UNITED STATES DISTRICT COURT FOR THE WESTERN DIVISION OF LOUISIANA

IN RE: ACTOS (PIOGLITAZONE))
PRODUCT LIABILITY LITIGATION) JUDGE REBECCA DOHERTY
	_) MAGISTRATE HANNA
This Document Relates To:)
) MDL NO: 2299
William L. Novak v. Takeda Pharmaceuticals)
International, Inc., et al.)
Civil Action No. 6:12-CV-01241)

UNOPPOSED MOTION FOR LEAVE TO SUBSTITUTE THE ESTATE OF WILLIAM L. NOVAK AS PLAINTIFF FOR PLAINTIFF WILLIAM L. NOVAK DECEASED AND LEAVE TO AMEND COMPLAINT *INSTANTER*

NOW INTO COURT, through undersigned counsel, comes the Plaintiff, William L. Novak, and hereby moves this Court for an Order granting Plaintiff leave to substitute Linda Rogers, Fiduciary of the Estate of William L. Novak, as the new Plaintiff for plaintiff, William L. Novak, who died on May 31, 2013 and leave to file a First Amended Complaint, *Instanter*, to add a wrongful death cause of action pursuant to Ohio Rev. Code, Chapter 2125.

In support of this Motion, Plaintiff attaches the Certificate of Death as Exhibit 1 and the Entry Appointing Fiduciary; Letter of Authority appointing Linda Rogers, Fiduciary of the Estate of William L. Novak as Exhibit 2.

Respectfully submitted,

PISCITELLI LAW FIRM

/s/ Frank E. Piscitelli, Jr.

Frank E. Piscitelli, Jr. (0062128) 6151 Wilson Mills Road, Suite 110 Cleveland, Ohio 44143 216.931.7000 Telephone 216.931.9925 Facsimile frank@feplaw.com

Attorney for Plaintiff

Certificate of Service

I hereby certify that on September 9, 2013 a true copy of the foregoing Notice of

UNOPPOSED MOTION FOR LEAVE TO SUBSTITUTE THE ESTATE OF

WILLIAM L. NOVAK AS PLAINTIFF FOR PLAINTIFF WILLIAM L. NOVAK

DECEASED AND LEAVE TO AMEND COMPLAINT INSTANTER was filed

electronically. Notice of this filing was sent to all parties by operation of the Court's

electronic filing system. Parties may access this filing through the Court's CM/ECF

system.

/s/ Frank E. Piscitelli, Jr.

Frank E. Piscitelli, Jr. (0062128)

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I HEREBY CERTIFY THIS

DOCUMENT IS AN EXACT

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J# -413062238

MORRY A MESON, LOCAL MESICIFIAR
OFFICE OF UTIAL STATISTICS
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Case 6:11-md-02299-RFD-PJH Document 3353-1 Filed 09/27/13 Page 2 of 2 PageID #: 63833

Ohio Department of Health * Office of Vital Statistics

727948

Application to File an Affidavit to an Ohio Birth or Death Certificate Please Read All Instructions Before Completing This Form

Crossouts, corrective fluid and typos will not be accepted on this form

Eligibility
For birth records: You must be the person named on the record and at least 18 years old, a parent listed on the record, or a legal guardian for the child named on the record. If both parents are listed, and the child is a minor (under 18 years old), both parents must sign the affidavit. Corrections to last names, date of birth and gender will not be accepted. This affidavit cannot be used to add a father to a birth record.

For death records: Only the Informant or the funeral director may change the non-medical information as listed on the record. Cause of death information may only be changed by the attending physician or the coroner/medical examiner using a medical supplement.

Social Security number information will only be changed if documentation is provided.

Once a correction of an i	pe ·		m cannot be cor	rected or amend	ed agai	n except on the o				
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ANTHONY A RIPE				- <u>-</u>						
I represent the Person as	s: Self	Parent	Guardian	☐ Informant	N I	uneral director	Other			
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City MIDDLEBURG HE	IGHTS					State OHIO		44130		
Original certifica		nation 🗆	Birth record	☑ Death rec		☐ Fetal death	record			
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Father's full name first, FRANK NOVAK	middle, last	-								
Items to be corre	ected									
Item # / Item name Informants Mailing Address			irs on original	certificate		orrect Informat	ion			
	· Carva nacing measures									
Informants City	NORTH ROYA	ALTON	•		BA	UNSWICK				
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PROBATE COURT OF CUYAHOGA COUNTY, OHIO

ANTHONY J. RUSSO, PRESIDING JUDGE LAURA J. GALLAGHER, JUDGE

ESTATE OF: WILLIAM L. NOVAK **DECEASED**

Case Number: 2013EST189939

	an action and control of the control						
On	hearing in open cour	t the application of t	he above fiducia	ry for authority to:	administer :	decedent's es	state the

	RY; LETTERS OF AUTHORITY d all Administrators)
Name of Fiduciary: LINDA ROGERS; ; ;	
On hearing in open court the application of the above Court finds that:	e fiduciary for authority to administer decedent's estate, the
Decedent died (check one of the following) ☑ testate □ intestate	
on 05/31/2013, domiciled in BROOKPARK, OH 4	4142-0000.
(Check one of the following) ☑ Bond is dispensed with by the Will	
☐ Bond is dispensed with by law	
☐ Applicant has executed and filed an appropria	ate bond, which is approved by the Court; and
Applicant is a suitable and competent person to exec	eute the trust.
The court therefore appoints applicant as such fid decedent's estate. This entry of appointment constitutes the	uciary, with the power conferred by law to fully administer fiduciary's letters of authority.
06/18/2013 Date appointed	JUDGE LAURA J. GALLAGHER
CERTIFICATE OF APPOINT	TMENT AND INCUMBENCY
The above document is a true copy of the original constitutes the appointment and letters of authority of the nan	I kept by me as custodian of the records of this Court. It ned fiduciary, who is qualified and acting in such capacity.

ANTHONY J. RUSSO, PRESIDING JUDGE

(Seal)

06/18/2013 Issue Date

UNITED STATES DISTRICT COURT WESTERN DISTRICT OF LOUISIANA

LINDA ROGERS, Fiduciary of the Estate)	
of WILLIAM L. NOVAK, decedent,	
	MDL NO.: 6:11-MD-2299
Plaintiff,	
)	Civil Action No. 6:12-CV-01241
v.)	
)	JUDGE DOHERTY
TAKEDA PHARMACEUTICALS)	
NORTH AMERICA, INC.; TAKEDA)	MAG. JUDGE HANNA
PHARMACEUTICALS)	
INTERNATIONAL, INC., TAKEDA)	FIRST AMENDED COMPLAINT
PHARMACEUTICALS COMPANY)	
LIMITED; TAKEDA)	Jury Demand Endorsed Hereon
PHARMACEUTICALS, LLC; TAKEDA)	
GLOBAL RESEARCH &	
DEVELOPMENT CENTER, INC.;)	
TAKEDA SAN DIEGO, INC.; TAKEDA)	
PHARMACEUTICALS AMERICA, INC.;)	
ELI LILLY AND COMPANY,	
)	
Defendants.	

Plaintiff, LINDA ROGERS, Fiduciary of the Estate of WILLIAM L. NOVAK, (hereinafter "Plaintiff"), by and through his counsel of record, hereby alleges in this First Amended Complaint against the Defendants, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., TAKEDA PHARMACEUTICALS COMPANY LIMITED, TAKEDA PHARMACEUTICALS, LLC, TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC. and TAKEDA SAN

DIEGO, INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and ELI LILLY AND COMPANY as follows:

JURISDICTION

- 1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business in states other than the state in which the Plaintiff resides. This court has supplemental jurisdiction over the remaining law and state claims pursuant to 28 U.S.C. § 1367 with respect to claims that form part of the same case or controversy.
- 2. Venue is proper in this court pursuant to 28 U.S.C. § 1391 because a substantial part of Defendants business activities giving rise to Plaintiffs' claims occurred in the Northern District of Ohio.
- 3. Defendants have transacted and conducted business within the state of Ohio. Defendants have derived substantial revenue from goods and products disseminated and used in the state of Ohio. Defendants expected or should have expected their acts to have consequences within the state of Ohio.

NATURE OF THE CASE

4. This is an action for personal injury and wrongful death on behalf of LINDA ROGERS, Fiduciary of the Estate of WILLIAM L. NOVAK, against Defendants who were responsible for the prescription drug Actos, a diabetes medication used by WILLIAM L. NOVAK, decedent, that caused WILLIAM L. NOVAK's bladder cancer, pain and suffering and death.

PARTIES

- 4. On June 18, 2013, Plaintiff, **LINDA ROGERS**, was appointed the fiduciary of the Estate of **WILLIAM L. NOVAK**, who died on May 31, 2013. *See* Exhibit 1 Death Certificate; Exhibit 2, Entry Appointing Fiduciary; Letters of Authority.
- 5. Decedent, was and at all times mentioned herein was, a citizen of the State of Ohio, and nineteen (19) years of age or older.
- 6. Upon information and belief, Defendant TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA PHARMAEUTICALS NORTH AMERICA, INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.
- 7. Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan. As part of its business, TAKEDA PHARMACEUTICAL COMPANY LIMITED is involved in the research, development, sales, and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.
- 8. Defendant TAKEDA PHARMACEUTICALS, LLC is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA PHARMACEUTICALS, LLC is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

- 9. Defendant TAKEDA PHARMACEUTICALS INTERNATIONAL, INC. is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA PHARMACEUTICALS INTERNATIONAL, INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.
- 10. Defendant TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC. is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.
- 11. Defendant TAKEDA SAN DIEGO, INC. is a California corporation, having a principal place of business at 10410 Science Center Drive, San Diego, CA 92121. As part of its business TAKEDA SAN DIEGO, INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.
- 12. TAKEDA PHARMACEUTICALS AMERICA INC. is a Delaware corporation, which has its principal place of business at One Takeda Pkwy., Deerfield, IL 60015. TAKEDA PHARMACEUTICALS AMERICA INC. is a wholly-owned subsidiary of TAKEDA NORTH AMERICA, INC. TAKEDA PHARMACEUTICALS AMERICA INC. has transacted in conducting business within the State of Illinois.
- 13. Eli Lilly and Company is and Indiana Corporation with its principal place of business located at Lily Corporate Ctr., Indianapolis, Indiana 46285.
- 14. Upon information and belief, at relevant times, Defendants were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling,

marketing, and/or introducing into interstate commerce and into the State of Illinois, either directly or indirectly through third parties or related entities, its products, including Actos and pioglitazone hydrochloride.

- 15. At relevant times, Defendants conducted regular and sustained business and engaged in substantial commerce and business activity in the State of Illinois, which included but was not limited to selling, marketing and distributing its products including Actos and pioglitazone hydrochloride in Illinois.
- 16. Upon information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America including the State of in Illinois, and Defendants derived and derive substantial revenue from interstate commerce.
- 17. Upon information and belief, Defendant, TAKEDA PHARMACEUTICAL COMPANY LIMITED is a company domiciled in Japan and is the parent/holding company of Defendants TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS, LLC, TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., TAKEDA SAN DIEGO, INC., TAKEDA PHARMACEUTICALS AMERICA, INC.
- 18. Upon information and belief, at all relevant times, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED exercised and exercises dominion and control over Defendants TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS, LLC, TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., TAKEDA SAN DIEGO, INC., TAKEDA PHARMACEUTICALS AMERICA, INC.

- 19. Upon information and belief, at all relevant times, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED expected or should have expected that its acts would have consequences within the United States of America and the State of Illinois, and Defendant derived and derives substantial revenue from interstate commerce.
- 20. Upon information and belief, at all relevant times, Defendants, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED have transacted and conducted business in the State of Illinois and/or contracted to supply goods and services within the State of Illinois and these causes of action have arisen from same.
- 21. Upon information and belief, at all relevant times, Defendants, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED committed a tortious act within the State of Illinois causing injury within the State of Illinois out of which act(s) these causes of action arise.
- 22. Upon information and belief, at all relevant times, Defendants, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED committed tortious act(s) within the State of Illinois out of which act(s) these causes of action arise.

FACTUAL BACKGROUND

- 23. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Actos and pioglitazone hydrochloride for treatment of Type 2 Diabetes Mellitus.
 - 24. Actos received FDA approval in 1999 to treat Type 2 Diabetes Mellitus.
- 25. Prior to applying for and obtaining approval for Actos, Defendants knew or should have known that Actos use in humans was associated with and/or would cause the induction of bladder cancer and Defendants possessed pre-clinical scientific studies including

animal evidence, which evidence Defendants knew or should have known was a signal that the risk of bladder cancer needed to be further tested and studied before placing Actos on the market.

- 26. Despite bladder cancer findings in animal model carcinogenicity studies and other pre-clinical evidence, Defendants failed to adequately conduct complete and proper testing of Actos prior to filing its New Drug Application for Actos.
- 27. It is now known that additional bladder cancer evidence from human clinical trials also became known to Defendants in the early 2000's.
- 28. From the date of market approval for Actos, Defendants made, distributed, marketed and sold Actos without adequately warning WILLIAM L. NOVAK's prescribing physicians or WILLIAM L. NOVAK that Actos was associated with and/or could cause bladder cancer and presented a risk of bladder cancer in patients who used it and without adequate notice that Defendants had not sufficiently conducted complete and proper testing and studies of Actos with regard to carcinogenicity.
- 29. For over 10 years and to date, Defendants concealed and failed to completely disclose its knowledge that Actos was associated with or could cause bladder cancer or its knowledge that it had failed to fully study and test regarding that risk.
- 30. Defendants' failure to disclose information that they possessed regarding the failure to adequately study and test Actos for bladder cancer risk further rendered warnings for this medication inadequate.
- 31. Upon information and belief, Defendants ignored the association between the use of Actos and pioglitazone hydrochloride and the risk of developing bladder cancer.

- 32. On June 7, 2011, the Caisse nationale de l'assurance maladie, at the request of the French regulatory agency, published a report concluding that there is a statistically significant association between exposure to pioglitazone (Actos) and bladder cancer and that the risk increased with exposure longer than one year.
- 33. On June 9, 2011, the European Medicine Agency suspended the use of Actos in light of the French Marketing Authorization Committee and the French National Pharmacovigilance Committee's findings regarding the increased risk of bladder cancer.
- 34. On June 10, 2011, Germany's Federal Institute for Drugs and Medical Devices suspended the use of Actos.
- 35. On June 15, 2011, the FDA informed the public that use of the diabetes medication Actos for more than one year may be associated with an increased risk of bladder cancer. The Actos label was then changed to reflect this information in the Warnings and Precautions section as well as the patient Medication Guide to include information regarding the risk of bladder cancer.
- 36. FDA further recommended on June 15, 2011 that healthcare physicians discontinue pioglitazone use in patients with active bladder cancer.
- 37. On June 17, 2011, Health Canada Press Release indicated that in light of studies suggesting an increased risk of bladder cancer with the diabetes drug pioglitazone, as well as actions taken by other regulatory agencies, Health Canada informed healthcare professionals and Canadians that it is undertaking a review of the drug's status.
- 38. As a proximate result of Defendants' conduct, WILLIAM L. NOVAK's physician prescribed Actos to WILLIAM L. NOVAK and WILLIAM L. NOVAK used Actos to treat and/or control his diabetic condition.

- 39. As a result of using Defendants' Actos, **WILLIAM L. NOVAK** was caused to suffer bodily injury including cancerous tumor(s) in his bladder and was thus caused to sustain severe and permanent personal injuries, pain, suffering, and mental anguish.
- 40. The injuries and damages sustained by **WILLIAM L. NOVAK** were caused or substantially contributed to by Defendants' Actos and the Defendants' wrongful conduct.
- 41. The product warnings for Actos in effect during the time period WILLIAM L. NOVAK used Actos were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians as well as WILLIAM L. NOVAK of the bladder cancer risk associated with this drug.
- 42. The Defendants did not provide adequate warnings to **WILLIAM L. NOVAK's** doctors, **WILLIAM L. NOVAK**, the health care community and the general public about the increased risk of serious adverse events that are described herein.
- 43. Had **WILLIAM L. NOVAK** been adequately warned of the potential life-threatening side effects of the Defendants' Actos, **WILLIAM L. NOVAK** would not have purchased or taken Actos and would have chosen to request other treatments or prescription medications.
- 44. By reason of the foregoing, **WILLIAM L. NOVAK** has developed serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by **WILLIAM L. NOVAK's** bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

FIRST CAUSE OF ACTION DEFECT IN MANUFACTURING AND CONSTRUCTION OHIO REVISED CODE § 2307.74

- 45. Plaintiff re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein
- 46. Defendants defectively manufactured Actos because when it left their control those prescription drugs deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards.
- 47. As a direct and proximate cause of Defendants' defective manufacturing, WILLIAM L. NOVAK suffered injuries and damages, the full extent of which will be proven at trial.

SECOND CAUSE OF ACTION PRODUCT DEFECT IN DESIGN OR FORMULATION OHIO REVISED CODE § 2307.75

- 48. Plaintiff re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.
- 49. At all times herein mentioned, Defendants manufactured, designed, formulated, produced, created, made, constructed and/or assembled Actos used by WILLIAM L. NOVAK.
- 50. Defendants' Actos was defective in that at the time Actos left the control of Defendants, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

- 51. The Defendants' Actos was in an unsafe, defective, and inherently dangerous condition that was unreasonably dangerous to its users and, in particular, WILLIAM L. NOVAK.
- 52. At all times herein mentioned, Defendants' Actos was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said Actos was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.
- 53. The nature and magnitude of the risk of harm associated with the design and formulation of Defendants' Actos, including bladder cancer, is high in light of the intended and reasonably foreseeable use of Actos for type II diabetes.
- 54. It is highly unlikely that Actos users would be aware of the risks associated with Defendants' Actos through either warnings, general knowledge or otherwise. **WILLIAM L. NOVAK** was not aware of said risks.
- 55. The likelihood was high that the design or formulation would cause the of bladder cancer, in light of the intended and reasonably foreseeable use of Actos for type II diabetes.
- 56. The design or formulation did not conform to any applicable public or private product standard that was in effect when the Actos left the control of its manufacturer.
- 57. The design or formulation of Defendants' Actos is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner. It was more dangerous than Plaintiff expected.
- 58. The intended or actual utility of Defendants' Actos is not of such benefit to justify the risk of bladder cancer and even death.

- 59. There was both technical and economic feasibility, at the time the Defendants' Actos left Defendants' control, of using an alternative design or formulation that would not cause bladder cancer.
- 60. The defective design or formulation of Defendants' Actos was not caused by an inherent characteristic of Actos which is a generic aspect of anti-diabetic medications that cannot be eliminated without substantially compromising Actos' usefulness or desirability and which is recognized by the ordinary person. This is demonstrated by numerous safer alternative therapies that are available on the market to treat type II diabetes, that effectively reduce blood sugar without the harmful side effects, such as bladder cancer, that can result from long-term Actos use.
- 61. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which **WILLIAM L. NOVAK** suffered.
- 62. By reason of the foregoing, the Defendants are liable to the **WILLIAM L. NOVAK**, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling Actos that is defective in design and formulation.
- 63. As a direct and proximate cause of Defendants' defective design and formulation, **WILLIAM L. NOVAK** suffered injuries and damages, the full extent of which will be proven at trial.

THIRD CAUSE OF ACTION PRODUCT DEFECT DUE TO INADEQUATE WARNING AND/OR INSTRUCTION OHIO REVISED CODE § 2307.76

64. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

- 65. Defendants had a duty to warn **WILLIAM L. NOVAK** of the risks associated with the Defendants' Actos, namely, the risk of bladder cancer.
- 66. Defendants knew, or in the exercise or reasonable care, should have known about the risk bladder cancer.
- 67. Defendants failed to provide warning or instruction that a manufacturer exercising reasonable care would have provided concerning the risk of bladder cancer, in light of the likelihood that their product would cause bladder cancer, for which **WILLIAM L. NOVAK** suffered.
- 68. Defendants' Actos is defective due to inadequate post-marketing warning or instruction.
- 69. Defendants knew, or in the exercise or reasonable care, should have known about the risk that their Actos causes bladder cancer.
- 70. Defendants failed to provide post-marketing warning or instruction that a manufacture exercising reasonable care would have provided concerning the risk of bladder cancer, for which **WILLIAM L. NOVAK** suffered.
- 71. Defendants' Actos does not contain a warning or instruction regarding bladder cancer for normal healthy individuals.
- 72. The risk of bladder cancer is not an open and obvious risk or a risk that is a matter of common knowledge in regards to Actos.
- 73. By reason of the foregoing, the Defendants are liable to the WILLIAM L. NOVAK, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling of Actos that is defective due to inadequate warning or instruction.

74. As a direct and proximate cause of Defendants' defective warning, WILLIAM

L. NOVAK suffered injuries and damages, the full extent of which will be proven at trial.

FOURTH CAUSE OF ACTION PRODUCT DEFECT IN FAILURE TO CONFORM TO REPRESENTATIONS OHIO REVISED CODE § 2307.77

- 75. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.
- 76. The Defendants' Actos was defective in that, when it left the control of Defendants, the Actos did not conform to representations made by Defendants.
 - 77. Said representations are false, misleading, and inaccurate.
- 78. Defendants describe and represent that their Actos has characteristics that simply do not conform to reality. Rather then acknowledging that Defendants' Actos causes bladder cancer, Defendants describe their Actos as being safe.
- 79. These representations are in stark contrast to the bladder cancer that Defendants' Actos does actually cause.
- 80. While Plaintiff believes and avers that Defendants acted negligently and recklessly in making the representations, in the event Defendants are not found to have acted negligently or recklessly, Defendants are still liable for the damages and injuries suffered by Plaintiffs pursuant to Ohio Revised Code § 2307.77.
- 81. By reason of the foregoing, the Defendants are liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling or a Actos that is defective in that it did not conform, at the time it left the control of Defendants, to representations made by Defendants.

82. As a direct and proximate result of Defendants' violation of Ohio Revised Code §2307.77, **WILLIAM L. NOVAK** has suffered injuries and damages, the full extent of which will be proven at trial.

FIFTH CAUSE OF ACTION VIOLATION OF CONSUMER PROTECTION STATUTES

- 83. Plaintiff repeats, reiterates, re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
 - 84. Defendants engaged in commercial conduct by selling Actos.
- 85. Defendants misrepresented and omitted material information regarding Actos by failing to disclose known risks, including bladder cancer.
- 86. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Defendants' product in violation of Chapters 1345 and 4165 of the Ohio Revised Code.
- 87. Ohio has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that Defendants' products was fit to be used for the purpose for which it was intended, when Defendants knew it was defective, dangerous, unsafe and by other acts alleged herein.
- 88. Defendants engaged in the deceptive acts and practices alleged herein in order to sell Defendants' product to the public, including **WILLIAM L. NOVAK**.

89. As a direct and proximate result of the Defendants' violations of Chapters 1345 and 4165 of the Ohio Revised Code, **WILLIAM L. NOVAK** suffered bladder cancer and is entitled to compensatory damages, equitable relief, punitive damages, costs and reasonable attorneys' fees.

SIXTH CAUSE OF ACTION PUNITIVE DAMAGES

- 90. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.
- 91. **WILLIAM L. NOVAK's** injury was the result of misconduct of Defendants that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question.
- 92. Defendants fraudulently and in violation of applicable regulations of the FDA withheld from the FDA information known to be material and relevant to the harm that the **WILLIAM L. NOVAK** suffered or misrepresented to the FDA information of that type.
- 93. By reason of the foregoing, the Defendants are liable to the Plaintiff for punitive damages, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective under the Ohio Product Liability Act.

SEVENTH CAUSE OF ACTION CONSCIOUS PAIN AND SUFFERING

94. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

95. As a direct and proximate cause of Defendants' negligence, WILLIAM L. NOVAK endured conscious pain and suffering.

EIGHTH CAUSE OF ACTION WRONGFUL DEATH

- 96. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.
- 97. As a direct and proximate result of the Defendants' negligence, **WILLIAM L. NOVAK** suffered a premature and wrongful death on May 31, 2013.
- 98. Pursuant to Ohio Revised Code § 2125.02, the **WILLIAM L. NOVAK's**Estate is entitled to Compensatory damages, including, but not limited to:
 - (1) Loss of support from the reasonably expected earning capacity of the decedent;
 - (2) Loss of services of the decedent;
 - (3) Loss of the society of the decedent, including loss of companionship, consortium, care, assistance, attention, protection, advice, guidance, counsel, instruction, training, and education, suffered by the surviving spouse, dependent children, parents, or next of kin of the decedent;
 - (4) Loss of prospective inheritance to the decedent's heirs at law at the time of the decedent's death;
 - (5) The mental anguish incurred by the surviving spouse, dependent children, parents, or next of kin of the decedent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

- a. Awarding monetary damages to Plaintiff for all of Plaintiff's injuries in an amount to be determined at trial, as alleged herein;
- b. Awarding pre-judgment and post-judgment interest to Plaintiff;
- c. Awarding the costs and the expenses of this litigation to Plaintiff;
- d. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law;
 and,
- e. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues triable by jury

Respectfully submitted,

PISCITELLI LAW FIRM

/s/ Frank E. Piscitelli, Jr.

FRANK E. PISCITELLI, JR. (0062128)

6151 Wilson Mills Road, Suite 110 Cleveland, Ohio 44143 216.931.7000 Telephone 216.931.9925 Facsimile frank@feplaw.com

Attorney for Plaintiff

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	ļ.	4. Social Security Nur 289-26-2468	5a. Age (Years)	5b. Under 1 Months	Year 5c. Un Days Hours	der 1 day Minutes	6. Date of Birth November	Dec 1	SOCIETY THE V	A STATE OF THE PARTY OF THE PAR	ELAND,		eign Country)
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		12. Decedent's Educa HIGH SCHOO GED	tion			I of Hispanic	Origin		14. De White	cedent's i	Race		
848		15. Father's Name FRANK NOV	/AK				16. Mother's Na JENNIE			marriage)			
279		17a. Informant's Name LINDA ROG					17b. Relationsh Daughter	ip to De	cedent	100	Mailing Address GLENNA		et and Number, City. State, Zip Code)
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	#				Coroner								cause(s) and manner stated.
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	8	26e. Signature and Ti	Gentlier	Fellen		0/3//.	13		nse numb		100,000	Date Sign	ned /
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		Sequentially list conditions, if any, leading to immediate cause.	COR	Consequence	oi) of	RIER	Y Pis	Se01-5	E				YEARS
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	CAUSE OF DEATH	initiated events resulting in a death)		s Consequence	of)	42 CP	r_			207,200-007			
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		☐ Yes ☐ No	Unknown	☐ Not		pregnant with	hin 42 days of de		100	☐ Acc		_ [Pending Investigation
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							., Decedent's ho	me, con	struction	site, res	taurant, woode	d area)	33d. Injury at Work?
	92	33e. Location of Injury (Street and Nur	nber or Rural F	Route Number, (City or Town	, State)						
	504	33f. Describe How Injury	y Occurred:			-						A COLUMN TO SERVICE STATE OF THE PARTY OF TH	n Injury, Specify:
	0130	HEA 2774 Rev 01/07									Driver/Operat Other:	or DF	Pedestrian Passenger

I HEREBY CERTIFY THIS

DOCUMENT IS AN EXACT

OUT OF THE RECORD ON FILE WITH

THE OURS OLD APPRICATE TO PLEALTH.

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MORRY A MESON, LOCAL MESICIFIAR
OFFICE OF UTIAL STATISTICS
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Case 6:11-md-02299-RFD-PJH Document 3353-4 Filed 09/27/13 Page 2 of 2 PageID #: 63854 727948

Ohio Department of Health * Office of Vital Statistics

Application to File an Affidavit to an Ohio Birth or Death Certificate Please Read All Instructions Before Completing This Form

Crossouts, corrective fluid and typos will not be accepted on this form

Eligibility
For birth records: You must be the person named on the record and at least 18 years old, a parent listed on the record, or a legal guardian for the child named on the record. If both parents are listed, and the child is a minor (under 18 years old), both parents must sign the affidavit. Corrections to last names, date of birth and gender will not be accepted. This affidavit cannot be used to add a father to a birth record.

For death records: Only the Informant or the funeral director may change the non-medical information as listed on the record. Cause of death information may only be changed by the attending physician or the coroner/medical examiner using a medical supplement.

Social Security number information will only be changed if documentation is provided.

Once a correction of an i		made, that iter	n cannot be cor	rected or amend	ied agaiı	n except on the o	rder of the court.				
*Please print in lnk or ty Applicant (Person r	55	cormetion)			No. 20 William						
Name first, middle, last ANTHONY A RIPE		correction		NA)			03	56512			
I represent the Person as	: Self	☐ Parent	☐ Guardian	☐ Informant	∑ F	uneral director	Other				
Address 18149 BAGLEY RO	OAD					Daytime phone	number 440260	8800			
City MIDDLEBURG HE	14.					State OHIO		ZIP 44130			
Original certifica		ation 🗆	Birth record	☑ Death rec		☐ Fetal death	record				
State filing number vol/c 2013050492				180	registra 10-201	number cert 3005616					
Name as recorded first WILLIAM L NOVAI					□No	Name Listed	Sex Female	[X] Male			
Date of event date of bird May 31, 2013		Place o	f event City DLEBURG I	HEIGHTS		THE LIGHT	County CUYAHOG				
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Father's full name first, FRANK NOVAK	middle, last										
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Item # / Item name			rs on original	certificate		orrect Informati	ion				
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Informants City	NORTH ROYA	LTON	k		BRUNSWICK						
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Affidavit of perso	nal know	ledge (thi	s section must be	e signed before a	notary p	ublic)					
State of OHIO				Cor	unty of	CUYAHOG	Α .				
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Street	. 175-11		City				State	ZIP			
eing duly affirmed say tha	er	sonal knowled	ige that the fore	going facts are	true and	correct relative t	0				
WILLIAM L NOVAK					Affirm	ed to and subsci	ribed before me, this	3			
ilgnature** Oxtobay O. R. De no Please sign EXACTLY as the name printed above appears						Signature of Notary Signature of Notary					
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PROBATE COURT OF CUYAHOGA COUNTY, OHIO

ANTHONY J. RUSSO, PRESIDING JUDGE LAURA J. GALLAGHER, JUDGE

ESTATE OF: WILLIAM L. NOVAK DECEASED

Case Number: 2013EST189939

			•					
On hea	arina in open cour	t the application	of the above	fiduciary for auth	ority to ad	minister	decedent's	estate, the

ENTRY APPOINTING FIDUCIARY; LE (For Executors and all Admin	
Name of Fiduciary: LINDA ROGERS; ; ;	
On hearing in open court the application of the above fiduciary Court finds that:	for authority to administer decedent's estate, the
Decedent died (check one of the following) ☑ testate □ intestate	
on 05/31/2013, domiciled in BROOKPARK, OH 44142-0000) .
(Check one of the following) Bond is dispensed with by the Will	
☐ Bond is dispensed with by law	
☐ Applicant has executed and filed an appropriate bond, w	vhich is approved by the Court; and
Applicant is a suitable and competent person to execute the tru	st.
The court therefore appoints applicant as such fiduciary, wit decedent's estate. This entry of appointment constitutes the fiduciary's	
00/10/2013	LAURA J. GALLAGHER
CERTIFICATE OF APPOINTMENT AN	ND INCUMBENCY
The above document is a true copy of the original kept by constitutes the appointment and letters of authority of the named fiducia	

CO

ANTHONY J. RUSSO, PRESIDING JUDGE

(Seal)

06/18/2013 Issue Date

UNITED STATES DISTRICT COURT FOR THE WESTERN DIVISION OF LOUISIANA

IN RE: ACTOS (PIOGLITAZONE) PRODUCT LIABILITY LITIGATION))
This Document Relates To:) MAGISTRATE HANNA) MDL NO: 2299
William L. Novak v. Takeda Pharmaceuticals International, Inc., et al. Civil Action No. 6:12-CV-01241))))
[proposed] ORDER GRANTING SUBST AND MOTION TO AMEND COMP	
For good cause shown it is hereby ORDERE	D, ADJUDGED and DECREED that
The Motion to Substitute plaintiff in this matter	r is GRANTED. Linda Rogers, as
Executrix of the Estate of William L. Novak, shall be	pe substituted as Plaintiff for William
L. Novak, Deceased. Further, Plaintiff's Motion	to Amend Complaint, Instanter, is
granted.	

Date

Judge Rebecca Doherty