;

(b) Suffered physical impairment and disfigurement; and

(c) Suffered physical pain and suffering;

(d) Suffered mental pain and suffering; and

(e) Suffered from loss of enjoyment of life; and

(f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiffs injuries; and

(g) Incurred attorney's fees and expenses of litigation related to this action.

100. Defendants' actions were intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences and acted only out of self interest and personal gain and evidenced a specific intent to cause harm to Plaintiffs.

101. Plaintiffs' serious and permanent injuries, came about as a foreseeable and proximate result of the Defendants' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the effects of exposure and ingestion of Plavix to the medical community, physicians, Plaintiffs' physician, Plaintiffs and other foreseeable users of Plavix.

102. Plaintiffs have experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries suffered caused by the ingestion of Defendants' Plavix drug products.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

103. Plaintiffs incorporate by reference paragraphs 1 through 102 above, as if fully set forth.

104. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through failing to disclose, for eight years, the truth about the safety and efficacy of Plavix, to Plaintiffs' physicians and/or Plaintiffs, and misrepresenting Plavix as safe and efficacious for its intended use, actively

concealed from said individuals the true risks associated with the use of Plavix drug products.

105. Plaintiffs had no knowledge that Defendants was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Plaintiffs could not have reasonably discovered the wrongdoing at any time prior to the commencement of this action.

106. Plaintiffs, nor Plaintiffs' physicians, could have possibly determined the nature, extent and identity of related health risks associated with Plavix. Plavix and reasonably relied on Defendants' to disseminate truthful and accurate safety and efficacy information about its drug and warn of the side effects complained of herein.

107. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of Plavix. Defendants were under a duty to disclose the true character, quality, and nature of Plavix because this was non-public information over which the Defendants have, and continue to have, exclusive control, and because Defendants knew this information was not available to the Plaintiffs or their physicians. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

WHEREFORE, Plaintiffs pray for judgment against Drug Company Defendant, jointly and severally, in an amount, which will compensate the Plaintiffs for their injuries.

WRONGFUL CONDUCT

COUNT I
STRICT PRODUCTS LIABILITY

108. Plaintiffs incorporate by reference paragraphs 1 through 107 above, as if fully set forth.

109. At all relevant times the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling Plavix.

110. Plavix is defective and unreasonably dangerous to consumers.

111. At all times mentioned in this Complaint Plavix was defective and/or unreasonably dangerous to Plaintiffs and other foreseeable users at the time it left the control of the Defendants.

112. Plavix is defective in its design or formulation in that when it left the hands of the Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.

113. The foreseeable risks associated with the design or formulation of Plavix, include, but are not limited to, the fact that the design or formulation of Plavix is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

114. At all times material to this action, Plavix was expected to reach, and did reach consumers in the State of Illinois and throughout the United States, including the Plaintiffs, without substantial change in the condition in which it was sold.

115. Defendants, developed, marketed and distributed Plavix drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of Plavix.

116. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that Plavix created a high risk of bodily injury and serious harm.

117. The dangerous propensities of Plavix drug products were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time said Defendants distributed, supplied, or sold Plavix, and not known to ordinary physicians who would be expected to prescribe Plavix for their patients.

118. Plavix drug products, as distributed, were defective and unreasonably dangerous inasmuch as Plavix were not accompanied by warnings and instructions that were appropriate and adequate to render Plavix reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of Plavix.

119. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of Plavix drug products with knowledge that consumers would be exposed to serious danger.

120. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was placed in the stream of commerce in ways that include, but are not limited to one or more of the particulars:

(a) At the time Plavix left the control of the Defendants Plavix was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because Plavix breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiffs' physicians justifiably relied, or because it breached an implied warranty, all of

which proximately caused the damages for which Plaintiffs seek recovery herein.

(b) Plavix drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time Plavix left the possession of the Defendants, and that such risks clearly outweighed the utility of Plavix therapy or its therapeutic benefits, and subjected Plaintiffs to the risk of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and even death in an unacceptably high number of its users;

(c) At the time Plavix left the control of the Defendants Plavix possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time Plavix left the possession of the Defendants. Specifically, although the Defendants were well aware that Plavix products could potentially cause severe side effects.

(d) The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of Plavix taking into account the characteristics of the Plavix, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases Plavix, such as the Plaintiffs.

(e) Plavix manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of injury from Plavix drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about the risks of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and death associated with the use of Plavix.

(f) When placed in the stream of commerce of commerce, Plavix was defective in design and formulation, making the use of Plavix more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other similar drugs on the market including Aspirin;

(g) Plavix was insufficiently tested.

121. The Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiffs seek recovery.

122. The Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of Plavix that caused the damages for which Plaintiffs seek recovery.

123. The reasonably foreseeable use of Plavix involved substantial dangers not readily recognizable by the ordinary physician who prescribed Plavix or the patient, including Plaintiffs, who consumed Plavix drug products.

124. The Defendants knew that Plavix drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that Plavix were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

125. Plaintiffs and Plaintiffs physicians did not know, nor had reason to know, at the time of the use of Defendants' Plavix drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

126. The above defects caused serious injuries to Plaintiffs when Plavix was used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

127. In addition, at the time that Plavix left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiffs' injuries without impairing the reasonably

anticipated or intended function of Plavix. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiffs' injuries without substantially impairing Plavix's utility.

128. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

129. For the above reasons, the Defendants are strictly liable under Illinois product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs for their injuries and which will deter the Defendants and others from like conduct.

COUNT II
MANUFACTURING DEFECT

130. Plaintiffs repeat, Plaintiffs incorporate by reference paragraphs 1 through 129 above, as if fully set forth.

131. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Plavix.

132. At all times material to this action, Plavix was expected to reach, and did reach consumers in the State of Illinois and throughout the United States, including the Plaintiff, without substantial change in the condition from which it was sold.

133. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following particulars posing a serious risk of injury and death.

a. When placed in the stream of commerce, Plavix contained manufacturing defects that rendered the product unreasonably dangerous;

b. Plavix's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. Plavix was not made in accordance with the Defendants' product specifications or performance standards; and,

d. Plavix's manufacturing defects existed before it left the control of the Defendants.

134. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

135. For the above reasons, the Defendants are strictly liable under Illinois product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs for their injuries and which will deter the Defendants and others from like conduct.

COUNT III
FAILURE TO WARN

136. Plaintiffs repeat, Plaintiffs incorporate by reference paragraphs 1 through 135 above, as if fully set forth.

137. Plavix was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiffs and/or their health care providers, of the dangerous risks and reactions associated with Plavix, including but not limited to its propensity to cause avoidable strokes, heart attacks, abnormal bleeding, and other serious injuries and side effects despite the Defendants' knowledge of the increased risk of these injuries over similar drugs such as aspirin.

138. Plavix was defective due to inadequate post-marketing warnings or instruction because after Defendants knew or should have known of the risk and danger of serious bodily harm and/or death from the use of Plavix, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and/or death.

139. Plaintiffs were prescribed and used Plavix for its intended purpose.

140. The Plaintiffs could not have known about the dangers and hazards presented by Plavix.

141. The warnings that were given by the Defendants were not accurate, clear, complete and/or were ambiguous.

142. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of stroke, heart attack, bleeding and other serious injuries and side effects, and failed to instruct physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.

143. The warnings that were given by the Defendants failed to properly warn consumers of the increased risk of stroke, heart attack, bleeding, and other serious injuries and side effects.

144. The Plaintiffs, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants. The Defendants had a continuing duty to warn the Plaintiffs of the dangers associated with Plavix. Had the Plaintiffs received adequate warnings regarding the risks of Plavix, they would not have used Plavix.

145. As a direct and proximate result of Plavix's defective and inappropriate warnings, the Plaintiffs suffered severe physical injuries and damages as described above.

146. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs' earnings capacity; incurred and will continue to incur expenses for medical treatment of

Plaintiffs' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

147. For the above reasons, the Defendants are strictly liable under Illinois product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs for their injuries and which will deter the Defendants and others from like conduct.

COUNT IV
NEGLIGENCE

148. Plaintiffs repeat, Plaintiffs incorporate by reference paragraphs 1 through 147 above, as if fully set forth.

149. Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of Plavix to ensure the safety of Plavix and to ensure that the consuming public, including the Plaintiffs and Plaintiffs' physicians and agents, obtained accurate information and instructions for the use of Plavix.

150. Defendants owed a duty toward foreseeable users of Plavix drug products to exercise reasonable care to ensure that Plavix drugs were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks increased heart attack or stroke, blood disorders and excessive bleeding described above.

151. Defendants failed to exercise reasonable care in testing Plavix for side effects in ordinary and foreseeable users; and failed to disseminate to physicians accurate and truthful information concerning the effects of Plavix; thus, physicians were not able to make informed choices concerning the use of Plavix drug products.

152. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of Plavix into the stream of commerce in that Defendants knew or should have known that Plavix drug products created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

153. The dangerous propensities of Plavix drug products as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe Plavix for Plaintiffs and other patients, similarly situated.

154. The information Defendants disseminated to physicians concerning Plavix drug products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

155. As a proximate result, Plaintiffs suffered grievous bodily injuries and consequent economic and other losses when they ingested Plavix.

156. The Defendants was negligent, and breached their duties of reasonable care to Plaintiffs with respect to Plavix drug products in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of Plavix;

(b) Defendants failed to conduct adequate testing; and

(c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product; and

(d) Despite knowledge of hazards, Defendants failed to adequately warn Plaintiffs' physicians or Plaintiffs that the use of Plavix drug products could result in severe side effects as described above;

(e) Despite the fact that the Defendants knew or should have known that their Plavix drug products caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks associated with Plavix as set forth above; Defendants willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiffs safety and/or welfare;

(f) Defendants failed to design, develop, implement, administer, supervise and monitor its clinical trials for Plavix;

(g) Defendants, in its promotion of Plavix, were overly aggressive and deceitful, and promoted Plavix in a fraudulent manner, despite evidence known to Defendants that Plavix was dangerous.

157. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiffs developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiffs' earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiffs' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

158. The negligence, carelessness, and the willful and wanton misconduct of the Defendants was a proximate cause of Plaintiffs' harms and injuries that Plaintiffs suffered and will continue to suffer.

159. In the alternative, Defendants' acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing Plavix drug products.

160. Furthermore, the economic damages and physical harm caused by Defendants' conduct would not have occurred had Defendants exercised the high degree of care imposed upon it and Plaintiffs therefore also pleads the doctrine of *res ipsa loquitur*.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs for their injuries and which will deter the Defendants and others from like conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief against Defendants as follows:

161. For judgment for damages sufficient to compensate for damages, including but not limited to past, present, and future economic expenditures in connection with the injuries sustained by Plaintiffs as a result of ingesting Defendants' Plavix drug products;

162. For compensatory damages according to proof, including lost wages, pain, suffering and mental anguish;

163. For reasonable costs, including attorneys fees as permitted by law; and

164. For all other just and proper relief.

BY: _____

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Sidney Brooks,

Plaintiff,

vs.

Bristol-Myers Squibb Company,
Sanofi-Aventis U.S. L.L.C.,
Sanofi-Aventis U.S., Inc.
Sanofi-Synthelabo, Inc.

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY

DOCKET NO.: L 325 8-11

COMPLAINT AND JURY DEMAND

COMES NOW, the Plaintiff, Sidney Brooks, bringing this action for injuries and damages suffered as a result of ingesting the drug, Plavix. In support, Plaintiff alleges the following.

I. PARTIES

1. Plaintiff, Sidney Brooks is a natural person currently residing, and at all times material to this complaint, residing at 12433 Lansdown Street, Detroit, Michigan 48224. Plaintiff brings this Complaint for Sidney Brooks' personal injuries caused by ingesting Plavix.

2. Defendant Bristol-Myers Squibb Company (hereinafter referred to as "BMS") is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.) to manufacture and market Plavix in the United States. The headquarters for Bristol-Meyers Squibb Company is located at 345 Park Avenue, New York, New York 10145-0037.

3. Defendant, Sanofi-Aventis U.S. L.L.C. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb

Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.

4. Defendant, Sanofi-Aventis U.S., Inc. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S., Inc. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.

5. Defendant, Sanofi-Synthelabo, Inc. is a Delaware corporation with its commercial headquarters at 90 Park Avenue, New York, New York 10016. Sanofi-Synthelabo Inc. did business as Sanofi Pharmaceuticals, Inc. and was the sponsor for the drug application for Plavix. Sanofi-Synthelabo, Inc. is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc. that was instrumental in bringing Plavix to market.

6. The three Sanofi Defendants—Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S., Inc. and Sanofi-Synthelabo, Inc.—will be collectively referred to as "Sanofi" in this Complaint.

II. JURISDICTION AND VENUE

7. This is an action for damages that exceeds the jurisdictional limits of this Court.

8. Venue in this action properly lies in Atlantic County in that Defendants do business in this county.

9. This action is brought under the New Jersey Products Liability Act, N.J.S.A. 2A: 58C-1, et seq., ("Products Liability Act"), the New Jersey Consumer Fraud Act, N.J.S.A. 56: 8-1, et seq. ("Consumer Fraud Act"), the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, et seq., ("Punitive Damages Act"), and the common law of the State of New Jersey, to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, to

compensate the Plaintiff for injuries the Plaintiff sustained as a result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix.

FACTS

10. This is an action for damages suffered by Plaintiff, Sidney Brooks as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Plavix.

11. At all material times, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants.

12. The Sanofi Defendants and BMS co-developed Plavix, applying in April 1997 for a rare, priority regulatory review by the FDA (Food and Drug Administration), which cleared the way for the Defendants to bring Plavix to market in November 1997.

13. The rush to obtain FDA approval of Plavix is indicative of the Defendants' emphasis on marketing and profit making over patient safety.

14. Plavix was heavily marketed directly to consumers through television, magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin. Those assertions have proven to be false.

15. The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies, should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking Plavix, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death far outweigh any potential benefit.

16. Still, BMS and Sanofi continued to exaggerate the results of their own studies and to make false statements in their advertising and promotional materials for the purpose of increasing their profit from Plavix sales.

17. The profit at stake for the Defendants is enormous. By way of illustration, in 2005, Plavix was the sixth top selling drug in the United States and the Defendants enjoy annual sales of Plavix totaling $3.8 Billion Dollars.

18. BMS and the Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about the drug they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promoting practices.

19. As examples, in 1998, the FDA requested the Defendants stop promoting Plavix for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were the Defendants marketing Plavix to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA-approved dosage nearly four (4) times that of other applications be given.

20. That same FDA warning criticized the Defendants' attempts at over-promotion of Plavix for unapproved use for lacking fair balance and failing to disclose any of the risks associated with its use. In particular, the FDA criticized that the Defendants were claiming to physicians, in their promotional letter, that Plavix was safe for use with other drugs. This, said the FDA, was overstating the safety profile of Plavix. In particular, its safety when combined with aspirin (known as "dual therapy") had not been established, yet Defendants were making a claim that the dual combination therapy of aspirin plus Plavix was safe. This claim has now been proven to be untrue in a recent study called CHARISMA (The Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance), which was reported on in *The New England Journal of Medicine*, April 20, 2006.

21. Again in 1998, the FDA issued a letter demanding the Defendants immediately cease distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.

22. Undaunted, the Defendants were back in the business of hiding bad facts about their drug and fabricating more favorable information so they could sell large quantities of Plavix and make giant corporate profits. In 2001, the FDA was again forced to order Defendants to immediately cease distribution of promotional material that made unsubstantiated claims about Plavix and was misleading. Specifically, the Defendants promotional material misled consumers about their own study, called CAPRIE, (Clopidogrel Versus Aspirin in Patients at Risk of Ischemic Events). While the Defendants' trumped-up promotional material claimed that Plavix was 19.2% better than Aspirin, the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin—providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given aspirin. Defendants again claimed that the use of Plavix combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.

23. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved.

24. Defendants, through their drug representatives, and their promotional efforts, have encouraged physicians to prescribe Plavix to a broad population of people who would receive the same therapeutic benefit from aspirin alone, (without risking death) and to use Plavix for

unapproved applications.

25. The result is that physicians are prescribing Plavix to people who could be cheaply and effectively protected against ischemic events by a simple aspirin, to pay approximately four dollars ($4) a day for a dose of Plavix.

26. Defendants' run of lying to physicians and the public about the safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies which reveal that not only is Plavix not worth its high price—it is dangerous.

27. The Chan study, written about in *The New England Journal of Medicine* and named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertions that Plavix is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin.

28. The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than paying for a four- dollar ($4) a-day Plavix pill that greatly increases the risk of stomach bleeding.

29. Most recently, the CHARISMA (Clopidogrel and aspirin Versus Aspirin Alone For The Prevention of Atherthrombotic Events) study uncovered another truth about Plavix. It found that Plavix plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing athertohrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), Plavix

plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other words, in those patients without ACS or PAD, dual therapy with aspirin and Plavix does more harm than good.

30. Despite the growing body of scientific knowledge that the four-dollar ($4) Plavix pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.

31. It was not until March 12, 2010 that Defendants updated the Plavix label with a warning regarding increased risk of bleeding.

32. Despite Defendants' longstanding knowledge of these dangers, Plavix's label only warns about increased risk at the time of or shortly after an invasive surgical procedure. The label does not warn about bleeding risks associated with long-term use of Plavix, and in particular with dual therapy use with aspirin.

33. Defendants knew of these dangerous defects in Plavix from the many trials which it performed and to which it had access and from its own analysis of these studies but took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to disclose the dangers.

34. As a result of Defendants' omissions and/or misrepresentations, Plaintiff ingested Plavix and suffered injury.

35. From in or around 2005 until in or around March 2010, Plaintiff Sidney Brooks took Plavix along with aspirin as ordered by his treating physicians. In 2008, Plaintiff Sidney Brooks was found to have gastrointestinal bleeding that required a week of hospitalization.

36. Plaintiff files this lawsuit within the applicable limitations period of first suspecting or having reason to suspect any wrongdoing. Plaintiff had no knowledge of the defects in Plavix and the wrongful conduct of Defendants as set forth herein, nor access to the

information regarding other injuries and complaints in the possession of Defendants. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants misrepresented and continue to misrepresent to the public and to the medical profession that Plavix is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

COUNT I

PRODUCT LIABILITY-DEFECTIVE DESIGN (N.J.S.A. 2A:58C-1 *et seq.*)

37. Plaintiff incorporate by reference, paragraphs 1 through 36, as if fully set forth.

38. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Plavix.

39. Plavix is defective and unreasonably dangerous to consumers.

40. Plavix is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

41. At all times material to this action, Plavix was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including the Plaintiff, without substantial change in the condition in which it was sold.

42. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective, unreasonably dangerous condition, at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a) When placed in the stream of commerce, Plavix contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks that exceeded the benefits of Plavix, including but not limited to the risks of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and even death in an unacceptably high number of its users;

b) When placed in the stream of commerce, Plavix was defective in design and formulation, making the use of Plavix more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other similar drugs on the market including aspirin;

c) Plavix's design defects existed before it left the control of the Defendants;

d) Plavix was insufficiently tested;

e) Plavix caused harmful side effects that outweighed any potential utility; and

f) Plavix was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including the Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff individually and collectively.

43. In addition, at the time that Plavix left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Plavix's utility.

44. As a direct and proximate result of Plavix's defective design, the Plaintiff suffered the severe physical injuries and damages described above.

45. The Plaintiff Sidney Brooks suffered grave injuries and endured substantial pain

and suffering for months following his gastrointestinal bleeding.

46. Plaintiff was economically harmed in that he has incurred significant expenses for medical care.

47. For these reasons and the reasons stated below, the Plaintiff seeks actual and punitive damages from the Defendants.

WHEREFORE, the Plaintiff demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT II

PRODUCT LIABILITY-MANUFACTURING DEFECT
N.J.S.A. 2A-58C-1 et seq.)

48. Plaintiff incorporate by reference paragraphs 1 through 47 as if fully set forth.

49. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Plavix.

50. At all times material to this action, Plavix was expected to reach, and did reach consumers in the State of New Jersey and throughout the United States, including the Plaintiff, without substantial change in the condition from which it was sold.

51. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a) When placed in the stream of commerce, Plavix contained manufacturing defects that rendered the product unreasonably dangerous;

b) Plavix's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c) Plavix was not made in accordance with the Defendants' specifications or performance standards; and,

d) Plavix's manufacturing defects existed before it left the control of the Defendants.

52. As a direct and proximate result of Plavix's manufacturing defects, the Plaintiff Sidney Brooks was severely injured.

53. The Plaintiff Sidney Brooks suffered grave injuries and endured substantial pain and suffering for months following his gastrointestinal bleeding.

54. Plaintiff was economically harmed in that he has incurred significant expenses for medical care.

55. Sidney Brooks' injuries and damages were severe and some aspects of it are permanent and will continue into the future. As a result, the Plaintiff seeks actual and punitive damages from the Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT III

PRODUCT LIABILITY-FAILURE TO WARN N.J.S.A. 2A:58C-1 et seq.)

56. Plaintiff incorporate by reference paragraphs 1 through 54 as if fully set forth.

57. Plavix was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff, of the dangerous risks and reactions associated with Plavix, including but not limited to

its propensity to cause avoidable strokes, heart attacks, abnormal bleeding and other serious injuries and side effects despite the Defendants' knowledge of the increased risk of these injuries over other similar drugs such as aspirin.

58. Sidney Brooks was prescribed and used Plavix for its intended purpose.

59. Neither Sidney Brooks, nor his physician could have discovered any defect in Plavix through the exercise of reasonable care.

60. The Defendants, as manufactures and/or distributors of Plavix are held to the level of knowledge of an expert in the field.

61. The warnings that were given by the Defendants were not accurate, clear, or complete, and/or were ambiguous.

62. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of stroke, heart attack, and other serious injuries and side effects, and failed to instruct physicians to test and monitor for the presence of the injuries for which Plaintiff's decedent and others had been placed at risk.

63. The warnings that were given by the Defendants failed to properly warn consumers of the increased risks of stroke, heart attack, and other serious injuries and side effects.

64. Sidney Brooks, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants. The Defendants had a continuing duty to warn the Plaintiff of the dangers associated with Plavix. Had Plaintiff received adequate warnings regarding the risks of Plavix, he would not have used it.

65. As a direct and proximate result of Plavix's defective and inappropriate warnings, the Sidney Brooks suffered severe physical injuries and damages, as described above.

66. Plaintiff has endured substantial pain and suffering, and has incurred significant

expenses for medical care and recovery.

67. Because of Sidney Brooks' severe physical injuries, he has been emotionally and economically injured.

68. Sidney Brooks suffered severe injuries, damages, and a painstaking recovery. Some of the harm caused to him is permanent. Plaintiff is emotionally and economically harmed and as a result, and he seeks actual and punitive damages from the Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VI

PRODUCT LIABILITY-NEGLIGENCE (N.J.S.A. 2A:58C-1 et. seq.)

69. Plaintiff incorporate by reference paragraphs 1 through 68 as if fully set forth.

70. At all material times, the Defendants, and each of them individually, had a duty to exercise reasonable care to consumers, including the Plaintiff, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Plavix.

71. The Defendants, and each of them individually, breached their duty of reasonable care to the Sidney Brooks in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold Plavix.

72. Sidney Brooks' severe injuries and damages are all direct and proximate results of the carelessness and negligence of the Defendants in at least the following ways:

a) In their design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of Plavix;

b) In their failure to warn or instruct, and/or adequately warn or adequately instruct, users of Plavix, including Plaintiff, of Plavix's dangerous and defective characteristics;

c) In their design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Plavix;

d) In their promotion of Plavix in any overly aggressive, deceitful and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;

e) In representing that Plavix was safe for its intended use when, in fact, Plavix was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of Plavix;

g) In failing to perform appropriate post-market testing of Plavix; and

h) In failing to perform appropriate post-market surveillance of Plavix.

73. The Defendants knew or should have known that consumers such as the Plaintiff would suffer injury or die as a result of the Defendants' failure to exercise reasonable and ordinary care.

74. As a direct and proximate result of Defendants' misrepresentations, carelessness and negligence, Sidney Brooks suffered severe injury and he has suffered continuing emotional and economic injuries and damages.

75. Plaintiff has endured substantial pain and suffering, and has incurred significant expenses for medical care and recovery.

76. Because of Sidney Brooks' severe physical injuries, he has been emotionally and economically injured.

77. Sidney Brooks suffered severe injuries, damages and a painstaking recovery. Some of the harm caused to his is permanent. Plaintiff was emotionally and economically harmed and as a result, he seeks actual and punitive damages from the Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VII

NEGLIGENT MISREPRESENTATION

78. Plaintiff incorporate by reference paragraphs 1 through 77 as if fully set forth.

79. Defendants, having undertaken the manufacturing, marketing, distribution, and/or promotion of Plavix, owed a duty to provide accurate and complete information regarding Plavix.

80. Defendants falsely represented to Plaintiff, in direct to consumer advertising and indirectly through misrepresentations to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact, false, and Plavix was not safe and was in fact dangerous to Plaintiff's health.

81. At the time the representations were made, Defendants concealed from Plaintiff and his prescribing physician information about the propensity of Plavix to cause great harm.

82. Defendants negligently misrepresented claims regarding the safety and efficacy of Plavix despite the lack of information of the representations' accuracy.

83. Defendants' misrepresentations were made by Defendants with the intent to induce Plaintiff to use Plavix, to his enormous detriment.

84. At the time of Defendants' misrepresentations and omissions, Plaintiff and his physician were ignorant of the falsity of these statements and reasonably believed them to be true.

85. Defendants represented and marketed Plavix as being safe and effective. After Defendants became aware of the risk of ingesting Plavix, however, Defendants failed to communicate to Plaintiff, his physician and/or the general public that the ingestion of this drug could cause a person serious and potentially fatal bodily injury.

86. Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for at least the following reasons:

a) Plaintiff incorporates all facts and allegations previously stated in this Complaint;

b) Defendants failed to warn Plaintiff, his physician and other consumers of the defective condition of Plavix as manufactured and/or supplied by Defendants;

c) Defendants individually and through their agents, representatives, distributors, and/or employees negligently misrepresented material facts about Plavix in that they made the representations when they knew or reasonably should have known of their falsity. Alternatively, Defendants made their misrepresentations without exercising reasonable care to ascertain their accuracy.

87. Defendants' misrepresentations were made to Plaintiff, as well as the general public. Plaintiff and his healthcare provider justifiably relied on Defendants' misrepresentations and consequently, Sidney Brooks' ingestion of Plavix was to his detriment.

88. Defendants' misrepresentations proximately caused Sidney Brooks' injuries and as a result, Plaintiff has both suffered damages and monetary losses.

89. As a direct and proximate result of Defendants' carelessness and negligence, Sidney Brooks suffered severe physical injuries, as described above.

90. Plaintiff has endured substantial pain and suffering, and has incurred significant

expenses for medical care and recovery.

91. Plaintiff suffered a loss of earning capacity and because of Sidney Brooks' severe physical injuries, he has been emotionally and economically injured.

92. Sidney Brooks suffered severe injuries, damages and a painstaking recovery. Some of the harm caused to him is permanent. Plaintiff was emotionally and economically harmed and as a result, he seeks actual and punitive damages from the Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VIII

VIOLATIONS OF NEW JERSEY CONSUMER FRAUD ACT N.J.S.A. 56:8-1 et seq.)

93. Plaintiff incorporate by reference paragraphs 1 through 92 as if fully set forth.

94. Plavix is considered "merchandise" as that term is defined by N.J.S.A. 56:8-1 (c). The Defendants are designers, manufacturers, promoters, marketers, developers, sellers and/or distributors of Plavix.

95. The Defendants knew or should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects.

96. Despite their knowledge, the Defendants omitted material facts in the disclosures they made to the public, the medical community and to consumers, including the Plaintiff, concerning the use and safety of Plavix.

97. The Defendants have violated the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1 et seq.), in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff and his

physician, concerning the use and safety of Plavix.

98. The Defendants' practices relating to their promotion of Plavix created and/or reinforced a false impression as to its safety.

99. The Defendants' practice of promoting Plavix placed and continues to place all consumers of Plavix at risk for serious injury resulting from its potentially lethal side effects.

100. The Defendants' statements and omissions were made with the intent that the Plaintiff and his prescribing physician would rely on them.

101. The Plaintiff purchased and used Plavix for personal, family or household purposes and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices.

102. Defendants' promotion, statements and/or omissions concerning Plavix constitute unconscionable commercial practices, deceptions, false pretenses, misrepresentations, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by Defendants, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*

103. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff has suffered ascertainable economic loss that includes the purchases of Plavix and additional out-of-pocket healthcare related costs, for which the Defendants are liable to the Plaintiff for treble Plaintiff's actual damages.

104. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff Sidney Brooks was seriously injured.

105. Plaintiff has endured substantial pain and suffering, and has incurred significant expenses for medical care and recovery.

106. Due to Plaintiff's severe physical injuries, he has been emotionally and economically injured.

107. Sidney Brooks suffered severe injuries, damages and a painstaking recovery. Some of the harm caused to him is permanent. Plaintiff was emotionally and economically harmed and as a result, they seek actual and punitive damages from the Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT IX

PUNITIVE DAMAGES UNDER COMMON LAW, PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, et seq.) and PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1 et seq.)

108. Plaintiff incorporate by reference paragraphs 1 through 107, as if fully set forth.

109. At all material times, the Defendants knew or should have known that Plavix was inherently more dangerous than aspirin with respect to the risk of bleeding injuries, heart attacks, stroke and death.

110. At all material times, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Plavix.

111. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff, concerning the safety of Plavix.

112. At all material times, the Defendants knew and recklessly disregarded the fact that Plavix causes debilitating and potentially lethal side effects with greater frequency than safer alternative drugs, such as aspirin.

113. Despite their knowledge, the Defendants continued to aggressively market Plavix

to consumers, including Plaintiff, without disclosing the lethal side effects when there exist safer alternatives such as aspirin.

114. The Defendants knew of Plavix's defective and unreasonably dangerous nature, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Plavix.

115. Defendants intentionally concealed and/or recklessly failed to disclose to the public, including the Plaintiff and his physician, the potentially life threatening side effects of Plavix in order to ensure continued and increased sales.

116. The Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff of necessary information to enable Plaintiff, and his physician to weigh the true risks of using Plavix against its benefits.

117. Plaintiff is entitled to punitive damages because the Defendants' failure to warn was reckless and without regard for the public's safety and welfare. The Defendants misled both the medical community and the public at large, including the Plaintiff, and his physician, by making false representations about the safety of Plavix. Defendants downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Plavix despite available information demonstrating that Plavix was likely to cause serious and even fatal side effects to users. Defendants' actions and/or inactions were willful and wanton.

118. Defendants were or should have been in possession of evidence demonstrating that Plavix caused serious side effects. Nevertheless, Defendants continued to market Plavix by providing false and misleading information with regard to safety and efficacy. Defendants failed to provide warnings that would have dissuaded physicians from prescribing Plavix and

consumers from purchasing and consuming Plavix, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Plavix.

119. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff Sidney Brooks, he suffered grievous injuries.

120. Plaintiff has endured substantial pain and suffering; and has incurred significant expenses for medical care and recovery.

121. Due to Plaintiff's severe physical injuries, he has been emotionally and economically injured.

122. Sidney Brooks suffered severe injuries, damages and a painstaking recovery. Some of the harm caused to his is permanent. Plaintiff was emotionally and economically harmed and as a result, he seeks actual and punitive damages from the Defendants.

123. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against each of the Defendants as follows:

a) Awarding actual damages to the Plaintiff incidental to the purchase and

use of Plavix in an amount to be determined at trial;

b) Awarding Plaintiff compensatory damages against Defendants in an amount sufficient to fairly and completely compensate them for all damages;

c) Awarding Plaintiff treble damages against Defendants so as to fairly and completely compensate them for all damages, and to deter similar wrongful conduct in the future;

d) Awarding Plaintiff punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter similar wrongful conduct in the future;

e) Awarding pre-judgment and post-judgment interest to the Plaintiff;

f) Awarding the costs and expenses of this litigation to Plaintiff;

g) Awarding reasonable attorney's fees and costs to the Plaintiff as provided by law; and,

h) Granting all such other and further relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

PERSKIE & FENDT, P.C.

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ATTORNEYS FOR PLAINTIFF

Date: 2-28-11