IN THE SUPREME COURT

OF THE STATE OF NEVADA

Electronically Filed
Apr 17 2020 05:15 p.m.
Elizabeth A. Brown
Clerk of Supreme Court

Supreme Court Case No.: 81024

Dist. Court Case No.: A-18-778471-C
Consolidated with: A-18-781820-C
A-18-782023-C

TEVA PARENTERAL MEDICINES, INC., fka SICOR, INC.; BAXTER HEALTHCARE CORPORATION; and MCKESSON MEDICAL-SURGICAL INC.,

Petitioners,

v.

THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, IN AND FOR THE COUNTY OF CLARK; THE HONORABLE TREVOR ATKINS, DISTRICT JUDGE, DEPT. 8; THE HONORABLE NANCY ALLF, DEPT. 27; and THE HONORABLE JIM CROCKETT, DISTRICT JUDGE, DEPT. 24,

Respondents,

And concerning:

YVETTE ADAMS; MARGARET ADYMY; THELMA ANDERSON; JOHN ANDREWS; MARIA ARTIGA; LUPITA AVILA-MEDEL; HENRY AYOUB; JOYCE BAKKEDAHL; DONALD BECKER; JAMES BEDINO; EDWARD BENAVENTE; MARGARITA BENAVENTE; SUSAN BIEGLER; KENNETH BURT; MARGARET CALAVAN; MARCELINA CASTANEDA; VICKIE COLE-CAMPBELL; SHERRILL COLEMAN; NANCY COOK; JAMES DUARTE;

PETITIONER'S APPENDIX

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and

SOSSY ABADJIAN; GLORIA ACKERMAN; VIRGINIA ADARVE; FRANCIS ADLER; CARMEN AGUILAR; RENE NARCISO; RHEA ALDER; GEORGE ; ALLSHOUSE SOCORRO ALLSHOUSE; LINDA ALPY; JOYCE ALVAREZ; REBECCA L. ANDERSON ANDREI; EMANUEL; TERRIE ANTLES; KELLIE APPLETON-HULTZ; ANTHONY ARCHULETA; ESTEBAN ARELLANOS; RICKIE ARIAS; MARK ARKENBURG; ROGER ARRIOLA; MARIA ARTIGA; ROBIN ASBERRY; WINIFRED BABCOCK; ROBERT BACH; SUSAN F. BACHAND; ELAINE BAGLEY-TENNER; MELISSA BAL; BRYAN BALDRIDGE; RONALD BARKER; RONALD BARNCORD; PEGGY JO BARNHART; DONALD BARTLETT; SHERYLE BARTLETT; JOSEPH BAUDOIN; BARBARA BAXTER; VENUS BEAMON; BARBARA ROBIN BEATTY; RODNEY BEHLINGS; CRISTINA BEJARAN; TOMAS BENEDETTI; VERNA BENFORD; RICHARD BENKERT; MARSHALL BERGERON; DONNA BERGERON; SYLVIA BIVONA; ROBERT BLAIR; HARRY BLAKELEY; DAWN BLANCHARD; BONNIE BLOSS; DARRELL BOLAR; ROY BOLDEN; VICTOR BONILLA; GRACIELA BORRAYES; BILLY BOWEN; SHIRLEY BOWERS; SHIRLEY BRADLEY; CARLA BRAUER; CAROLYN BROWN; JACK BROWN; LESLIE BROWN; MICHAEL BROWN; ROBERTA BROWN; AMELIA B.

BRUNS; CARL L. BURCHARD; TRACI BURKS; ELIZABETH BURTON; ANGELITE BUSTAMANTE- RAMIREZ; ANASTASIO BUSTAMANTE; DOROTHY ANN BUTLER; LEE CALCATERRA; EVELYN CAMPBELL; MARIA CAMPOS; BOONYUEN CANACARIS; MELISSA CAPANDA; MARTIN CAPERELL; PEDRO CARDONA; SUSIE CARNEY; TERESA CARR; BERNARDINO CARRASCO; TRUMAN CARTER; XANDRA CASTO; SPENCE CAUDLE; MARGARET CAUSEY; XAVIER CEBALLOS; ROBERT CEDENO; DINORA CENTENO; ROY CHASE; CARIDAD CHEA; ELSA CHEVEZ; LUCILLE CHILDS; ALICIA CLARK; CAROL CLARK; PATRICIA CLARK; RICHARD COIRO; PERCELL COLLINS, JR.; ERNEST CONNER; SUSAN COREY; PATRICIA CORREA; PAUL A. COULOMBE; AMBER CRAWFORD; RONALD CROCKER; HOWARD CROSS; ROSSLYN CROSSLEY; WILLIAM R. DANIELS.; EVELYN DAVIS; MARY JEAN DAVIS; VIRGINIA A. DAVIS; JESSIE L. DAWSON; EMELYN DELACRUZ; SILVIA DERAS; SHERIDA DEVINE; CLAIRE DIAMOND; JOSE DIAZ-PEREZ; OTIS L. DIXON; EMILIO DOLPIES; PAMELA DOMINGUEZ; EUQENA DOMKOSKI; JOSEPH DONATO; HUGO DONIS; PATRICIA L. DONLEY; LJUBICA DRAGANIC; DELORIS K. DUCK; KATHLEEN J. DUHS; LILLIAN DUNCAN; HAROLD DUSYK; ALLYSON R. DYER, JR.; LOIS EASLEY; DEISY ECHEVERRIA; ROLAND E. ELAURIA; DARIO E. ESCALA; ENGARCIA B. ESCALA; KATHY A. ESCALERA; MARIA ESCOBEDO; TERESA I. ESPINOSA; LEON EVANS;

MARY FAULKNER; ABRAHAM FEINGOLD; MURIEL FEINGOLD; OSCAR FENNELL; MARIETTA FERGUSON; WILLIE FERGUSON; DANIEL FERRANTE; CAROLYN FICKLIN; JOE FILBECK; ETHEL FINEBERG; MADELINE C. FINN; ALBERT L. FITCH; ADRIAN FLORES; MARIA FLORES;; RAUNA FOREMASTER; JOSEPH E. FOSTER; PHYLLIS G. FOSTER; CYNTHIA D. FRAZIER; VICTORIA FREEMAN; LAWRENCE FRIEL; BONITA M. FRIESEN; NESS FRILLARTE; NANCY C. FRISBY; JODI GAINES; ESPERANZA GALLEGOS; NEOHMI GALLEGOS; BRENDA GARCIA; MARTHA GARCIA; SANDRA GARDNER; MICHAEL GARVEY; E THERESA GEORG; TINA GIANNOPOULOS; ARIS GIANNOPOULOS; WANDA GILBERT; JEAN GOLDEN; GOLOB LUCIANO; PASTOR GONZALES; JESUS GONZALEZ-TORRES; JEFF GOTLIEB; ALLEN GOUDY; BILL GRATTAN; ARNOLD GRAY; BONNIE GRAY; TANIA GREEN; ROY GREGORICH; WILLIE GRIFFIN; VERNA GRIMES; CANDELARIO GUEVARA; NICHOLAS GULLI; JULIA GUTIERREZ; DENISE F. HACHEZ; SUE HADJES; FRANK J. HALL; TINA HALL; CHARDAI C. HAMBLIN; ROBERT HAMILTON, JR.; JOANN HARPER; DORIS HARRIS; GLORICE HARRISON; SHARA HARRISON; RONALD K. HARTLEY; ESTHER A. HAYASHI; SAMUEL HAYES; CANDIDO HERNANDEZ; MARIA HERNANDEZ; THOMAS HERROLD; LUZ HERRON; SUSAN M. HILL; ISHEKA HINER; ARLENE HOARD; BETH HOBBS; MICHELLE HOLLIS; JAQUELINE A. HOLMES; JAMES HORVATH; ANA

HOSTLER; AUGUSTAVE HOULE; CARL II; HOWARD HOVIETZ; RUTH HOWARD; MICHELE HOWFORD; EDWARD L. HUEBNER; LOVETTE M. HUGHES; VIRIGINIA M. HUNTER; PATRICIA HURTADO-MIGUEL; ANGELA HYYPPA; JOSEPH INFUSO; FRANK INTERDONATI; BRIAN IREY; CECIL JACKSON; ROLANDO JARAMILLO; RICHARD JILES; LETHA JILES; CLIFTON JOHNSON; DORIS JOHNSON; JOHNNY JOHNSON; JOYCE JOHNSON; ARNOLD JONES; ANN KABADAIAN; ANTHONY K. KALETA; ARUN KAPOOR; LINDA J. KEELER; MICHAEL F. KELLY; DARRELL KIDD; CONNIE KIM; SOO-OK KIM; TAESOOK KIM; SONDRA I. KIMBERS; ELIZABETH I. KINDLER; IRIS L KING; JOANNA KOENIG; MICHAEL J. KRACHENFELS; CORINNE M. KRAMER; DAVID KROITOR; OLGA KUNIK; KAREN A. KUNZIG; ANEITA LAFOUNTAIN; BARBARA LAKE; BERTHA LAUREL; ANGES G. LAURON; MARIE LAWSON; PHYLLIS LEBLANC; ARLENE LETANG; JAMES A. LEWIS; JOAN LIEBSCHUTZ; MINERVA L. LIM; EDWARD LINDSEY; WILLIAM LITTLE; DOROTHY LIVINGSTON-STEEL; FELISA LOPEZ; IRAIDA LOPEZ; NOE LOPEZ; FLORENCE LUCAS; DARLENE LUTHER; FRANK L LYLES; DEBORAH MADRID; MARWA MAIWAND**; DOROTHY J. MAJOR; MARIO MALDONADO; IDA MALWITZ; AUDREY MANUEL; GABRIEL MARES; CAROL A. MARQUEZ.; HUGO MARTINEZ; JORGE B. MARTINEZ; JOSE MARTINEZ; MARY LOUISE MASCARI; LUCY MASTRIAN; LEROY MAYS; LISA MAYS; VIRGINIA A. MCCALL ; STELLA

MCCRAY; LAURENCE MCDANIEL; JOHN MCDAVID, JR.; DOLORES MCDONNELL; DENISE ANNE MCGEE; MAE MCKINNEY; JANET MCKNIGHT; FRED MCMILLEN, III; MYRON MEACHAM; AIDA A. MEKHJIAN; CHELSEY L. MELLOR; JIGGERSON MENDOZA; SUSAN MERRELL-CLAPP; JAMES MIDDAUGH; SYLVIA MILBURN; CORINNE MILLER; JANICE MITCHEL; MIKHAIL MIZHIRITSKY; KIRK MOLITOR; MARY MOORE; JOSE MORA; YOLANDA MORALES; ELIZABETH CASTRO MORALES;YOLANDA MORCIGLIO; BIVETTA MORENO; DAVID MORGAN; DENISE M. MORGAN; DOUGLAS MORGAN; SONIA MORGAN; ANDREW MORICI; BARRY MORRIS; JAMES MORRIS; JUANITA E. MORRIS; MICHELE MORSE; DAN R. MORTENSEN; MIGDALIA MOSQUEDA; ANDREA MOTOLA; ANNIE MUNA; LUCILA MUNGUIA; WILLIE MURRAY; JOSEPH NAGY; BONNIE NAKONECZNY; ERLINDA NATINGA; LEEANNE NELSON; LANITA NEWELL ; ROSEMARIE NORLIN; MARSHALL NYDEN; WADE OBERSHAW; JOSEPH O’CONNELL; DIGNA OLIVA; JOHN O'MARA; L NORMA J. O'NEA; LINDA ORCULLO; PAULA OROZCO-GALAN; ANGELA PACHECO; DENIS PANKHURST; MATT PARK; KATHY PARKINSON; JESUS PAZOS; TERESA PECCORINI; PHYLLIS PEDRO; JOSE O. PENA; PATRICIA PEOPLES; DELMY C. PERDOMO; DORA PEREZ; LOUISE PEREZ; LUIS PEREZ; MARIA PEREZ; MERCEDES PEREZ; AGUSTIN PEREZ-ROQUE; ANDRE PERRET; JANET P. PERRY; ALAN K.

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and

MAUREEN BRIDGES; MARIA LISS; MARY CATTLEDGE; FRANKLIN CORPUZ; BARBARA EDDOWES; ARTHUR EINHORN; CAROL EINHORN;

WOODROW FINNEY; JOAN FRENKEN; EMMA FUENTES; JUDITH GERENCES; ANNIE GILLESPIE; CYNTHIA GRIEM-RODRIGUEZ; DEBBIE HALL; LLOYD HALL; SHANERA HALL; VIRGINIA HALL; ANNE HAYES; HOMERO HERNANDEZ; SOPHIE HINCHLIFF; ANGEL BARAHONA; MARTA FERNANDEZ VENTURA; WILLIAM FRALEY; RICHARD FRANCIS; GEORGINA HETHERINGTON; JANICE HOFFMAN; GEORGE JOHNSON; LINDA JOHNSON; SHERON JOHNSON; STEVE JOHNSON; SEAN KEENAN; KAREN KEENEY; DIANE KIRCHER; ORVILLE KIRCHER; STEPHANIE KLINE; KIMBERLY KUNKLE; PATRICIA LEWIS-GLYNN; BETTE LONG; PETER LONGLY; DIANA LOUSIGNONT; MARIA KOLLENDER; DAVID MAGEE; FRANCISCO MANTUA; DANA MARTIN; MARIA MARTINEZ; JOHN MAUIZIO; ANGA MCCLAIN; BARRY MCGIFFIN; MARIAN MILLER; HIEP MORAGA; SONDRA MORENO; JIMMY NIX; NANCY NORMAN; GEORGIA OLSON; MARK OLSON; BEVERLY PERKINS; MARYJANE PERRY; RICKY PETERSON; BRANDILLA PROSS; DALLAS PYMM; LEEANN PINSON; SHIRLEY PYRTLE; EVONNE QUAST; RONALD QUAST; LEANNE ROBIE; ELEANOR ROWE; RONALD ROWE; DELORES RUSS; MASSIMINO RUSSELLO; GEOLENE SCHALLER; JAN MICHAEL SHULTZ; FRANCINE SIEGEL; MARLENE SIEMS; RATANAKORN SKELTON; WALLACE STEVENSON; ROBERT STEWART; RORY SUNDSTROM; CAROL SWAN; SONY SYAMALA; RICHARD TAFAYA;

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COYNE; NIKKI DAWSON; LOU DECKER; PETER DEMPSEY; MARIA DOMINGUEZ; CAROLYN DONAHUE; LAWRENCE DONAHUE; CONRAD DUPONT; DEBORAH ESTEEN; LUPE EVANGELIST; KAREN FANELLI; LAFONDA FLORES; MADELINE FOSTER; ELOISE FREEMAN; ELLAMAE GAINES; LEAH GIRMA; ANTONIO GONZALES; FRANCISCO GONZALES; RICHARD GREEN; ISABEL GRIJALVA; JAMES HAMILTON; BRENDA HARMAN; DONALD HARMAN; SUSAN HENNING; JOSE HERNANDEZ; MARIE HOEG; JAMES H. MCAVOY; MARGUARITE M. MCAVOY; WILLIAM DEHAVEN; VELOY E. BURTON; SHIRLEY CARR; MARY DOMINGUEZ; CAMILLE HOWEY; LAVADA SHIPERS; JANNIE SMITH; MILDRED J. TWEEDY; KATHERINE HOLZHAUER; ALICIA HOSKINSON; GREG HOUCK; DIONNE JENKINS; JOHN JULIAN; WILLIAM KADER; MARY ELLEN KAISER; VASILIKI KALKANTZAKOS; WILLIAM KEELER; ROBERT KELLAR; SHIRLEY KELLAR; MELANIE KEPPEL; ANITA KINCHEN; PETER KLAS; LINDA KOBIGE; LINDA KORSCHINOWSKI; DURANGO LANE; JUNE LANGER; NANCY LAPA; EDWARD LEVINE; MERSEY LINDSEY; ZOLMAN LITTLE; STEVE LYONS; MARSENE MAKSYMOWSKI; PAT MARINO; BILLIE MATHEWS; KRISTINE MAYEDA; CARMEN MCCALL; MICHAEL MCCOY; ANNETTE MEDLAND; JOSPEHINE MOLINA; LEN MONACO; RACHEL MONTOYA; THEODORE MORRISON; XUAN MAI NGO; JACQUELINE NOVAK; FAITH O'BRIEN; DENISE ORR; JAVIER

PACHECO; ELI PINSONAULT; FLORENCE PINSONAULT; STEVE POKRES; TIMOTHY PRICE; STEVEN RAUSCH; CLIFTON ROLLINS; JOHN ROMERO; JEAN ROSE; RONALD RUTHER; JUAN SALAZAR; PRISCILLA SALDANA; BUDDIE SALSBURY; BERNICE SANDERS; DANNY SCALICE; CARL SMITH; VICKIE SMITH; WILLIAM SNEDEKER; EDWARD SOLIS; MARY SOLIZ; ROGER SOWINSKI; CYNTHIA SPENCER; STEPHEN STAGG; TROY STATEN; LINDA STEINER; GWEN STONE; PHAEDRA SUNDAY; CLARENCE TAYLOR; CATHERINE THOMPSON; MARGRETT THOMPSON; VERNON THOMPSON; DAVID TOMLIN; VON TRIMBLE; CHUONG VAN TRONG; JOHN VICCIA; STEVEN VIG; JANET VOPINEK; KATHY WALENT; LINDA WALKER; SHIRLEY WASHINGTON; MARY WENTWORTH; BETTY WERNER; SALLY WEST; DEE LOUISE WHITNEY; SHIRLEY WOODS; TONY YUTYATAT; CATALINA ZAFRA; METRO ZAMITO; CHRISTINA ZEPEDA; ANDREW ZIELINSKI; CAROLYN ARMSTRONG; BETTY BRADLEY; CHARLEEN DAVIS-SHAW; REBECCA DAY; DION DRAUGH; VINCENZO ESPOSITO,

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VII	APP1568-1574	2/24/20	Notice of Entry of Order Granting Plaintiffs' Motion to Consolidate for Trial Per NRCP 42; and EJDCR 2.50 filed in Yvette Adams, et al. v. Teva Parenteral Medicines, Inc., et al.
VII	APP1575-1582	3/3/20	Notice of Entry (Stipulation and Order to (1) Deem Case Complex; (2) Appoint Special Master/Settlement Judge; and (3) Stay all Case Deadlines filed in Yvette Adams, et al. v. Teva Parenteral Medicines, Inc., et al.
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ALPHABETICAL INDEX OF PETITIONER'S APPENDIX

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VII	APP1499-1506	11/19/19	Amended Notice of Entry of Order Denying Defendants' Motion to Dismiss filed in Maureen Bridges, et al. v. Teva Parenteral Medicines, Inc., et al.
I	APP0030-45	10/1/18	Complaint filed in Maureen Bridges, et al. v. Teva Parenteral Medicines, Inc., et al.
I	APP0014-29	9/27/18	Complaint filed in Sossy Abadjian, et al. v. Teva Parenteral Medicines, Inc., et al.
I	APP0001-13	7/26/18	Complaint filed in Yvette Adams, et al. v. Teva Parenteral Medicines, Inc., et al.
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V	APP1083-1212	10/3/19	Plaintiffs' Opposition to Defendants' Motion to Dismiss filed in Sossy Abadijian, et al. v. Teva Parenteral Medicines, Inc., et al.
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VII	APP1530-1542	12/26/19	Recorder's Transcript of December 26, 2019 Proceedings re: Motions filed in Sossy Abadijian, et al. v. Teva Parenteral Medicines, Inc., et al.
VII	APP1484-1492	11/5/19	Recorder's Transcript of November 5, 2019 Hearing on Defendant's Motion to Dismiss filed in Yvette Adams, et al. v. Teva Parenteral Medicines, Inc., et al.
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CERTIFICATE OF SERVICE

Pursuant to NRAP 25.1 certify that I am an employee of GREENBERG TRAURIG, LLP, that in accordance therewith, on April 17, 2020, I caused a copy of ***Petitioner's Appendix*** to be served via U.S. Mail, first class postage prepaid, and via the 8th Judicial District Court's e-service system, to

Glen J. Lerner, Esq. GLEN LERNER INJURY ATTORNEYS 4795 South Durango Drive Las Vegas, NV 89147 *Attorneys for Real Parties in Interest*	Peter C. Wetherall, Esq. WETHERALL GROUP, LTD. 9345 w. Sunset Rd., Ste. 100 Las Vegas, NV 89148 *Attorneys for Real Parties in Interest*
With courtesy copies via email (pursuant to March 20, 2020 order of the Chief Judge of the EDJC that courtesy copies be submitted via email) :	
Hon. Nancy Allf Eighth Judicial District Court Clark County, Nevada Regional Justice Center Department 27 200 Lewis Avenue Las Vegas, NV 89155 Hon. Trevor Atkins Eighth Judicial District Court Clark County, Nevada Regional Justice Center Department 8 200 Lewis Avenue Las Vegas, NV 89155, and	Hon. Jim Crockett Eighth Judicial District Court Clark County, Nevada Regional Justice Center Department 24 200 Lewis Avenue Las Vegas, NV 89155

/s/ Andrea Lee Rosehill
An Employee of Greenberg Traurig LLP

GensiaSicor™
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December 21, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
N/A F

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

TELEPHONE AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia Sicor's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion 1% containing 0.025% Sodium Metabisulfite. Reference is also made to the Agency's facsimile dated December 21, 1998.

Therefore, in accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, Gensia Sicor Pharmaceuticals, Inc., hereby amends this application and commits to incorporate the labeling revisions specified in the Agency's facsimile dated December 21, 1998. We further commit to assuring that the revisions requested by FDA will be reflected in the labeling utilized for the commercial launch of this product.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PRO7510Z\AMENDS\AMEND14.WPD
cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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Gensia Sicor Pharmaceuticals, Inc. • 19 Hughes • Irvine CA • 92618-1902 • USA
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NDA DRUG AMENDMENT
AC

December 28, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

TELEPHONE AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia Sicor's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion 1% containing 0.025% Sodium Metabisulfite. Reference is also made to the telephone conversation between Mr. Raymond Brown of the Agency and myself on December 28, 1998, in which Mr. Brown requested that Gensia Sicor reinstitute the Free Fatty Acid test and specification (NMT neq/mL) for the finished product.

Therefore, in accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, Gensia Sicor Pharmaceuticals, Inc., hereby amends this application and commits to incorporating the Free Fatty Acid test and specification for the finished product as specified by the Agency. We further commit to assuring that the addition requested by FDA will be reflected in the quality control and stability documentation prior to the commercial launch of this product. This documentation will be provided as a post-approval supplement.

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We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PRO\7512\AMENDS\AMEND15.WPD

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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December 15, 1998

NEW NUMBER?
N/C

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite in the formulation, ANDA 75-102, submitted January 16, 1998.

In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21*, we hereby amend our application to update the exclusivity statement.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain K. Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

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cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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December 14, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

NDA [illegible] AMENT
N/A F

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite in the formulation, ANDA 75-102, submitted January 16, 1998. Reference is also made to the Agency's facsimile dated December 11, 1998.

In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21*, we hereby amend our application to provide the change in labeling as requested.

Please note that a number of changes to the package insert requested by the Agency were not required. Specifically, we did not incorporate the deletion of the text in the insert as identified in sections b. and c.(ii). After careful review of our labeling, we determined that this text does not appear in the last revision of our package insert for the propofol vial products.

Furthermore, we did not add the text to the insert as identified in section c.(iii). Upon review of our previous revision of the package insert, we determined that this text had already been incorporated.

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000003

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain K. Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PRO75102\AMENDS\AMEND12.WPD

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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November 10, 1998

Desk Copy
for
Mr. Peter Rickman

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

At this time we wish to notify the Agency of the legal actions taken by Zeneca Ltd. against Gensia Sicor regarding the Paragraph IV Patent Certification for Gensia Sicor's Propofol Injectable Emulsion 1% containing 0.025% Sodium Metabisulfite (ANDA 75-102).

In accordance with the provisions of Section 314.107(f)(2) of the *Code of Federal Regulations, Title 21*, we hereby amend our application to inform the Agency of the legal actions taken by Zeneca Ltd. On April 3, 1998, Zeneca Ltd. initiated a patent infringement suit (patent 5,714,520) against Gensia Sicor in the United States District Court for the District of Delaware (Zeneca Limited v. Gensia Sicor Pharmaceuticals, Inc., Civil Action No. 98-170). On April 17, 1998, Zeneca dismissed the law suit. A copy of the initial action and the subsequent dismissal are provided in **Attachment 1** and **Attachment 2**, respectively.

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We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

Attachments

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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August 24, 1998

VIA FACSIMILE AND FEDERAL EXPRESS

Mr. Gordon Johnston
Office of Generic Drugs
Center for Drug Evaluation & Research
Food and Drug Administration
Metro Park North II, HFD-600
7500 Standish Place
Rockville, MD 20855-2773

Confidential Communication
Contains Proprietary Information
Exempt from Disclosure under
the Freedom of Information Act

RE: Propofol Injectable Emulsion
Alternative Preservative System
ANDA 75-102

Dear Mr. Johnston:

Reference is made to Gensia Sicor's correspondence dated July 17, 1997, in which we requested the FDA's evaluation of an alternate Propofol formulation utilizing sodium metabisulfite as the preservative agent. Reference is also made to our response to the Agency dated June 15, 1998, regarding the adult exposure levels of sulfites expected under the ICU indication, when a patient receives the proposed formulation of Propofol Injectable Emulsion in combination with total parenteral nutrition (TPN) products that also contain sulfites. Further reference is made to the recent telephone conference on August 19, 1998, between Gensia Sicor and the Office of Generic Drugs to discuss additional information relative to the safety of sodium metabisulfite as a preservative in our proposed product.

As a result of the telephone conference, we wish to provide additional information to support the safety of sodium metabisulfite as a preservative in our proposed formulation of Propofol Injectable Emulsion. Specifically, we wish to address the following issues that were raised during this conference:

1) The potential for sulfite hypersensitivity reactions occurring from the sodium metabisulfite contained in our formulation of Propofol.

2) Pediatric dose exposure levels of sulfites expected for the proposed formulation of Propofol as indicated in anesthesia maintenance when compared to sulfite-containing TPN products.

3) Pediatric dose exposure levels of sulfites expected for the proposed formulation of Propofol as indicated in anesthesia induction when

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compared to other sulfite-containing injectable products.

4) A comparison of adult and elderly dose exposure levels of sulfites expected from more immediate administration (i.e., dose administered within 1 minute) of the proposed formulation of Propofol and other sulfite-preserved injectable products.

5) A comparison of risk between the preserving agents that is used in Zeneca's Diprivan (propofol) Injectable Emulsion, and sodium metabisulfite, that is used in Gensia Sicor's formulation of Propofol Injectable Emulsion.

Sulfite Hypersensitivity

Sulfite hypersensitivity is an adverse reaction associated with food and drug products preserved with sulfite agents. In the 1970's and 1980's, FDA received several case reports of adverse reactions to sulfite additives from foods and drugs. The reported adverse reactions included wheezing, bronchospasm, dyspnea, stomach cramps, flushing, hypotension, urticaria, and anaphylaxis.[1] In 1986, Celeste reported that FDA was aware of approximately 500 reports of adverse reactions to sulfites in foods, including 12 fatal cases allegedly involving sulfites. Adverse reactions to drugs containing sulfites were also reported. FDA noted that the adverse reactions appeared to be relegated to a sub-population of asthmatics; and to a rare number in the non-asthmatic population. In response to the reports of hypersensitivity reactions associated with sulfites, FDA took three separate regulatory actions. In August 1986, FDA promulgated a regulation to ban the use of sulfites in fresh fruits and vegetables.[2] In another regulation, the Agency required packaged foods containing sulfites to be labeled if sulfites are present at levels equal to or greater than 10 ppm.[3] The third regulatory action in June 1987 was to amend the drug labeling regulations to require a

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[1] Celeste, A. Update on Sulfites. *Assoc. Food Drug U.S. Off. Q. Bull.* 50:46, 1986. (As reported in Gunnison, A.F. & Jacobsen, D.W. Sulfite Hypersensitivity: A Critical Review. *CRC Critical Reviews in Toxicology*. 17 (3):185-214, 1987.)

[2] Sulfiting agents: revocation of GRAS status for use on fruits and vegetables intended to be served or sold raw to consumers. *Federal Register*, 51 (131):25021-25026, July 9, 1986.

[3] Food labeling: declaration of sulfiting agents. *Federal Register*, 51 (131):25012-250206, July 9, 1986.

sulfite warning in the package insert of drug products containing sulfite preservatives.[4] The Agency's actions were taken to safeguard, in particular, the hypersensitive asthmatic sub-population.

According to Gunnison and Jacobsen, approximately 5-10% of all asthmatics are sulfite hypersensitive.[5] Of the nearly 14.6 million Americans with asthma as estimated in 1994,[6] this translates to a sub-population of 0.73 - 1.46 million asthmatics who are possibly reactive to sulfites and, in general, represents 0.3 - 0.6% of the U.S. population.[7] According to Gunnison and Jacobsen, chronic asthma is the predominant predisposing factor that leads to sulfite hypersensitivity.[5]

It is suggested that sulfite oxidase deficiency in chronic asthmatics may play a role in the sulfite hypersensitivity. Specifically, chronic asthmatics with sulfite oxidase deficiency may be unable to adequately metabolize exogenous sulfites. However, the mechanism by which systemic sulfites trigger a hypersensitivity reaction is not yet know. From the review of several studies involving provocative challenge protocols and case reports of individual patients as summarized by Gunnison and Jacobsen, the hypersensitivity reaction to sulfites does not appear to be dose-related, but represents an idiosyncratic response.[5] Variations in the dose and route of administration appear to elicit varying degrees of reaction in different individuals.

In general, exogenous sulfites are rapidly oxidized to sulfate via sulfite oxidase and secreted in the urine as sulfate. The capacity of sulfite oxidase for sulfite oxidation is extremely high compared with the normal sulfite load from exogenous and endogenous sources. Because of its rapid metabolic clearance, sulfite does not accumulate in the tissues. Usually, no free sulfite is detected in plasma. Free sulfite has been reported in the plasma of a child diagnosed as deficient in sulfite oxidase.[8]

Furthermore, sedation does not affect the elimination of sulfite. This is supported by the similar sulfite clearance in a rhesus monkey while sedated as compared to normal

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[4] Sulfiting agents: labeling in drugs for human use, warning statement. *Federal Register*, 51 (234):43900-43904, December 5, 1986.

[5] Gunnison, A.F. & Jacobsen, D.W. Sulfite Hypersensitivity: A Critical Review. *CRC Critical Reviews in Toxicology*. 17 (3):185-214, 1987.

[6] *Vital and Health Statistics*. Series 10, No. 193

[7] Based upon U.S. population of 265.3 million in 1996 by the U.S. Census Bureau.

[8] Gunnison, A. F. Sulphite Toxicity: A Critical Review of In-Vitro and In-Vivo Data. *Food and Cosmetic Toxicology*. 19: 667-682, 1981.

experimental conditions.[9] Therefore, we believe that Propofol Injectable Emulsion with sodium metabisulfite will be well tolerated over an extended period, and also the clearance of sodium metabisulfite will not be affected by the action of Propofol.

In relation to the sodium metabisulfite added to our formulation of Propofol Injectable Emulsion, Gensia Sicor recognizes the potential risk of sulfite hypersensitivity reactions by this sub-population of asthmatics, and in rare cases, a sub-population of non-asthmatics. We believe this risk is mitigated by the application of the FDA-required warning statement for sulfites on the drug labeling. The warning is intended to alert health care practitioners of the risk to patients with *known* hypersensitivity to sulfites.

In the event the hypersensitivity is not disclosed in the course of the patient's history, and a reaction is manifested following the administration of Gensia Sicor's Propofol product, the patient will present with the reaction in a hospital setting, pursuant to the indications, to allow immediate medical measures to be taken. The key indices of the sensitivity reaction are wheezing and bronchospasm in the asthmatic. Both reactions are readily identifiable by the clinician (even when the patient is under anesthesia) such that treatment can be initiated immediately.

Propofol Pediatric Dose for Maintenance of General Anesthesia - Exposure Levels of Sulfites from Propofol Compared to TPN Products

To determine pediatric dose exposure levels of sulfites resulting from the administration of Gensia Sicor's formulation of Propofol as indicated in anesthesia maintenance and compared to sulfite-containing TPN products, we have performed an evaluation for pediatric patients assuming standard weights for a newborn (3.5 kg), an infant (12 kg), and a child (30 kg). It should be noted that **Propofol is not recommended for administration to children less than 3 years old nor is the product recommended for ICU or MAC sedation in children, in general. Propofol is only indicated for general anesthesia in children age 3 years and older.** Although the sulfite exposure due to TPN products in children (≥ 3 years) is of most interest for the purposes of direct comparison to sulfite doses resulting from administration of Propofol, information regarding the sulfite exposure levels from TPN products in newborns and infants are also presented as a point of interest.

For a pediatric patient 3 years of age or older undergoing maintenance of general anesthesia, the theoretical levels of sulfite exposure expected from the administration of Gensia Sicor's sodium metabisulfite formulation of Propofol is expected to be 13.5 mg/hr. We arrived at a theoretical hourly amount of sodium metabisulfite based upon a maintenance dose for general anesthesia of 18 mg/kg/hr of Propofol, assuming a standard weight pediatric patient of 30 kg, i.e.,

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[9] Gunnison et al. Comparative Sulfite Metabolism in the Rat, Rabbit, and Rhesus Monkey. *Toxicology and Applied Pharmacology*. 42: 99-109, 1977.

(18 mg/kg/hr) X (30 kg) X [(0.25 mg/mL SMBS)/(10 mg/mL Propofol)]

= 13.5 mg SMBS/hr.

Table 1 summarizes information from *Facts and Comparison* (1997),[10] which lists the amounts of sulfite preservatives contained in various amino acid solutions and the relation to pediatric product doses in newborns, infants, and children. The dosage information for each TPN product is based upon the *pediatric* TPN protocols described in *Facts and Comparison* (1997).[10] This table further summarizes the amount of sulfite exposure expected.

Table 1

Product	Preservative	Preservative Dose (mg/hr)*		
		Newborn (3.5 kg)	Infant (12 kg)	Child (30 kg)
Aminosyn II 5% (Abbott)	20 mg/dL Sodium Hydrosulfite	2.2	7.5	19
Aminosyn II 10% (Abbott)	20 mg/dL Sodium Hydrosulfite	1.1	3.8	9.4
Aminosyn-PF 10% (Abbott)	230 mg/100 mL Sodium Hydrosulfite	13	43	108
Aminosyn 15% (Abbott)	60 mg/100 mL Sodium Hydrosulfite	2.2	7.5	19
TrophAmine 6% (McGaw)	< 50 mg/100 mL Sodium Metabisulfite	4.6	16	39
TrophAmine 10% (McGaw)	< 50 mg/100 mL Sodium Metabisulfite	2.7	9.4	23
FreeAmine III 8.5% (McGaw)	<0.1 g/100 mL Sodium Bisulfite	6.4	22	55
FreeAmine III 10% (McGaw)	<0.1 g/100 mL Sodium Bisulfite	5.5	19	47
Novamine 15% (Abbott)	30 mg/100 mL Sodium Bisulfite	1.1	3.8	9.4
Aminosyn-RF 5.2% (Abbott)	60 mg/100 mL Sodium Metabisulfite	6.3	22	54
NephrAmine 5.4% (McGaw)	< 0.05 g/100 mL Sodium Bisulfite	5.1	17	43
HepatAmine 8% (McGaw)	< 100 mg/100 mL Sodium Bisulfite	NP**	NP	59

* TPN Pediatric Protocol: 150 mL/kg/day of a 2.5% Amino Acid solution (equivalent to 3.75 g/kg/day)
** NP = Not Provided

[10] For the specific list of page references for each drug product discussed, refer to **Attachment 1.**

For children 3 years of age or older, TPN solutions were determined to yield sulfite preservative doses (up to 108 mg/hr), in general, greater than or equivalent to the theoretical level of exposure (13.5 mg/hr) from Propofol containing sodium metabisulfite, when administered for pediatric anesthesia maintenance. Additionally, the sulfite exposure for newborns (up to 13 mg/hr) and infants (up to 43 mg/hr) when receiving TPN products are also in the range of the 13.5 mg/hr exposure experienced by a pediatric patient (≥ 3 years) receiving Gensia Sicor's formulation of Propofol. It is important to note that Aminosyn-PF 10% is marketed specifically for pediatric administration and, in this evaluation, represents the highest dose of sulfite (108 mg/hr) to the pediatric patient 3 years of age and older in comparison to other TPN products.

In certain clinically compromised states, TPN products containing sulfites are indicated for pediatric administration. Specifically, Aminosyn-RF 5.2% and NephrAmine 5.4% are indicated for treatment of renal failure; and HepatAmine is specially formulated for the treatment of hepatic failure/hepatic encephalopathy. Pediatric patients (≥ 3 years) receiving these TPN solutions are exposed to sulfites of 43 to 54 mg/hr, which is in excess of the expected sulfite exposure of 13.5 mg/hr when our proposed formulation of Propofol is administered. Based upon the pediatric dose contributed from approved TPN products in the most compromised patients, it is expected that the levels of sulfite from Gensia Sicor's formulation of Propofol should be well tolerated in both health and compromised patients.

In conclusion, the total contribution of sulfite from amino acid TPN products for pediatric indications correlates to levels of sulfite expected to be safe for administration of Gensia's Propofol Injectable Emulsion for pediatric maintenance anesthesia.

Propofol Pediatric Dose for Induction of General Anesthesia - Exposure Levels of Sulfites from Propofol Compared to Other IV Products

For a comparison of immediate administration (i.e., dose administered within 1 minute), theoretical levels of sulfite exposure expected for pediatric patients receiving parenteral products containing sulfites were compared to sulfite levels expected to be contributed by Gensia Sicor's formulation of Propofol based upon the pediatric dosing for induction of general anesthesia. For purposes of this analysis, pediatric dosing will focus upon children 3 years or older, however, information for newborns and infants is also of interest. The evaluation includes the overall scope of sulfite exposure to pediatric patients from two approved drug products, Gallamine Triethiodide (20 mg/mL) and Tubocurarine Chloride (3 mg/mL). As in the previous section, the assumption for pediatric standard weights remains the same. Since Propofol is not recommended for administration to children less than 3 years old, comparison to short term exposure to sulfites in children 3 years of age or older is of greatest value.

For a pediatric patient 3 years of age or older, the theoretical levels of sulfite exposure expected from the administration of the Gensia Sicor's sodium metabisulfite formulation of Propofol for induction of general anesthesia (i.e., per labeling, 2.5 - 3.5 mg/kg over

20 - 30 sec.) have been calculated. The theoretical amounts of sodium metabisulfite based upon dosing for induction were determined as follows:

Induction

(2.5 - 3.5 mg/kg) X (30 kg) X [(0.25 mg/mL SMBS)/(10 mg/mL Propofol)]

= 1.9 - 2.6 mg SMBS in 20 to 30 sec.

Review of *Facts and Comparison* (1997)[11] for other products containing sulfites which list pediatric dosing protocols provided two drugs used as adjuncts to anesthesia: Gallamine Triethiodide (20 mg/mL) and Tubocurarine Chloride (3 mg/mL). These two products compare well to Gensia Sicor's Propofol, because both contain the same sulfite preservative, sodium metabisulfite, and both are used in a surgical setting. The levels of sodium metabisulfite exposure from these products based upon the pediatric protocols are provided in **Table 2** below:

Table 2

Product	Preservative	Method of Administration	Preservative Dose (mg)		
			Newborn (3.5 kg)	Infant (12 kg)	Child (30 kg)
Gallamine Triethiodide, 20 mg/mL (Davis + Geck)	2.5 mg/mL Sodium Metabisulfite	*Initial: 1.5 mg/kg* *Repeat: 1 mg/kg after 30-40 min. as needed*			
		Initial Dose	0.66	2.3	5.6
		Repeat Dose	0.44	1.5	3.8
Tubocurarine Chloride, 3 mg/mL (Abbott)	1 mg/mL Sodium Metabisulfite	*Neonates: 0.3 mg/kg* *Children: 0.6 mg/kg* *Sustained injection in 1-1.5 min.*			
		Initial (1 min.)	0.35	2.4	6.0
		Repeat Dose	0.35	2.4	6.0

In pediatric protocols for immediate administration, the exposure level of sodium metabisulfite ranges from 3.8 to 6.0 mg for the two approved products, Gallamine Triethiodide and Tubocurarine Chloride. This range is comparable to the expected levels of sulfite from the dosing of Propofol with sodium metabisulfite during pediatric induction. Therefore, the sulfite exposure due to Propofol for pediatric induction would

[11] For the specific list of page references for each drug product discussed, refer to **Attachment 1.**

be expected to correlate with safe levels as supported by the two approved products.

Adult and Elderly Dose-Exposure Levels of Sulfites from Propofol Compared to Other IV Products

For a comparison of immediate administration in adult and elderly patients, theoretical levels of sulfite exposure expected for these groups receiving parenteral products containing sulfites were compared to sulfite levels expected from Gensia Sicor's formulation of Propofol. Comparisons were made based upon the recommended Propofol dosing for bolus injection, induction and maintenance for general anesthesia and MAC sedation. Information with regard to the dosing of the comparator products was obtained from *Facts and Comparison* (1997).

The levels of sulfite exposure from various injectable products as well as the sulfite exposure levels from Propofol were calculated for the adult and elderly indications. The theoretical amounts of sulfite for the Propofol and the comparator products are summarized in **Table 3** and **Table 4**, respectively.

Table 3

Product Description	Preservative Concentration	Method of Administration	Preservative Dose	
			Elderly (70 kg)	Adult (70 kg)
Propofol Injectable Emulsion, 1% (Gensia Sicor)	0.025% Sodium Metabisulfite	*General Anesthesia:* *Bolus injection - 50 mg per as required* *Elderly - 1.5 mg/kg for induction (10 sec)* *Maintenance @ 100 mcg/kg/min.* *Adult - 2.5 mg/kg for induction (10 sec)* *Maintenance @ 200 mcg/kg/min.*		
		Intermittent Bolus	12.5 mg	12.5 mg
		Induction	2.63 mg	4.38 mg
		Maintenance	10.5 mg/hr	21 mg/hr
		MAC Sedation: *Elderly - 0.5 mg/kg for induction (5 min)* *Maintenance @ 20% of 75 mcg/kg/min.* *Adult - 0.5 mg/kg for induction (5 min)* *Maintenance @ 75 mcg/kg/min.*		
		Induction	0.88 mg	0.88 mg
		Maintenance	6.3 mg/hr	7.9 mg/hr

Table 4

Product Description	Preservative Concentration	Method of Administration	Preservative Dose	
			Elderly (70 kg)	Adult (70 kg)
Gallamine Triethiodide, 20 mg/mL (Davis + Geck)	2.5 mg/mL Sodium Metabisulfite	*Adjunct to Anesthesia:* *Initial dose - Max of 100 mg* *Repeat dose - 1 mg/kg every 30-40 min as needed*		
		Initial Dose	12.5 mg	12.5 mg
		Repeat Dose	8.75 mg	8.75 mg
Tubocurarine Chloride, 3 mg/mL (Abbott)	1 mg/mL Sodium Metabisulfite	*Adjunct to Anesthesia:* *Initial dose - sustained injection of 0.6 mg/kg* *Repeat dose - 0.6 mg/kg every 30-40 min. as needed*		
		Initial (1 min.)	14 mg	14 mg
		Repeat Dose	14 mg	14 mg
Intropin (dopamine), 40 mg/mL (Faulding)	1% Sodium Metabisulfite	*Vasopressor in Shock:* *Elderly - calculated using lower dose of 2 mcg/kg/min.* *Adult - calculated using upper dose of 50 mcg/kg/min.*		
		IV Infusion	2.1 mg/hr	52.5 mg/hr
Epinephrine, 0.1 mg/mL (Abbott)	0.46 mg/mL Sodium Metabisulfite	*Vasopressor for Resuscitation: 1 mg every 5 min.*		
		Bolus every 5 min	4.6 mg	4.6 mg
Hydrocortisone Sodium Phosphate, 50 mg/mL (MSD)	3.2 mg/mL Sodium Bisulfite	*Adrenal Cortical Steroids:* *Elderly - calculated using lower dose of 15 mg/day* *Adult - calculated using upper dose of 240 mg/day*		
		Dosed every 12 hrs	0.32 mg	5 mg
Aminosyn-PF 10% (Abbott)	230 mg/100 mL Sodium Hydrosulfite	*500 mL/8 hr*		
		TPN	144 mg/hr	144 mg/hr

Table 5 below summarizes the our assessment of other parenteral drugs with comparable sulfite exposure levels correlated to the methods of administration for Propofol Injectable Emulsion to adult and elderly patients.

Table 5

Propofol Injectable Emulsion Method of Administration		**Other Parenteral Drugs with Comparable Sulfite Exposure Levels**
General Anesthesia in Elderly and Adult		
Intermittent Bolus	12.5 mg	Range: 12.5 - 14 mg Gallamine Triethiodide Tubocurarine Chloride
Induction	2.6 mg & 4.4 mg	Range: 4.6 - 14 mg Gallamine Triethiodide Tubocurarine Chloride Epinephrine Hydrocortisone Sodium Phosphate
Maintenance	10.5 mg/hr & 21 mg/hr	Range: 53 - 144 mg/hr Intropin (dopamine) Total Parenteral Nutrition Products (Amino Acids)
MAC Sedation in Adult and Elderly		
Induction	0.88 mg	Range: 4.6 - 14 mg Gallamine Triethiodide Tubocurarine Chloride Epinephrine Hydrocortisone Sodium Phosphate
Maintenance	6.3 mg/hr & 7.2 mg/hr	Range: 53 - 144 mg/hr Intropin (dopamine) Total Parenteral Nutrition Products (Amino Acids)

Based upon our assessment provided in **Table 4** and the data summarized in **Table 3**, the safety of sulfite exposure for adult and elderly patients when administered Propofol by intermittent bolus (12.5 mg), induction for general anesthesia (2.6 - 4.4 mg), and induction for MAC sedation (0.88 mg) are supported by the exposure levels which range from 4.6 to 14 mg for the approved products evaluated. When examining the sulfite exposure levels for patients administered propofol for the maintenance of general anesthesia and MAC sedation, our product is expected to deliver 6.3 - 21 mg/hr of sulfite compared to 53 - 144 mg/hr for the approved products.

Therefore, the sulfites levels due to adult and elderly doses of our proposed Propofol when used in general anesthesia and MAC sedation are equivalent or lower to sulfite

levels expected for previously approved products.

Risk Assessment - Sodium Metabisulfite vs. EDTA

As previously discussed in the section, "Sulfite Hypersensitivity," the risk is well known and well recognized as established by FDA in the 1980's. The safety of Propofol with sodium metabisulfite for long term administration is supported by the extended use of sulfite-containing amino acid TPN products. From the previous discussions, we determined that the sulfite exposure levels from Gensia Sicor's' Propofol would be less than levels contributed by the TPN products evaluated. Based upon sulfite exposure levels expected from administration of our Propofol for general anesthesia, equivalent sulfite exposure levels were determined from the dosing of approved drugs, specifically, Gallamine and Tubocurarine. In addition, the regulatory requirement to include the warning statement mitigates the risk associated with sulfites. The clinician is alerted to the potential effects of sulfites via the labeling. Since Propofol is administered for purposes of surgery, MAC sedation, or ICU sedation in a hospital setting under continuous medical monitoring, the patient is assured of immediate medical attention should a hypersensitivity reaction occur.

Sulfite preservatives are included in the formulations of many FDA-approved drug products.[12] In December 1986, FDA disagreed with a complete prohibition of the use of sulfites, however acknowledged that people should be provided sufficient information to avoid sulfites. Gensia Sicor is aware that sodium metabisulfite presents an inherent risk, especially to an asthmatic sub-population, as an additive in formulation of Propofol Injectable Emulsion. However, the limited preservative effect resulting from the presence of sodium metabisulfite accede to health benefits of the general public and outweigh the risk of sulfite hypersensitivity.

EDTA is also an inactive ingredient included in the formulations of many FDA-approved drug products. However, at the levels indicated in Zeneca's Diprivan (propofol) Injectable Emulsion with 0.005% EDTA, FDA recognized a potential risk of zinc depletion and mild renal damage due to long term exposure to EDTA from administration of Diprivan Injectable Emulsion for ICU use.[13, 14] Due to these potential risks, Zeneca was requested to add the following warning statement to the Diprivan

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[12] *Inactive Ingredient Guide (January 1996).* Division of Drug Information Resources, Office of Management, CDER, FDA.

[13] I.L. Tyler, Ph.D., M.D. Medical Officer Review NDA Report Propofol with 0.005% EDTA. Summary Basis of Approval for Diprivan Injectable Emulsion with 0.005% EDTA.

[14] Robert F. Bedford, M.D. Medical Officer Secondary Review. Summary Basis of Approval for Diprivan Injectable Emulsion with 0.005% EDTA.

product insert as follows:

> EDTA is a strong chelator of trace metals - including zinc. Calcium disodium edetate has been used in gram quantities to treat heavy metal toxicity. When used in this manner it is possible that as much as 10 mg of elemental zinc can be lost per day via this mechanism. Although with Diprivan Injectable Emulsion there are no reports of decrease zinc levels or zinc deficiency-related adverse events, Diprivan Injectable Emulsion should not be infused for longer than 5 days without providing a drug holiday to safely replace estimated or measured urine zinc losses.
>
> At high doses (2 - 3 grams per day), EDTA has been reported, on rare occasions, to be toxic to the renal tubules. Studies to date, in patients with normal or impaired renal function have not shown any alteration in renal function with Diprivan Injectable Emulsion containing 0.005% disodium edetate. In patients at risk for renal impairment, urinalysis and urine sediment should be checked before initiation of sedation and then be monitored on alternate days during sedation.
>
> The long-term administration of Diprivan Injectable Emulsion to patients with renal failure and/or hepatic insufficiency has not been evaluated.[15]

In addition due to FDA's concern regarding the potential risks of extended exposure to EDTA in an ICU setting, FDA informed Zeneca that approval of the EDTA formulation of Diprivan would be predicated upon a commitment from the company to perform a Phase IV Safety study to evaluate zinc loss and renal function in ICU patients.

In summary, sodium metabisulfite as an additive in parenteral drug products presents a known but limited risk of producing a hypersensitivity reaction, predominantly in chronic asthmatics. EDTA as an additive in an injectable at the levels defined in Zeneca's formulation of Diprivan presents an unknown risk. However, we understand that a phase IV safety study was requested by FDA to determine the level of risk associated with this exposure level of EDTA. The potential risks recognized by FDA are zinc depletion and mild renal damage. We trust that FDA is monitoring Zeneca for compliance with Zeneca's phase IV commitments.

Conclusion

We trust that the information provided herein, in conjunction with the information submitted to the Agency in correspondence dated July 17, 1997, June 15, and June 20, 1998, is adequate to support the Agency's decision that the substitution of sodium metabisulfite for edetate disodium as the preservative in our Propofol Injectable Emulsion does not affect the safety of our proposed product.

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[15] Warnings section of package insert of Diprivan Injectable Emulsion with 0.005% EDTA.

Should you have any questions or would like to further discuss this matter, please do not hesitate to contact me at (949) 455-4716. We will call you on Wednesday, August 26, to follow up on your meeting with the Office of New Drug Evaluation regarding this matter.

Sincerely,

Armand J. LeBlanc
Vice President, Scientific Affairs

Attachments

cc: Mr. Donald B. Hare - Office of Generic Drugs
Dr. Cynthia McCormick - Anesthetic, Critical Care & Addiction Drug Products
Dr. Roger Williams - Pharmaceutical Science

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McDERMOTT, WILL & EMERY

August 10, 1998

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NDA CORRESP

VIA FACSIMILE AND FEDERAL EXPRESS

ANDA 75-102

Mr. Douglas Sporn
Director
Office of Generic Drugs, HFD-600
Metro Park North II
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, Maryland 20855

Re: Telephone Conference with GensiaSicor Pharmaceuticals, Inc. Regarding the Use of Sodium Metabisulfite as a Preservative in its Propofol Injectable Emulsion, 10mg/mL

Dear Mr. Sporn:

I am writing to you on behalf of our client, GensiaSicor Pharmaceuticals, Inc. to request and confirm telephone conference with representatives of the Office of Generic Drugs ("OGD") and Dr. Roger Williams of the Office of Pharmaceutical Science to present and discuss additional information supporting the conclusion that the difference in preservative used by GensiaSicor does not affect the safety of the proposed product.

GensiaSicor is requesting that the teleconference be scheduled before August 25, the date on which I understand that there will be a meeting of CDER staff to discuss this matter. The additional information to be presented and discussed further supports the material previously submitted by GensiaSicor that the substitution of sodium metabisulfite for edetate sodium as a preservative does not affect the safety of Propofol Injectable Emulsion.

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As this matter is of the utmost importance to GensiaSicor, we appreciate your accommodation of this request. I will call you later this week to arrange a date and time for the telephone conference.

Attendees. The following people will participate in the telephone conference:

GensiaSicor Pharmaceuticals, Inc.

Armand J. LeBlanc, Vice President, Scientific Affairs

Rosalie Lowe, Associate Director, Regulatory Affairs

Consultants

Meeting Agenda. The proposed agenda for the telephone conference is as follows:

1. Brief Introduction

2. Review of the Difference in Preservative Systems Between the GensiaSicor and Reference Listed Product

3. Review of Safety and Clinical Impact Concerning the Use of Sodium Metabisulfite as a Preservative in Propofol Injectable Emulsion

4. Discussion of GensiaSicor's ANDA

I appreciate your assistance in arranging the telephone conference and look forward to the discussion. Again, I will call you later this week to confirm the date and time for telephone conference. Of course, please do not hesitate to call me at (202) 756-8075 if you need any further information.

Sincerely yours,

David L. Rosen

cc: Armand J. LeBlanc
Rosalie Lowe
GensiaSicor Pharmaceuticals, Inc.

Rita Hassall, OGD
Gordon Johnston, OGD
Ted Sherwood, OGD

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NEW CORRESP

June 30, 1998

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Exempt from Disclosure
Under FOIA

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

RECEIVED
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RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Containing 0.025% Sodium Metabisulfite
Technical Response to Citizens Petition 98P-0221/PSA 1

GENERAL CORRESPONDENCE

Dear Mr. Sporn:

Reference is made to Docket No. 98P-0221/PSA 1, the citizens petition (the "Petition") submitted by Stephen Mahinka, Esq., counsel to Zeneca Inc., to stay the effective date of pending, tentative, or final decisions to approve ANDAs for certain generic versions of Diprivan® (Propofol) Injectable Emulsion.

We have provided a "General Response" to the Petition which was submitted to the Dockets Management Branch on June 30, 1998, to support the position that the Commissioner deny the Petitioner's request (a copy of this response is enclosed as **Attachment 1**). This "General Response" provides adequate justification for the Commissioner to deny the Petitioner's request. However, in the "General Response" we have not addressed the specific technical issues related to our sodium metabisulfite formulation of propofol. As you know, Gensia Sicor has submitted paragraph IV certification in this ANDA. In addition, Gensia Sicor has sent notice to Zeneca stating that, in our opinion, and to best of our knowledge, our Propofol Injectable Emulsion with a preservative other than EDTA does not infringe Zeneca's patents pertaining to Diprivan® with EDTA. In such notices to Zeneca, we have not disclosed the preservative used in our product. Consequently, due to the confidential nature of this information, Gensia Sicor has decided to respond to these technical issues within our

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ANDA. Therefore, the information contained within this submission will provide the Agency with Gensia Sicor's position with respect to the technical issues brought forth in the aforementioned Petition.

Furthermore, since this technical response contains confidential, commercial, and trade secret information and data, in our opinion, it is exempt from public disclosure. Should you believe otherwise, we request that you notify us prior to disclosing any information concerning the preservative in our propofol product.

Clearly, the Petitioner and Zeneca are once again attempting to block entry of a legitimate generic product in an effort to maintain Zeneca's monopoly of the propofol market. This is evidenced by the fact that the Petition does not direct the Agency to undertake any additional administrative action beyond those defined within the existing statutes and regulations. Pursuant to these statutes and regulations, FDA will appropriately rule to approve or deny an application based upon relevant scientific review of the application to determine the safety and efficacy of a drug product. However, we recognize that the Petition provides points-to-consider with respect to review of an application for a propofol formulation containing an alternate preservative. It is to these specific points that we wish to respond.

Gensia Sicor wishes to defend its application in light of the issues raised by the Petitioner. Accordingly, we request the opportunity to meet with the Agency to discuss these latest developments no later than July 31, 1998. I will call your office next week to arrange a mutually convenient date and time for the meeting. In the interim, if additional information is required or if there are any questions concerning this matter, please do not hesitate in contacting me at (949) 455-4716.

Sincerely,

Armand J. LeBlanc
Vice President, Scientific Affairs

Enclosure

cc: Mr. Gordon Johnson
Mr. Don Hare
Mr. Peter Rickman
Office of Generic Drugs

Ms. Elaine Messa
Los Angeles District

Ms. Paula Botstein, MD
Office of Drug Evaluation III

Ms. Cynthia McCormick, MD
Division of Anesthesiology, HFD 170

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NEW CORRESP

May 27, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025%
Sodium Metabisulfite

RECEIVED

AMENDMENT

MAY 28 1998

GENERIC DRUGS

Dear Mr. Sporn:

Reference is made to our abbreviated new drug application for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite, ANDA 75-102. Further reference is made to the two amendments, which contained Paragraph IV Patent Certification Statements, dated February 11, 1998 and April 13, 1998.

In accordance with the provisions of Section 314.95(e) of the *Code of Federal Regulations, Title 21*, we hereby amend this application. We wish to document receipt of the notices as required under paragraph (a) of Section 314.95 by three of the four entities provided the notices. Copies of the return receipts are attached. Please note that the Return Receipt requested of the U.S. Postal Service (USPS) for the notice regarding Patent No. 5,714,520, which was sent to Zeneca Ltd. in the United Kingdom on February 11, 1998, has not been returned. A trace to locate the document was placed with the USPS on April 17, 1998, however, USPS has been unsuccessful in obtaining the Return Receipt to date. Therefore, it is our contention that Zeneca Ltd. received adequate notice since a Return Receipt was received from Zeneca Inc. in Wilmington, Delaware. In addition, Zeneca formally responded to our notice by filing a lawsuit on April 3, 1998, which was subsequently withdrawn.

GensiaSicor Pharmaceuticals • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

We trust you will find the attached documentation satisfactory. Should you have any questions or require further clarification, please contact me at (949) 457-2808 or by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

Attachments
S:\PRO7510Z\AMEND6\AMEND6.WPD

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

GensiaSicor™
PHARMACEUTICALS
A GensiaSicor Company

VIA FACSIMILE AND FEDERAL EXPRESS MAIL

NEW CORRESP NAI 4/20/4

April 13, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite.

At this time we wish to submit a updated Patent/Exclusivity Statement which provides a certification statement regarding the two patents granted Zeneca Ltd. on March 24, 1998, for Diprivan®. The referenced information was obtained on April 3, 1998, from FDA's web site at http://www.fda.gov/cder/orange/docket.pdf.

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APR 14 1998
GENERIC DRUGS

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Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (714) 455-4724 or by facsimile at (714) 583-7351. (Please be advised that our area code will change from "714" to "949" on April 18, 1998.)

Sincerely,

Elvia O. Gustavson

Elvia O. Gustavson
Associate Director, Regulatory Affairs

Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

Mr. Peter Rickman
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-615
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

GensiaSicor™
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A GensiaSicor Company

March 12, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia Sicor's amendment to ANDA 75-102 for Propofol Injectable Emulsion (with 0.025% Sodium Metabisulfite), 10 mg/mL, which was submitted January 16, 1998. Reference is also made to a telephone conversation on February 12, 1998, between Mr. Ray Brown, Chemistry Reviewer in the Office of Generic Drugs, and myself regarding the submission of referenced information from ANDA 74-816. Mr. Brown's request is intended to consolidate all relevant information within a single application. As agreed, we have provided all sections of the ANDA 75-102 which previously included references to ANDA 74-816.

Therefore, in accordance with Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, we hereby amend this application (ANDA 75-102) for Propofol Injectable Emulsion (with 0.025% Sodium Metabisulfite), 10 mg/mL, with additional information. These revised sections provided herein supersede all previous information submitted for these specific sections of the ANDA.

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Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

100003

The sections listed below were previously referenced by incorporation and were not included in the amendment dated January 16, 1998. These sections are provided in this amendment.

Section IX	Description of Manufacturing Facility
Section X	Outside Firms Including Contract Testing Laboratories
Section XIII	Packaging and Labeling Procedures
Section XVIII	Control Numbers
Section XX	Environmental Impact Statement
Section XXI	Other

In addition, **Section XI** and **Section XVI** has been provided in their entirety. Please note that these sections were submitted previously, but included several references to ANDA 74-816.

Finally, **Section 3** of the Sterility Assurance Validation package has also been revised to include the information referenced in ANDA 74-816.

The amendment consists of two (2) volumes and has been formatted in accordance with the Office of Generic Drug's Policy and Procedure Guide #30-91 issued April 10, 1991; and, as modified by FDA's October 14, 1994 letter to all NDA, ANDA, and AADA applicants. Copies are provided as follows:

1) One (1) Archival Copy bound in Blue Jackets
2) One (1) Review Copy bound in Red Jackets

A true copy of this amendment, which was bound in Burgundy Jackets, has been submitted to the U.S. Food and Drug Administration of Irvine, California, District Office.

Since **Section XVI** has been provided in its entirety, three (3) complete methods validation packages (i.e., packages which include information referenced in ANDA 74-816) have been included and are marked "Analytical Methods." These three additional copies are identical to **Section XVI** as presented in the archival and review copies, and have been separately bound in Black Jackets.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting myself at (714) 457-2808.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

GensiaSicor™
PHARMACEUTICALS

NEW CORRESP
NC

February 11, 1998

VIA FACSIMILE AND FEDERAL EXPRESS MAIL

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite. Reference is also made to a telephone conversation on February 2, 1998 between myself and Ms. Margo Bartel, Office of Generic Drugs, FDA, regarding the Patent/Exclusivity Statement provided in our application.

Ms. Bartel requested that Gensia Sicor amend its application for Propofol Injectable Emulsion (0.025% Sodium Metabisulfite) to include a certification statement for the new patent which was recently granted the innovator, Zeneca Ltd., for their formulation of propofol containing EDTA. Pursuant to Ms. Bartel's request, the Patent/Exclusivity Statement (Section III) has been revised and is included in this amend

RECEIVED
FEB 12 1998
GENERIC DRUGS

GensiaSicor Pharmaceuticals • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (714) 457-2808 or by facsimile at (714) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PRO7510\AMENDS\AMENDS\AMENDS.WPD
Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

Mr. Peter Rickman
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-615
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

GENSIA
LABORATORIES LTD

December 3, 1997

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: Propofol Injectable Emulsion
(with 0.005% EDTA), 10 mg/mL
Prefilled Syringe
ANDA: 75-102

MINOR AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion (Prefilled Syringe) containing 0.005% Disodium Edetate (EDTA) in the formulation, ANDA 75-102. Reference is also made to the Agency's letter dated October 22, 1997. In accordance with the provisions of Section 314.96 of the Code of Federal Regulations, Title 21, we hereby amend our application to provide the additional information as requested.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting Ms. Rosalie A. Lowe, Associate Director, Regulatory Affairs, at (714) 457-2808, or myself at (714) 455-4709, or by facsimile at (714) 583-7351.

Sincerely,

Donald J. Harrigan

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

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GENERIC DRUGS
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Gensia Laboratories, Ltd. ■ 19 Hughes, Irvine, CA 92618 ■ (714) 455-4700 ■ FAX (714) 855-8210
Gensia Inc. ■ 9360 Towne Center Drive, San Diego, CA 92121 ■ (619) 546-8300 ■ FAX (619) 453-0095

GENSIA
LABORATORIES, LTD.

NEW CORRESP

NC

May 20, 1997

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: Propofol Injectable Emulsion
(with 10 mg/mL
Prefilled Syringe
ANDA: 75-102

AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion (Prefilled Syringe) containing e formulation, ANDA 75-102. Reference is also made to the Agency's letter dated May 8, 1997 regarding the Patent/Exclusivity Statement (Section III, Volume 1) provided in this application. In accordance with the provisions of Section 314.96 of the Code of Federal Regulations, Title 21, we hereby amend our application to provide the additional information as requested.

The Patent/Exclusivity Statement (Section III) was revised to include the new exclusivity date of June 11, 1999 for Zeneca's new product. Page 13 from the *Approved Drug Products with Therapeutic Equivalence Evaluations, 17th Edition*, Supplement 1, January 1997, which lists the new exclusivity date is also included.

Section III of the ANDA which was revised is being provided in its entirety. To facilitate your review, text changes have been redlined. All other pages within the section remain identical to the original ANDA submission.

RECEIVED
MAY 21 1997
GENERIC DRUGS

Gensia Laboratories, Ltd. ■ 19 Hughes, Irvine, CA 92718-1902 ■ (714) 455-4700 ■ FAX (714) 855-8210
Gensia Inc. ■ 9360 Towne Center Drive, San Diego, CA 92121 ■ (619) 546-8300 ■ FAX (619) 453-0393
Gensia Europe, Ltd. ■ Genaresa House ■ 1 Bracknell Beeches, Old Bracknell Lane, Bracknell, Berkshire RG127BW
44-344-308803 ■ FAX 44-344-360515

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting Ms. Rosalie A. Lowe, Associate Director, Regulatory Affairs, at (714) 457-2808, or myself at (714) 455-4709, or by facsimile at (714) 583-7351.

Sincerely,

Donald J. Harrigan

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

S:\PRO75102\AMENDS\AMEND1.WPD
Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

ANDA 75-102

Gensia Laboratories, Ltd.
Attention: Donald J. Harrigan
19 Hughes
Irvine, CA 92618

MAY 5

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Propofol Injectable Emulsion 1%, (10 mg/mL), in 20 mL syringe

DATE OF APPLICATION: March 31, 1997

DATE OF RECEIPT: April 1, 1997

We will correspond with you further after we have had the opportunity to review the application.

Please amend your application with a revised patent certification and exclusivity statement using the most current version of the Approved Drug Products with Therapeutic Equivalence Evaluations and supplement.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Kassandra Sherrod
Project Manager
(301) 827-5849

Sincerely yours,

/S/ 5/6/97

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

GENSIA
LABORATORIES, LTD.

March 31, 1997

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1997
GENERIC DRUGS

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: Propofol Injectable Emulsion (with 0.005% EDTA), 10 mg/mL Prefilled Syringe
ANDA: Number to be Assigned

Dear Mr. Sporn:

Reference is made to a telephone conversation on December 19, 1996 between Ms. Cecilia Parise, Consumer Safety Officer, Office of Generic Drugs and myself regarding the safety issues related to the formulation of Propofol Injectable Emulsion. Ms. Parise indicated that the Agency would only accept ANDA applications for Propofol Injectable Emulsion which contain n the formulation. Therefore, pursuant to Ms. Parise's instructions and in accordance with Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, we hereby submit an Abbreviated New Drug Application for Propofol Injectable Emulsion (Prefilled Syringe) containing in the formulation.

Propofol Injectable Emulsion (with , is a parenteral emulsion preparation to be supplied as:

Strength	Drug Content	How Supplied
10 mg/mL	200 mg Propofol Injectable Emulsion/syringe	200 mg in a 20 mL syringe

Propofol Injectable Emulsion, 10 mg/mL ., is the generic version of Diprivan® (Propofol Injectable Emulsion) which is currently manufactured by Zeneca, Ltd. Zeneca's drug product appears in the FDA listing titled *Approved Drug Products with Therapeutic Equivalence Evaluation, 16th Edition.* Our drug product has the same

Gensia Laboratories, Ltd. ■ 19 Hughes, Irvine, CA 92718-1902 ■ (714) 455-4700 ■ FAX (714) 855-8210
Gensia Inc. ■ 9360 Towne Center Drive, San Diego, CA 92121 ■ (619) 546-8300 ■ FAX (619) 453-0095
Gensia Europe, Ltd. ■ Genaresa House ■ 1 Bracknell Beeches, Old Bracknell Lane, Bracknell, Berkshire RG127BW
44-344-308803 ■ FAX 44-344-360515

100003

active and inactive ingredients, dosage form, strength, route of administration, and conditions of use as Zeneca's listed drug product containing

Gensia's manufacturing processes used for Propofol Injectable Emulsion supplied in a prefilled syringe are equivalent to the processes used for Gensia's product supplied in vials for the processes described in the sections listed below. Therefore, reference is made to our amendment ANDA 74-816, which was submitted December 24, 1996 with respect to these sections.

Section VI	Bioavailability/Bioequivalence
Section VII	Components and Composition Statements *
Section VIII	Raw Material Controls
Section IX	Description of Manufacturing Facility
Section X	Outside Firms Including Contract Testing Laboratories
Section XIII	Packaging and Labeling Procedures
Section XVI	Analytical Methods **
Section XVIII	Control Numbers
Section XIX	Sample Availability and Identification
Section XX	Environmental Impact Statement
Section XXI	Other

* Except as this section relates to the container
** Except for the specific lots of finished product

The table below identifies the variation from the vial amendment of ANDA 74-816 which were changed or included to differentiate the prefilled syringe product. These differences include changes to the basis for ANDA, patent certification, labeling, chemistry, manufacturing, control changes, container/closure, and stability. Documentation supporting this information are provided in the sections listed:

Section	Variations from ANDA 74-816 Amendment	Supporting Documentation
II	A summary of the supporting stability lot.	Tables summarizing the information. Reference to **Section XI** for the stability lot.
III	Patent certification and exclusivity statements submitted to reflect current status of the innovator's product.	Orange Book reference.

Section	Variations from ANDA 74-816 Amendment	Supporting Documentation
IV	Comparison between Gensia's versus Zeneca's products for propofol ormulations supplied in a prefilled syringe.	Table summarizing the comparison between Gensia's and the innovator's formulations supplied in a prefilled syringe.
	Comparison between Gensia's versus Zeneca's labeling for both propofo ilations supplied in a prefilled syringe.	Side-by-side comparison of Gensia's versus Zeneca's labeling for both propofol EDTA formulations supplied in a prefilled syringe.
V	Labeling for Gensia's Propofol Injectable Emulsion	Draft labeling.
VII	Components and composition statements to reflect the 20 mL prefilled syringe container.	Components and composition statements, and tables for Propofol Injectable Emulsion (with
XI 1.	Summary for manufacturing and processing which reflect the filling of Propofol Injectable Emulsion (with in a prefilled syringe.	The compounding procedure and manufacturing flow diagram for Propofol Injectable Emulsion
	Sterility assurance of the product references volume 4.	Specific sterility assurance information for the manufacture of Propofol Injectable Emulsion plied in prefilled syringe.
2.	Blank batch records which specific for the prefilled syringe product.	Blank batch records for the 20 mL prefilled syringe.
XII	One stability lot to support the prefilled syringe product.	Copies of the executed batch records for the stability lot of Propofol Injectable Emulsion): Lot No. XP6C319F2.
	Finished Product Sampling Plans specific to the prefilled syringe product.	**Finished Product Sampling Plan** for Propofol Injectable Emulsion (with

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Section	Variations from ANDA 74-816 Amendment	Supporting Documentation
XV	**Finished Product Specifications and Data Sheet** specific to the prefilled syringe product.	Blank current **Finished Product Specifications and Data Sheet.**
	Stability lot of the prefilled syringe product.	**Finished Product Specifications and Data Sheet** for the stability lot.
XVI	**Finished Product Specifications and Data Sheet** specific to the prefilled syringe product.	Blank current **Finished Product Specifications and Data Sheet.**
	Stability lot of the prefilled syringe product.	**Finished Product Specifications and Data Sheet** for the stability lot.
XVII	One stability lot of the 20 mL prefilled syringe was manufactured and stability data is presented. In addition, the 20 mL vial lot (Lot No. XP6N319), which is the subject of ANDA 74-816, is presented in support of the stability section of this application.	Stability Report

Four copies of the proposed labeling have also been provided in **Section V** of the application in both the archival and review copies.

The application consists of four (4) volumes and has been formatted in accordance with the Office of Generic Drug's Policy and Procedure Guide #30-91 issued April 10, 1991; and, as modified by FDA's October 14, 1994 letter to all NDA, ANDA, and AADA applicants. Copies are provided as follows:

1) One (1) Archival Copy bound in Blue Jackets
2) One (1) Review Copy bound in Red Jackets

A true copy of this application, which was bound in Burgundy Jackets, has been submitted to the U.S. Food and Drug Administration of Irvine, California, Los Angeles District Office.

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Since the product which is the subject of this application is non-compendial, three (3) additional methods validation packages have been included and are marked "Analytical Methods." These three additional copies are identical to **Section XVI** as presented in the archival and review copies, and have been separately bound in Black Jackets.

We trust you will find the information in this application satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting Ms. Rosalie A. Lowe, Associate Director, Regulatory Affairs, at (714) 457-2808, or myself at (714) 455-4709, or by facsimile at (714) 583-7351.

Sincerely,

Donald J. Harrigan

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

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Field Copy Certification

Gensia Laboratories, Ltd., certifies that a true copy of our application for Propofol Injectable Emulsion), 10 mg/mL, Prefilled Syringe, which was submitted to the Agency on March 31, 1997, was also provided to the Irvine, California, Los Angeles District Office of the U.S. Food and Drug Administration.

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

3/31/97
Date

Debarment Certification

As required by the Generic Drug Enforcement Act of 1992, Gensia Laboratories, Ltd., certifies that we did not and will not use in any capacity the services of any person debarred under subsections (a) or (b) [section 306 (a) or (b)] of the Act, in connection with our application for Propofol Injectable Emulsion (with 0.005% EDTA), 10 mg/mL, Prefilled Syringe.

We are unaware of any convictions of crimes (as specified in section 306 (a) and (b) of the Act) within the previous five years of any Gensia employees or affiliated company, or employees of the affiliated companies responsible for the development or submission of this abbreviated application for Propofol Injectable Emulsion (with 0.005% EDTA), 10 mg/mL, Prefilled Syringe.

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

3/31/97
Date

Exhibit N

Tolling Agreement (Redacted)

Corey M. Eschweiler, Esq.
Nevada Bar No.: 6635
Adam D. Smith, Esq.
Nevada Bar No.: 9690
GLEN J. LERNER & ASSOCIATES
4795 South Durango Drive
Las Vegas, Nevada 89147
Tel.: (702) 877-1500
ceschweiler@glenlerner.com

Attorneys for Plaintiffs

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CLERK OF THE COURT

DISTRICT COURT
CLARK COUNTY, NEVADA
*****

In the Matter of Endoscopy Center and Associated Businesses and Coordinated Cases

CASE NO.: A558091

DEPT. NO.: XIX

STIPULATION REGARDING TOLLING OF THE STATUTE OF LIMITATIONS ON GLEN J. LERNER & ASSOCIATES NON-INFECTED CASES AND SPECIAL MASTER RECOMMENDATION

COMB NOW Glen J. Lerner & Associates "non-infected" clients identified below, by and through their counsel of record COREY M. ESCHWEILER, ESQ. and ADAM D. SMITH, ESQ. of the law firm of GLEN J. LERNER & ASSOCIATES, and SICOR, INC., TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., MECKESSON MEDICAL-SURGICAL, INC., and BAXTER HEALTHCARE CORPORATION (the "PRODUCT DEFENDANTS"), by and through

their counsel of record, JAMES R. OLSON, ESQ. and MICHAEL E. STOBERSKI, ESQ., of the law firm of OLSON, CANNON, GORMLEY & DESRUISSEAUX that the PRODUCTS DEFENDANTS, and hereby stipulate and agree as follows:

IT IS HEREBY STIPULATED AND AGREED that the "non-infected" clients of Glen J. Lerner & Associates, identified below, shall be granted an indefinite tolling of the applicable statute of limitations for each of their potential claims against each signator Defendant below.

IT IS FURTHER STIPULATED AND AGREED that said tolling may be terminated upon a minimum of 60 days advance notice from any party to this agreement.

Dated: February 26, 2010 GLEN J. LERNER & ASSOCIATES Corey M. Eschweiler, Esq. Nevada Bar No.: 6635 Adam D. Smith, Esq. Nevada Bar No.: 9690 GLEN J. LERNER & ASSOCIATES 4795 South Durango Drive Las Vegas, Nevada 89147 Tel.: (702) 877-1500 ceschweiler@glenlerner.com	Dated: February 26, 2010 OLSON, CANNON, GORMLEY & DESRUISSEAUX MICHAEL E. STOBERSKI, ESQ. NV Bar # 4762 MATT C. WOLF, ESQ. NV Bar # 10801 9950 West Cheyenne Avenue Las Vegas, Nevada 89129 Tel.: (702) 384-4012 Fax.: (702) 383-0701 Attorney for Defendants SICOR, INC., TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., MCKESSON MEDICAL-SURGICAL, INC., and BAXTER HEALTHCARE CORPROATION

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the Stipulation regarding tolling be approved and adopted.

DATED this 27th day of February, 2010.

FLOYD A. HALE, ESQ., SPECIAL MASTER

Submitted by:

GLEN J. LERNER & ASSOCIATES

By: _____
Corey M. Eschweiler, Esq.
Nevada Bar No.: 6635
Adam D. Smith, Esq.
Nevada Bar No.: 9690
GLEN J. LERNER & ASSOCIATES
4795 South Durango Drive
Las Vegas, Nevada 89147
Tel.: (702) 877-1500
ceschweiler@glenlerner.com

EXHIBIT A

1	Abadjian, Sossy		
2	[redacted]		
3			
4			
5			
6			
7	Adarve, Virginia		
8	Adler, Francis		
9	Aguilar, Carmen		
10	Aguilar, Narciso Rene		
11	[redacted]		
12	Alder, Rhea		
13	[redacted]		
14	Allen, George		
15	[redacted]		
16	Allshouse, Socorro		
17	Alpy, Linda		
18	Alvarez, Joyce		
19	Anderson, Rebecca L.		
20	Andrei, Emanuel		
21	Antles, Terrie		
22	Appleton-Hultz, Kellie		
23	[redacted]		
24	Archuleta, Anthony		
25	Arellanos, Esteban		
26	Arias, Rickie		
27	Arkenburg, Mark		
28	[redacted]		
29	Arriola, Roger		
30	Artiga, Maria		
31	Asberry, Robin		
32	[redacted]		
33			
34			
35			
36			
37			
38	Babcock, Winifred		
39	[redacted]		
40	Bach , Robert		
41	Bachand, Susan F.		
42	Baglev-Tenner, Elaine		
43	[redacted]		
44			
45	Bal, Melissa		
46	Baldridge, Bryan		
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49	Barker, Ronald		
50	Barncord, Ronald		
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52	Barnhart, Peggy Jo		

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55	Bartlett, Donald		
56	Bartlett, Sheryle		
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58	Baudoin, Joseph		
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60	Baxter, Barbara		
61	Beamon, Venus		
62	Beatty, Barbara Robin		
63	Behlings, Rodney		
64	Bejaran, Cristina		
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66	Benedetti, Tomas		
67	Benford , Verna		
68	Benkert, Richard		
69	[redacted]		
70	Bergeron , Marshall		
71	Bergeron, Donna		
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75	Bivona, Sylvia		
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78	Blair, Robert		
79	Blakeley, Harry		
80	Blanchard, Dawn		
81	Bloss, Bonnie		
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83	Bolar, Darrell		
84	Bolden, Roy		
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87	Bonilla, Victor		
88	[redacted]		
89	Borrayes, Graciela		
90	Bowen, Billy		
91	Bowers, Shirley		
92	Bradley, Shirley		
93	Brauer, Carla		
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97	Brown, Carolyn		
98	Brown, Jack		
99	Brown, Leslie		
100	Brown, Michael		
101	Brown, Roberta		
102	Bruns, Amelia B.		
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104	Burchard, Carl L.		

105	Burks, Traci		
106	Burton, Elizabeth		
107	Bustamante, Anastasio		
108	Bustamante- Ramirez, Angelite		
109	Butler, Dorothy Ann		
110	Calcaterra, Lee		
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114	Campos, Maria		
115	Canacaris, Boonyuen		
116	[redacted]		
117	Capanda, Melissa		
118	Caperell, Martin		
119	Cardona, Jaime		
120	Cardona, Pedro		
121	Carney, Susie		
122	Carr, Teresa		
123	Carrasco, Bernardino		
124	Carter, Truman		
125	[redacted]		
126	Casto, Xandra		
127	Caudle, Spence		
128	Causey, Margaret		
129	Ceballos, Xavier		
130	Cedeno, Robert		
131	Centeno, Dinora		
132	Chase, Roy		
133	Chea, Caridad		
134	Chevez, Elsa		
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137	Childs, Lucille		
138	Clark, Alicia		
139	Clark, Carol		
140	Clark, Patricia		
141	Coiro, Richard		
142	[redacted]		
143	Collins, Percell Jr.		
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156	Coulombe, Paul A.		

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159	Crocker, Ronald		
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162	Crossley, Rosslyn		
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165	Davis, Evelyn		
166	Davis, Mary Jean		
167	Davis, Virginia A		
168	Dawson, Jessie L		
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170	Delacruz, Emelyn		
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173	Deras, Silvia		
174	Devine, Sherida		
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178	Diaz-Perez, Jose		
179	Dixon, Otis L		
180	Dolpies, Emilio		
181	Dominguez, Pamela		
182	Domkoski, Eugena		
183	Donato, Joseph		
184	Donis, Hugo		
185	Donley, Patricia L		
186	Draganic, Ljubica		
187	Duck, Deloris K		
188	Duhs, Kathleen J		
189	Duncan, Lillian		
190	Dusyk, Harold		
191	Dyer, Allyson R. Jr.		
192	Easley, Lois		
193	Echeverria, Delsy		
194	[redacted]		
195	Elauria, Roland E		
196	Escala, Darlo E		
197	Escala, Engarcia B		
198	Escalera, Kathy A		
199	Escobedo, Maria		
200	[redacted]		
201	Espinosa,Teresa I		
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203	Evans, Leon		
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205	Faulkner, Mary		
206	Feingold, Abraham		
207	Feingold, Muriel		
208	Fennell, Oscar		

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210	Ferguson, Marietta		
211	Ferguson, Willie		
212	Ferrante, Daniel		
213	Fickiin, Carolyn		
214	Filbeck, Joe		
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217	Fineberg, Ethel		
218	Finn, Madeline C		
219	Fitch, Albert L		
220	Flores, Adrian		
221	Flores, Maria		
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223	Foremaster , Rauna		
224	[redacted]		
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226	Foster, Joseph E		
227	Foster, Phyllis G		
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230	Frazier, Cynthia D		
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233	Freeman, Victoria		
234	Friel, Lawrence		
235	Friesen, Bonita M		
236	Frillarte, Ness		
237	Frisby, Nancy C		
238	Gaines, Jodi		
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240	Gallegos, Esperanza		
241	Gallegos, Neohmi		
242	Garcia, Brenda		
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246	Gardner, Sandra		
247	Garvey, Michael		
248	George, Theresa		
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250	Giannopoulos , Tina		
251	Giannopoulos, Aris		
252	Gilbert, Wanda		
253	Golden, Jean		
254	Golob, Luciano		
255	Gonzales, Pastor		
256	Gonzalez-Torres, Jesus		
257	Gottleb, Jeff		
258	[redacted]		
269	Goudy, Allen		
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264	Green, Tania		
265	Gregorich, Roy		
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275	Gutierrez, Julia		
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280	Hachez, Denise F		
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283	Hadjes, Sue		
284	[redacted]		
285	Hall, Frank J		
286	[redacted]		
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288	Hamblin, Chardai C.		
289	Hamilton, Robert Jr.		
290	[redacted]		
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293	Harper, Joann		
294	Harris, Doris		
295	Harrison, Glorice		
296	Harrison, Shara		
297	Hartley, Ronald K		
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299	Harwood, Robert		
300	Hayes, Samuel		
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303	Heredia, Lucia		
304	Hernandez, Candido		
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306	Hernandez, Maria		
307	[redacted]		
308	Herrold, Thomas		
309	Herron, Luz		
310	Hill, Susan M.		
311	Hiner, Isheka		
312	Hoard, Arlene		

313	Hobbs, Beth		
314	[redacted]		
315	Hollis, Michelle		
316	Holmes, Jaqueline A		
317	Horvath, Belvia		
318	Horvath, James		
319	Hostler, Ana		
320	Houle, Augustave		
321	Hovietz, Carl II		
322	Howard, Ruth		
323	Howford, Michele		
324	Huebner, Edward L.		
325	Hughes, Lovette M		
326	Hunter, Virginia M		
327	Hurtado-Miguel, Patricia		
328	Hyyppa, Angela		
329	Infuso, Joseph		
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331	Interdonati, Frank		
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333	Irey, Brian		
334	Jackson, Cecil		
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338	Jaramillo, Rolando		
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341	Jiles, Letha		
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344	Johnson, Doris		
345	Johnson, Johnny		
346	Johnson, Joyce		
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350	Jones, Arnold		
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353	Kabadaian, Ann		
354	Kaleta, Anthony K		
355	Kapoor, Arun		
356	Keelor, Linda J		
357	Kelly, Michael F.		
358	Kidd , Darrell		
359	Kim, Connie		
360	Kim, Soo-ok		
361	Kim, Taesook		
362	Kimbers, Sondra I		
363	Kindler, Elizabeth I		
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365	King, Iris L		
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367	Koenig, Joanna		
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370	Krachenfels, Michael J		
371	Kramer, Corinne M		
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374	Kroitor, David		
375	Kunik, Olga		
376	Kunzig, Karen A		
377	LaFountain, Anelta		
378	Lake, Barbara		
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383	Lauron, Anges G		
384	Lawson, Marie		
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386	LeBlanc, Phyllis		
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390	LeTang, Arlene		
391	Lewis, James A		
392	[redacted]		
393	Liebschutz, Joan		
394	Lim, Minerva L		
395	Lindsey, Edward		
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397	Little, William		
398	Livingston-Steel, Dorothy		
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402	Lopez, Iralda		
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405	Lucas, Florence		
406	Luther, Darlene		
407	Lyles, Frank L.		
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410	Malwand, Marwa		
411	Major, Dorothy J.		
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413	Maldonado, Mario		
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415	Mares, Gabriel		
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417	Marquez, Carol A.		
418	[redacted]		
419	Martinez, Hugo		
420	Martinez, Jorge B.		
421	Martinez, Jose L.		
422	[redacted]		
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424	Mastrian, Lucy		
425	Mays, Leroy		
426	Mays, Lisa		
427	McCall, Virginia A.		
428	McCray, Stella		
429	McDaniel, Laurence		
430	McDavid, John Jr.		
431	McDonnell, Dolores		
432	McGee, Denise Anne		
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435	McMillen, Fred III		
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443	Mendoza, Jiggerson		
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451	Milburn, Sylvia		
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457	Mizhiritsky, Mikhail		
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459	Moore, Mary		
460	Mora, Jose		
461	Morales, Yolanda		
462	Morales-Castro, Elizabeth		
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464	Morehead, Carl		
465	Moreno, Bivetta		
466	Morgan, David		
467	Morgan, Denise M		
468	Morgan, Douglas		

469	Morgan, Sonia		
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474	Morse, Michele		
475	Mortensen, Dan R		
476	Mosqueda, Migdalia		
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480	Muna, Annie		
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484	Nagy, Joseph		
485	Nakoneczny, Bonnie		
486	Natinga, Erlinda		
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489	Newell, Lanita		
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491	Norlin, Rosemarie		
492	Nyden, Marshall		
493	O'Connell, Joseph		
494	O'Mara, John		
495	O'Neal, Norma J.		
496	Obershaw, Wade		
497	Oku, Andrew		
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500	Oliva, Digna		
501	Orcullo, Linda		
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503	Orozco, Paula		
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510	Pankhurst, Denis		
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514	Parkinson, Kathy		
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516	Pazos, Jesus		
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518	Peccorini, Teresa		
519	Pedro, Phyllis		
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521	Pena, Jose O.		
522	Peoples, Patricia		
523	Perdomo, Delmy C.		
524	Perez, Dora		
525	Perez, Louise		
526	Perez, Luis		
527	Perez, Maria		
528	Perez, Mercedes		
529	Perez-Roque, Agustin		
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531	Perret, Andre		
532	Perry, Janet P.		
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535	Peterson, Alan K		
536	Philip, Lowell		
537	Philip, Michelle		
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539	Pinsker, Donald		
540	Pitman, Jason B.		
541	Pittman, Wayne		
542	Polinski, Ron		
543	[redacted]		
544	Pourleymaur, Mohammed		
545	Powers, Donna		
546	Powers, Eva		
547	Powers, Jennifer		
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551	Prieto, Jose		
552	Prieto, Luisa		
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554	Quintero, Francisco		
555	Quiroz, Anthony Ray		
556	Rabadan, Maribel		
557	Ramirez , Adriana		
558	Ramirez, John		
559	Ramirez, Raul		
560	[redacted]		
561	Raposa, Robert		
562	Reves De Medina, Celia		
563	Reyes, Gabriel		
564	Reyes, Miguel		
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569	Roberts, Barbara		
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572	Robinson, Lloyd H.		

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574	Roby, Connie		
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576	Rochester, Antoinette		
577	Rodgers , Vicki		
578	Rodgers, Treva		
579	Rodriguez, Marla		
580	Rodriguez, Nenita		
581	Rodriguez, Ricardo		
582	Rodriguez, Yolanda		
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584	Rodriguez-Ramirez, Jose		
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586	Rogers, Freeman		
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588	Roggensee, Carole		
589	Rojas, Sonia		
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591	Romano, Joseph		
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693	Rose, Jean		
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595	Russell, Rosetta		
596	Saddler, Demetry		
597	Salas, Janisann		
598	Salcedo, Maria		
599	Salguero, Francisco		
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601	Sanders, Kerri		
602	Sanders, Lovie		
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608	Schilling, Ise		
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617	Shearer, Douglas		
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628	Slater, James		
629	Slaughter, Jacklyn		
630	Slaughter, John		
631	Smith, Catherine		
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637	Soto, Maria		
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639	Spalnhour, Julie		
640	Spangler, Jessica		
641	Sparks, Patricia		
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647	Stanley, Ginger		
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649	Stewart, Rodney		
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652	Strohecker, Leticia		
653	Stromgren, Harold		
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657	Sudo, Mafalda		
658	Swain, Barbara		
659	[redacted]		
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661	Tadeo, Norma		
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666	Tarnowiski , Mirka		
667	Tarnowski, Ryszard		
668	Tash, Roxanne E.		
669	[redacted]		
670	Taylor, Jill		
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674	Thibeault, Jeanne		
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682	Titus-Pliate, Catherine		
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685	Topple, Raymond		
686	Toribio, Dominga		
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690	Torres, Yadel		
691	[redacted]		
692	Townsley , Rita M.		
693	Trafton, Roselyn		
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699	Tromello , Salvatore		
700	Tropp , Patricia A.		
701	Tuckosh, Dorothy		
702	Turner, Lucy		
703	Turner, Terry		
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705	Tuzinski , Robert		
706	Unruh, William		
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709	Valls, Jesus		
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711	Valone, Dianne		
712	[redacted]		
713	Vandergaag, Hillegonda		
714	Veley , Henry		
715	[redacted]		
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718	Villegas, Stella		
719	Virgil, Louis		
720	Vital-Cedeno, Cecilia		
721	[redacted]		
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724	Volk, Colleen		
725	Vorglas, Christ		
726	Wadlow, William		
727	Wagner, Betty		
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734	Walters, John		
735	Walton , Jason		
736	[redacted]		
737	Wampole, Janice		
738	Ward, Barbara		
739	[redacted]		
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741	Warls, Sandra		
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743	Weddington, Lester		
744	[redacted]		
745	Welsner, Arlene		
746	[redacted]		
747	Wheeler, Kathryn		
748	[redacted]		
749	White, Frank E.		
750	White, Sharon		
751	[redacted]		
752			
753	Wilkins, Bridget		
754	Williams, Ace K.		
755	Williams, Anthony		
756	Williams, Aubrey		
757	[redacted]		
758	Williams, Charles		
759	Williams, Cheryl		
760	[redacted]		
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762	Williams, Mary		
763	[redacted]		
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765	Williams, Willie		
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769	Wilson, Gary		
770	Wilson, Robert		
771	Wilt, Steven		
772	Winslow, Angela		
773	Winterowd, Beverly		
774	Winters, Betty		
775	[redacted]		
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778	Wolf, James		
779	[redacted]		
780	Worthy, Derek		

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List of Plaintiffs from Abadjian (A-18-781820) Complaint that are NOT included in Tolling Agreement

1. Dorothy Barbee
2. Russell Barnes
3. Madalyn Barrall
4. Sarah Bolden
5. Scot Bolen
6. John Boone
7. Bridget Bowles
8. Cathy Boykins
9. Brenda Bradford
10. Kenneth Brown
11. Mario Bustamante
12. Robert Calderon
13. Sheila Callahan
14. Evelyn Campbell
15. John Campolo
16. Constantinos Canacaris
17. John Carpenter
18. Lester Carr
19. Helayne Celano
20. Vincent Celano
21. Guadalupe Cepeda
22. Mark Chiger
23. Donald Circle
24. Robert Compton
25. Cliff Cook
26. Pamela Crockett
27. William R. Daniels
28. Denise M. Delacruz
29. Gregory Derose
30. Mark DiPietro
31. Tamara Domingo
32. Donnedia D. Edmond
33. Ernest A. Esposito
34. William Evans
35. John J. Eversole
36. Ronald Folkenflik
37. Luis Garay
38. Lois Gass
39. Jeremy Gellens
40. Marion Geoghegan
41. Gregory Glenn
42. Tyra Golden-Lewis
43. Carrillo Gomez
44. TJ Gordy
45. Annetta Graham
46. Bill Grattan
47. Dorothy Green
48. Jeffrey Gresser

List of Plaintiffs from Abadjian (A-18-781820) Complaint that are NOT included in Tolling Agreement

49. Robert Grimblot
50. Cynthia Grimm
51. Robert Grimm
52. Patrick Gronna
53. Carl Guerette
54. Esther I. Hal
55. Deborah Hancock
56. Jessica M. Haro
57. Anna C. Harrington
58. Michael S. Harrington
59. Patricia Harrison-Carter
60. Brianna S. Harshman-Talbert
61. Linda K. Haugen-Rattazzi
62. Esther A. Hayashi
63. Susette A. Hein
64. Nita Henderson-Shepherd
65. Roy M. Hennick
66. Juanita Henson
67. Marcial A. Hernandez
68. Joshua Hooker
69. Willie Hoover
70. Patricia Hoppins
71. Robert E. Howell
72. Ho Nan Hwang
73. Jannette Ibarra
74. Barry Jackson
75. Dora Jackson
76. Eugene Johnson
77. William Johnson
78. Sharon Keeling
79. Rayann J. Keyes
80. Larry D. King
81. Raymond E. Koceja
82. Tracey Koenen
83. Patrick Koh
84. Michael Kopanski
85. Krystal Lampman
86. Darsel Lang
87. Jonathan Larson
88. Betty J. Leeman-Ross
89. Jane Lev
90. Debra Limes
91. Seth Linetsky
92. Demilio D. Lista
93. Martha Lopez
94. Toney E. Lopez
95. Francine R. Lopresto
96. Sterphanie Maclean

List of Plaintiffs from Abadjian (A-18-781820) Complaint that are NOT included in Tolling Agreement

97. Lori Magill
98. Marguerite Maldonado
99. Ida Malwitz
100. Audrey Manuel
101. Robert Marohl
102. Brenda Martigani
103. Lee Martin
104. Leonard Martin
105. Terri L. Martin
106. Grace Marzulli
107. Fatin Matti
108. Terry Mcall
109. Letta McClain
110. Alfred McClinton
111. David McDonald
112. Janet McKnight
113. Kelly Mejia
114. Gerald Mitchell
115. Steven Moody
116. Judith A. Munger
117. Diane Muranyi
118. Dioselina Muscara
119. Jose A. Najarro
120. Thang Nanod
121. Maria Navarro-Ortiz
122. Daniel Nevins
123. Paul Noga
124. Ronalee Novotny
125. Lucio F. O'Farril
126. Shawn O'Halloran
127. Robert Park
128. Marilyn Pearce
129. Craig Picard
130. Jeff Podrouzek
131. Roger Polillo
132. Judy Porter
133. Douglas Price
134. Ivor Price
135. Ely Prussin
136. Mario Ragazzo
137. Edward Ransom
138. Devin Rattazzi
139. Cantice M. Redding
140. Karen Reed
141. Helen Reyes
142. Michael Rice
143. Lester Roberson
144. Gwendolyn Ruckey

List of Plaintiffs from Abadjian (A-18-781820) Complaint that are NOT included in Tolling Agreement

145. Paul Saunders
146. Sherrilyn Saunders
147. Danny Sawyer
148. Shaun Schlappi
149. Stephen Schoeder
150. Jeffrey Schulman
151. Maurice Sforza
152. Julie Shanks
153. Mrytle Sipple
154. Charles Skinner
155. John Slone
156. Michelle Socorro
157. Wayne Sommer
158. Vidana Soussana
159. Sandra Sparks
160. Patricia Spellman
161. Jeffrey Stanford
162. Walter Stoklosa
163. Gilbert Vance
164. Elizabeth Watkins
165. Debra White
166. Serene White
167. Realinda Williams

MDSM
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Nevada Bar No. 6840
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EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

YVETTE ADAMS, *et al.*,

Plaintiffs,

vs.

TEVA PARENTERAL MEDICINES, INC., fka SICOR PHARMACEUTICALS, INC.; SICOR, Inc., a Delaware Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware Corporation; McKESSON MEDICAL-SURGICAL INC., a Delaware Corporation,

Defendants.

Case No.: A-18-778471-C

Dept. No.: 8

HEARING REQUESTED

MOTION TO DISMISS

Defendants Teva Parenteral Medicines, Inc. f/k/a Sicor Pharmaceuticals, Inc. ("TPM"); Sicor, Inc. ("Sicor"); Baxter Healthcare Corporation ("Baxter"); and McKesson Medical-Surgical, Inc. ("McKesson") (collectively "Defendants"), by and through their counsel of record, Greenberg Traurig, LLP and Hymanson & Hymanson, hereby move the Court to dismiss this matter for failure

to state a claim pursuant to Nevada Rule of Civil Procedure 12(b)(5). This motion is made and based upon the attached memorandum of points and authorities, the exhibits attached hereto, the pleadings and papers on file herein, and any argument to be entertained by the Court at the time of hearing.

DATED this 25th day of September 2019.

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MEMORANDUM OF POINTS AND AUTHORITIES

Over three years ago, Dr. Dipak Desai and two nurse anesthetists (who are not parties named in this case and are unaffiliated with Defendants) were convicted of and/or plead guilty to multiple counts of Medicare and Medicaid fraud, criminal patient neglect, insurance fraud, theft and obtaining money under false pretenses arising out of their criminal conduct while employed at the Endoscopy Center of Southern Nevada and other affiliated clinics. Their criminal conduct led to, at the time, the largest outbreak of Hepatitis-C in the country and the notification to over 60,000 patients (including Plaintiffs) that they may have been exposed to blood-borne pathogens as a result of being treated at those clinics.

Defendants here, on the other hand, manufactured and/or distributed FDA-approved prescription medicine, including the generic anesthesia product at issue, propofol, responsibly used by physicians around the country every day. Looking for deep pockets, Plaintiffs – a group of individuals who allege they were treated at the clinic located at 700 Shadow Lane in Las Vegas ("Clinic") but were *not* infected by any blood-borne pathogens – now try to claim that the generic propofol, manufactured and distributed by Defendants, and not the criminal conduct of the convicted felons, is responsible for their "emotional distress, anxiety and fear" that they allegedly endured after they received notification that they may have been (but were *not*) exposed to blood-borne pathogens as a result of being treated at the Clinic. Plaintiffs' claims fail as a matter of law.

It is clear here that Defendants were not the wrongdoers. Moreover, the United States Supreme Court has unequivocally ruled – twice – that every single claim Plaintiffs attempt to bring against Defendants must be dismissed because they are preempted by federal law pursuant to the Court's decisions in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). The propofol sold by Defendants was at all times an FDA-approved generic equivalent of the FDA-approved brand anesthesia drug, Diprivan, and therefore required to have the same labeling as Diprivan. The labeling for both Diprivan and Defendants' propofol contain express warnings against administering propofol in the very way Plaintiffs claim it was administered to them.[1] *Mensing* and *Bartlett* are entirely dispositive of this lawsuit.

[1] "Labeling" includes the container label, package insert, and, if applicable, a Medication Guide. 21 C.F.R. § 314.94(a)(8)(iv).

The United States Supreme Court expressly found in *Mensing* that Federal law **prohibits** generic manufacturers and distributors, like Defendants, from engaging in the exact conduct Plaintiffs allege they should have undertaken – that is unilaterally changing or enhancing any of the warnings in their labels. Federal law also **prohibits** Defendants, as generic manufacturers and distributors, from unilaterally sending the "Dear Doctor" letters Plaintiffs claim they should have sent to warn physicians of potential misuses of the drug in the absence of one being sent by the brand manufacturer.

Two years later, in *Bartlett*, the Court re-affirmed its decision that generic drug manufacturers are not permitted to unilaterally change or enhance the warnings on their products, and further found that any claim made by plaintiffs that a generic drug manufacturer can simply "stop selling" its product is also precluded. Accordingly, Plaintiffs' implicit theory that Defendants could avoid liability by simply not selling the FDA-approved 50 mL vials of propofol to the Clinic is, therefore, also barred by the United States Supreme Court. *Bartlett*, 570 U.S. at 475 ("The Court of Appeals' solution — that Mutual should simply have pulled Sulindac from the market in order to comply with both state and federal law — is no solution. Rather, adopting the Court of Appeals' stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court's pre-emption case law.").

While pled as violations of various Nevada state laws, the Complaint at its core challenges Defendants' alleged failure to do exactly what the United States Supreme Court has explicitly found they cannot do, which is to provide enhanced warnings different from those contained in the FDA-approved labeling for Diprivan, send Dear Doctor letters, or otherwise make use of FDA processes that are not available to them as generic manufacturers. Plaintiffs' Complaint also takes issue with Defendants' mere manufacturing and distribution of FDA-approved generic propofol in 50 mL vials for sale to the Clinic. But, again, the United States Supreme Court has found that Plaintiffs are unable to advance such a theory. Plaintiffs' Complaint must therefore be dismissed in its entirety because the United States Supreme Court has squarely rejected every single one of Plaintiffs' theories of liability based on these allegations.

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While Plaintiffs may claim that the dismissal of their claims because they are preempted may seem unfair or unjust, this result was explicitly acknowledged by the United States Supreme Court in the *Mensing* decision. In recognizing this perceived unfairness, the *Mensing* court noted that "we recognize that from the perspective of [plaintiffs], finding pre-emption here but not in *Wyeth* [a case involving a brand-name manufacturer] makes little sense" and that "[h]ad [plaintiff] taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted." *Mensing*, 564 U.S. at 625. After acknowledging "the unfortunate hand that federal drug regulation has dealt [plaintiffs] and others similarly situated[,]" the Court nonetheless reiterated that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre" and that "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire." Notwithstanding any perceived inequities, the Supreme Court was nonetheless required to dismiss plaintiffs' claims against a generic manufacturer as preempted. *Id*. at 625-26. As noted by *Mensing*, it is for Congress and the federal regulatory agencies, and not the courts, to make such policy decisions, emotions notwithstanding.

Even if these claims were not federally preempted—which they clearly are—Plaintiffs have nevertheless failed to state a claim for relief under any of their causes of action, as each is missing the essential element of causation or is otherwise invalid as a matter of law for numerous reasons.

For the foregoing reasons, Defendants respectfully request that the Court dismiss Plaintiffs claims in their entirety, with prejudice.

I. BACKGROUND

This lawsuit arises as a result of the criminal actions of non-party medical professionals with no meaningful connection to the named Defendants who, according to the Complaint, exposed Plaintiffs to the risk of bloodborne pathogens by unsafely administering generic propofol. Plaintiffs are a collection of *uninfected* prior patients of the Endoscopy Center of Southern Nevada (the "Clinic"). Compl. at ¶ 7. Each Plaintiff alleges that he or she received an injection of a generic form of propofol at the Clinic between March 2004 and January 2008. *Id*. at ¶ 8-10. While Plaintiffs allege that the generic product was designed, labeled, manufactured and distributed by Defendants (*id*. ¶ 8), they do not – and cannot - allege that there existed any defect in the actual product (anesthesia

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medicine) itself. Instead, they try to attack the packaging and labeling, specifically the adequacy of the warnings, dosage, and strength, and the Defendants' alleged failure to make use of warning processes that were not available to them per the United States Supreme Court's decisions in *Mensing* and *Bartlett*. *Id.*

In early 2008, it was revealed in the local news that certain individual healthcare professionals at the Clinic were purposefully and improperly re-using injection syringes and anesthesia bottles, in direct contravention of every established standard of safe care and in violation of the law. In particular, the owner of the Clinic, Dipak Desai, M.D. ("Desai"), and two of Desai's nurse-anesthetists, Ronald Lakeman ("Lakeman") and Keith Mathahs ("Mathahs"), hatched a deplorable scheme that began with insurance fraud and ended with murder.

Desai and his chief operating officer of the Endoscopy Center of Southern Nevada, Tonya Rushing ("Rushing"), were initially indicted in federal court in April 2011 and charged with one count of conspiracy to defraud Medicare, Medicaid, and private insurers, as well as twenty-five counts of health care fraud. **Exhibit A** ("Federal Indictment").[2] The Federal Indictment alleged an elaborate scheme by Desai and Rushing wherein Desai hired multiple certified registered nurse anesthetists ("CRNAs") to perform anesthesia services and specifically to intravenously administer propofol in connection with endoscopy and colonoscopy procedures at the Clinic. *See id*. Desai and Rushing instructed their CRNAs to falsely and fraudulently overbill for time spent administering anesthesia (*id*. at ¶ 19-20) and pressured their CRNAs to perform colonoscopies and endoscopies in an unreasonably short amount of time in order to perform (and bill to Medicare, Medicaid, and private insurers) as many procedures as possible throughout the day (*id*. at ¶ 20). Of course, in order to maximize profits, the CRNAs were explicitly instructed to ignore safety protocols and the express

[2] Defendants respectfully request that the Court take judicial notice of the referenced and attached state and federal court proceedings per NRS 47.150(2) ("A judge or court shall take judicial notice if requested by a party and supplied with the necessary information."). In particular, the Court "may appropriately take judicial notice of the public record of the state district court proceedings" and federal and state criminal prosecutions against Desai, Lakeman, and Mathahs. *Ainsworth v. Combined Ins. Co*., 105 Nev. 237, 267, 774 P.2d 1003, 1024, fn. 20 (1989) (citations omitted); *Ferm v. Office of the Ag of Nev*., 2017 Nev. Dist. LEXIS 1198, *4 (8th Jud. Dist. Feb. 27, 2017 ("Courts in this state may also take judicial notice of filings in federal court because they are public records and from a reliable source.") (citing, *Mack v. Estate of Mack*, 125 Nev. 80, 91, 206 P.3d 98, 106 (2009)); *see also*, *United States v. Howard*, 381 F.3d 873, 876, n.1 (9th Cir. 2004) (A court may take judicial notice of court records in another case).

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warnings on the propofol labels that the vials were for single patient use only, and to instead inject as many patients as possible, as quickly as possible, while using the least amount of propofol possible. This, of course, involved administering propofol from one vial to multiple patients in clear violation of the single patient use warnings on the vial, which were mandated, and approved, by the FDA.

Desai was accused in the Federal Indictment of directing Rushing to create a separate company to handle the billing for anesthesia services rendered by the CNRAs. *Id*. at ¶ 24. The Federal Indictment included a forfeiture count for $8.1 million. *Id*. at p. 11. Desai ultimately plead guilty to a count of conspiracy and a count of health care fraud and, in July 2015, was sentenced to sixty (60) months incarceration for conspiracy and seventy-one (71) months for fraud to run concurrent to the sentence ultimately imposed by the state court. **Exhibit B** (Federal Judgment of Conviction). Desai was also ordered to forfeit more than $2.2 million. **Exhibit C** (Federal Final Forfeiture Order).

Meanwhile, the State of Nevada had opened its own criminal investigation into Desai and others at the Clinic, at the conclusion of which it charged Desai, Lakeman, and Mathahs. **Exhibit D** (Docket in *State of Nevada v. Dipak Desai*, case no. C-12-283381-1). In exchange for his testimony against Desai and Lakeman, Mathahs was allowed to plead guilty to two counts of criminal neglect of patients, with one count resulting in death; one count of insurance fraud; one count of obtaining money under false pretenses; and one count of conspiracy to commit racketeering. **Exhibit E** (Mathahs Plea Agreement). Mathahs was sentenced to six year's incarceration with a minimum parole eligibility of 28 months. **Exhibit F** (Mathahs State Judgment of Conviction).

The fifth and final amended indictment filed in state court charged Desai and Lakeman with 28 total counts, including second degree murder (one count); criminal neglect of patients resulting in substantial bodily harm (seven counts); performing an act in reckless disregard of persons or property resulting in substantial bodily harm (seven counts); insurance fraud (ten counts); theft (one count); and obtaining money under false pretenses (two counts). **Exhibit G** (State's Fifth Superseding Indictment).

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Desai proceeded to trial and was convicted on 27 counts - including second degree murder - as a result of purposefully multi-dosing propofol contrary to the clear warnings on the product's labeling and infecting his patients with hepatitis C.[3] **Exhibit H** (Desai Jury Verdict). Lakeman was convicted of 16 counts, including multiple counts of criminal neglect of patients and performance of acts in reckless disregard of persons resulting in substantial bodily harm. **Exhibit I** (Lakeman Jury Verdict). Lakeman was sentenced to 21 years incarceration with a minimum parole eligibility of 8 years. **Exhibit J** (Lakeman Judgment of Conviction). Desai was sentenced to life in prison with the possibility of parole in 10 years. **Exhibit K** (Desai Amended State Judgment of Conviction).[4]

The Plaintiffs' alleged injuries were therefore the unfortunate result of the greed, dishonesty, recklessness and criminal activity of other individuals, not the result of any alleged defect in Defendant's generic propofol, its labeling, warnings, dosage, or strength, all of which were approved by the federal government pursuant to an exacting statutory and regulation scheme. Now that Desai is deceased and his estate is presumably assetless given the hefty legal fees and the forfeiture Desai was ordered to pay, Plaintiffs seek to attribute his and others' independent acts of purposeful, criminal conduct to Defendants.

It is anticipated that Plaintiffs will brush the criminal actions by Desai and his colleagues aside and instead attempt to rely on prior verdicts obtained against Defendants in Clark County in 2010 and 2011 regarding the propofol/Hepatitis-C scare as proof that Defendants herein are already pre-confirmed bad actors. Such a strategy would be improper because each of those verdicts was vacated and the cases were all dismissed, thus they are legal nullities. And, at the time those trials went forward, Desai and his partners had not yet been convicted of their criminal conduct, thus we did not have the benefit of factual findings from a Nevada state and federal court, reached subject to the highest legal burden in the world, that the outbreak was the result of criminal bad actors, with no meaningful connection to Defendants. Lastly, and perhaps most importantly, one of those verdicts was reached *prior* to *Mensing*, and the other two were reached in the weeks or months *immediately*

[3] Count four, one of the insurance fraud counts, was omitted. **Exhibits H** and **C**.

[4] Desai appealed and, before his case was heard, died in prison. The Nevada Supreme Court ultimately reversed the second-degree murder conviction but affirmed the convictions on all other counts. **Exhibit L** (Nevada Supreme Court Decision in *Desai v. State of Nevada*, issued July 27, 2017).

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following *Mensing*, before courts around the country had a fair opportunity to evaluate the decision and correctly apply it, as dozens, if not hundreds, of courts have now done, and all three were reached before *Bartlett* came out.

It is against this factual backdrop that the Court should evaluate Plaintiffs' claims, which themselves are misplaced and should be dismissed as a matter of law. The Complaint alleges state law claims for: (1) strict product liability; (2) breach of the implied warranty of fitness for a particular purpose; (3) negligence; (4) violation of the Nevada Deceptive Trade Practices Act; and (5) punitive damages. *See generally*, Complaint. Defendants now move the Court to dismiss this action for failure to state a claim pursuant to Nevada Rule of Civil Procedure 12(b)(5).

II. ARGUMENT

The Complaint must be dismissed because it fails to state a claim upon which relief can be granted. Nev. R. Civ. P. 12(b)(5). A complaint must be dismissed when "it appears beyond a doubt that [the plaintiff] could prove no set of facts, which, if true, would entitle [the plaintiff] to relief." *Buzz Stew, LLC v. City of N. Las Vegas*, 124 Nev. 224, 228, 181 P.3d 670, 672 (2008). To survive dismissal, a complaint must "set forth sufficient facts to demonstrate the necessary elements of a claim for relief so that the defending party has adequate notice of the nature of the claim and relief sought." *W. States Constr., Inc. v. Michoff*, 108 Nev. 931, 936, 840 P.2d 1220, 1223 (1992). While a court must accept factual allegations as true, the allegations must be legally sufficient to constitute the elements of the claim asserted. *Sanchez v. Wal-Mart Stores, Inc.*, 125 Nev. 818, 823, 221 P.3d 1276, 1280 (2009). "While plaintiffs are entitled to all reasonable factual inferences that logically flow from the particularized facts alleged, conclusory allegations are not considered as expressly pleaded facts or factual inferences." *In re Amerco Derivative Litig.*, 127 Nev. Adv. Op. 17, 252 P.3d 681, 706 (2011) (Pickering, J, dissenting and concurring) (internal quotation and citation omitted).

A. Plaintiffs' Claims are Preempted by Federal Law

While plead as five separate causes of action, in reality, Plaintiffs' claims are based upon alleged duties to enhance the warnings on the labeling for propofol and to provide additional warnings above and beyond what is already contained in the label regarding potential misuses of the drug. *See, e.g.,* Compl. at ¶ 50 (alleging Defendants should have known that "packaging, marketing, and

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distributing" the propofol to the Clinic in 50 mL vials would encourage multi-dosing); *see also, Moretti v. PLIVA, Inc.*, 2012 U.S. Dist. LEXIS 24113, *13, 2012 WL 62502 (D. Nev. Feb. 27, 2012) ("Despite being pled as numerous different causes of action, at their core, all plaintiff's claims arise from plaintiff's allegations that the content of [generic drug manufacturer's] labeling either was false, misleading, or inadequate.").[5] The caption on a given claim is irrelevant; what counts is its substance, and by design, claims involving pharmaceutical products necessarily challenge the adequacy of the product's labeling. After all, "sellers of '[u]navoidably unsafe products,' such as prescription drugs, can avoid liability by including adequate warnings with the products in lieu of redesigning them to make them safer," *Klasch v. Walgreen Co.*, 127 Nev. Adv. Op. 74, 264 P.3d 1155, 1158 n.7 (Nev. 2011) (quoting, Restatement (Second) of Torts § 402A (1965)), so every pharmaceutical products case ultimately boils down to whether the product's labeling is adequate.

In a roundabout way, and perhaps by design, the Complaint accuses Defendants of failing to properly warn health care professionals, either through amendment or as a supplement to the propofol label, of the alleged risks associated with the administration of propofol. However, the United States Supreme Court has found that federal law **expressly prohibits** Defendants from taking any steps Plaintiffs claim they should have made to amend the warnings in their propofol label or to

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[5] Since the United States Supreme Court decided *Mensing*, dozens—if not hundreds—of courts have similarly dismissed hundreds of different state law claims against *generic* drug manufacturers and distributors, including (among others) claims for strict liability, negligence, breach of implied warranty, and fraud—the very claims Plaintiffs bring here. *See, e.g., Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1231 (9th Cir. 2011), *cert. granted, judgment vacated and remanded sub nom. L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011) (summarily vacating Ninth Circuit's holding that state-law negligence and breach of warranty claims were not preempted because generic manufacturers can unilaterally change their product warnings or ask FDA to send a "Dear Doctor" letter on their behalf and remanding in light of *Mensing*); *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011) (ordering entry of judgment in generic defendants' favor on all plaintiffs' state-law tort claims); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (same); *Demahy v. Actavis, Inc.*, 650 F.3d 1045, 1046 (5th Cir. 2011) (same); *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337 (N.D. Ga. 2012) (dismissing failure-to-warn, strict products liability, negligence and gross negligence claims as preempted under *Mensing*); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, (D. Md. 2011) (dismissing all state-law claims—including negligence, failure to warn, breach of warranty, and design defect—because "*Mensing* disposes of all … claims"); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL 2243, 2011 WL 5903623, at *3-9 (D.N.J. Nov. 21, 2011) (dismissing defective design, failure to warn, negligence, breach of implied warranty, and fraud-based claims); *In re Accutane Prods. Liab. Litig.*, 2011 WL 6224546 (M.D. Fla. Nov. 9, 2011) (dismissing all of plaintiffs' state-law claims under *Mensing*); *Waguespack v. Plivia USA, Inc.*, 2011 WL 5826015, at *1-3 (E.D. La. Nov. 3, 2011); *Metz v. Wyeth, LLC, et al.*, 2011 WL 5024448, at *2-5 (M.D. Fla. Oct. 20, 2011) (dismissing state law claims against generic manufacturer for negligence, strict liability, breach of warranties, and fraud pursuant to *Mensing*); *Morris v. Wyeth, Inc.*, 2011 WL 4973839, at *2-3 (W.D. La. Oct. 19, 2011) (dismissing state law claims as grounded in failure to warn theory preempted by *Mensing*).

communicate the existence of any potential risks to health care professionals *beyond* what is stated in the FDA-approved labeling for the brand version, Diprivan. *Mensing*, 564 U.S. at 612-615. Federal law does not allow Defendants, as manufacturers and distributors of a generic drug, to utilize the FDA's changes-being-effected process ("CBE") to request changes to the label, a process reserved only for the brand-name manufacturer, as is made clear by the Supreme Court in *Mensing*. *Id*. at 614-15 ("We therefore conclude that the CBE process was not open to the [generic] Manufacturers for the sort of change required by state law."). Indeed, federal law makes it impossible for Defendants to comply with both those federal laws *and* the purported state law standards that Plaintiffs advocate. Likewise, to the extent Plaintiffs complain of the dosage form or strength of Defendants' propofol, those too are subject to regulation by the FDA, and state law may not interfere with federal mandates.

In such circumstances, the Supremacy Clause of the United States Constitution forbids states from imposing liability on Defendants and preempts the state law claims at issue. The United States Supreme Court confirmed that generic manufacturers cannot deviate from the federally-imposed requirements that a generic drug be identical to its corresponding brand drug in all respects, subject to certain limited exceptions not implicated here, and further made clear that generic manufacturers cannot utilize the FDA's CBE process in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and rejected Plaintiffs' implied "stop-selling" theory in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). Defendants are accordingly entitled to an affirmative defense of preemption as a matter of law, and Plaintiffs' claims must be dismissed in their entirety. *See, e.g., Moretti*, 2012 U.S. Dist. LEXIS 24113 at *12 (stating, "*Mensing* is the controlling preemption decision applicable to personal injury cases . . . against generic drug manufacturers" alleging violation of state-law tort claims based upon duties to warn).

1. Background on Federal Regulation of Generic Drugs.

As summarized by the Supreme Court in the *Mensing* case, "[u]nder the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 21 U.S.C. § 301 *et seq.*, a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." *Mensing*, 564 U.S. at 612 (*citing* 21 U.S.C. §§ 355(b)(1), (d); *Wyeth v. Levine*, 555 U.S. 555, 567, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009)).

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"Meeting those requirements involves costly and lengthy clinical testing." *Mensing*, 564 U.S. at 612 (*citing*, §§ 355(b)(1)(A), (d); D. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements § 2.02[A] (7th ed. 2008)).

Originally, the same rules applied to all drugs. *Mensing*, 564 U.S. at 612. In 1984, however, Congress passed the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments. *Id.* Under this law, generic drugs can gain FDA approval by submitting what is known as an Abbreviated New Drug Application ("ANDA"), showing that the generic drug is equivalent to a reference listed drug that has already been approved and deemed safe and effective by the FDA, *i.e.*, an approved brand-name drug. *Id*. (*citing*, 21 U.S.C. § 355(j)(2)(A)). By creating a streamlined approval process for generic drugs, Congress intended to encourage innovation in pharmaceutical research and to help generic manufacturers more quickly introduce lower-cost but equivalent drugs to the market. *See*, H.R. Rep. No. 98-857(I), at 14-15 (1984); *Mensing*, 564 U.S. at 612 ("This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug."). The law requires that a generic drug application, such as the one submitted by these Defendants, "show that the [safety and efficacy] labeling proposed . . . is the **same as** the labeling approved for the [brand-name] drug." *Id*. (*quoting* § 355(j)(2)(A)(v); *see also*, § 355(j)(4)(G)) (emphasis added).

As a result of the Hatch-Waxman Amendments, brand-name and generic drug manufacturers have different federal drug labeling duties. *Mensing*, 564 U.S. at 613. "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label." *Id*. (*citing*, 21 U.S.C. §§ 355(b)(1), (d); *Wyeth*, *supra*, at 570-571, 129 S. Ct. 1187, 173 L. Ed. 2d 51). On the other hand, a manufacturer that seeks approval of a generic drug, such as Defendants herein, is responsible for ensuring that its warning label is the **same as** the brand-name's. *Mensing*, 564 U.S. at 613 (*citing*, § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7)) (emphasis added). The requirement that a generic manufacturer keep its label identical to the FDA-approved brand drug's label is referred to as the duty of "sameness." *Mensing*, 564 U.S. at 613, 616. The sameness doctrine applies to every portion of Plaintiffs' complained-of conduct in this case, including the labeling,

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warnings, route of administration, dosage form, and strength. *See* 21 C.F.R. § 314.94(a)(6); 21 U.S.C. § 355(j)(2)(iii). For each, Defendants were expressly required by federal law to make their generic propofol identical to the brand name version, subject to certain limited exceptions not alleged by Plaintiffs to be at issue here.

2. Defendants Are Prohibited by Federal Law From Including Additional Warnings

The majority of the factual allegations in the Complaint detail what Plaintiffs view as precursive signs of their alleged harm. For example, Plaintiffs reference a study by the Annals of Internal Medicine in 1983 regarding multi-dose contamination (Compl. at ¶ 20), reports from the Center for Disease Control ("CDC") in 1990 (*id*. at ¶ 23), informal surveys on syringe reuse (*id*. at ¶ 24), CDC investigations at various hospitals from 1990 to 1993 (*id*. ¶ 25), warnings issued by an executive of an unrelated healthcare company in 1990 and 1991 (*id*. ¶ 26-27), articles in medical journals in 1995 (*id*. at ¶ 27), recommendations from professional associations (*id*. at ¶ 29), reports from the World Health Organization in 2003 (*id*. at ¶ 34), an alert by the FDA in 2007 (*id*. at ¶ 35), and calls to action by the New York State Health Commission (*id*. at ¶ 36), all prior to the outbreak in Las Vegas at the hands of Desai and his cohorts. Put differently, Plaintiffs' primary allegation is that all the signs of danger presented by the threat of healthcare providers improperly multi-dosing different patients using the same source (e.g., vial) were there, but that Defendants failed to adequately warn anybody about them.

However, Defendants' propofol already contained FDA-approved warnings and instructions that the product was for "single patient use." But moreover, federal law **expressly prohibited** Defendants from taking any of the actions suggested by Plaintiffs. As set forth, federal law mandates that generic drug labels be, at all times, the **same as** the corresponding brand-name drug labels. *Mensing*, 564 U.S. at 618 (*citing*, 21 CFR § 314.150(b)(10)). To implement that statutory mandate, FDA regulations require generic applicants to submit a "side-by-side comparison of the[ir] proposed labeling . . . with the approved labeling for the [brand-name] drug with all differences annotated and explained." 21 C.F.R. § 314.94(a)(8)(iv). "Labeling" includes the container label, package insert, and, if applicable, a Medication Guide. *Id*.

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The Supreme Court expressly found that if a manufacturer of a generic drug changes its labels in an effort to satisfy some purported state-law duty, the manufacturer would have violated federal law. *Mensing*, 564 U.S. at 618. The Hatch-Waxman Act itself prohibits the FDA from approving an ANDA if "information submitted in the application is insufficient to show that the labeling proposed for the [generic] drug is the **same as** the labeling approved for the [brand-name] drug referred to in the application." 21 U.S.C. § 355(j)(4)(G) (emphasis added). In turn, the FDA's implementing regulations authorize withdrawal of a generic drug product's prior approval if the product's labeling "is no longer consistent with that for the [brand-name] drug referred to in the [ANDA]." 21 C.F.R. § 314.150(b)(10). Most importantly, drug companies are subject to severe penalties, including withdrawal from the market, for marketing to consumers a "misbranded" product, *i.e.*, a product whose label does not conform to the FDA's labeling requirements. *See* 21 U.S.C. § 331, 333.

Here, Plaintiffs' Complaint centers around the outbreak of Hepatitis C in Las Vegas and elsewhere due to individual medical providers' purposeful, criminal and grossly negligent misuse of syringes and propofol vials, specifically by reusing them on more than one patient. Plaintiffs allege that these practices occurred "consistently enough during the time that Defendants supplied propofol to justify a mass warning of possible infection to all individuals who received an injection at the CLINIC . . ." Compl. at ¶ 10. However, Defendants were prohibited by federal law from unilaterally changing their labeling to provide such a warning proposed by plaintiffs. *Bartlett*, 133 S. Ct. at 2476 ("As [*Mensing*] made clear, federal law prevents generic drug manufacturers from changing their labels.") (citations omitted). When federal law forbids an action that state law requires, the state law is "'without effect.'" *Id*. at 2476-77 (quoting, *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Because it is impossible for Defendants to comply with federal law prohibiting them from altering the generic drug's labeling while at the same time complying with any purported Nevada law or standard requiring a stronger warning, Plaintiffs' claims are preempted as a matter of law. *Bartlett*, 133 S. Ct. at 2477; *see also, Moretti v. PLIVA, Inc.*, 2012 U.S. Dist. LEXIS 24113, *10, 2012 WL 628502 (D. Nev. 2012) ("In *Mensing*, the United States Supreme Court held that state-law tort claims against generic drug manufacturers based on an alleged failure to warn are preempted by federal law."). Plaintiffs' claims should thus be dismissed in their entirety.

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3. Defendants Were Prohibited From Sending "Dear Doctor" Letters.

The Complaint includes seemingly misplaced allegations that Nancy E. Nazari of non-party Stuart Pharmaceuticals sent "Dear Doctor" letters to healthcare professionals in 1990 and 1991 – years before Defendants' generic propofol was even approved – regarding the brand name, Diprivan, which warned of the potential for multi-dose vial contamination. *See*, Compl. at ¶ 26-27. Ms. Nazari's act of sending Dear Doctor letters to unrelated parties nearly three decades ago, and several years before Teva's propofol ANDA was approved, is irrelevant to this lawsuit.

Nonetheless, to the extent Plaintiffs allege that Defendants herein should have—or even could have—sent similar Dear Doctor letters to providers at the Clinic, they would be incorrect. In addition to requiring identical labeling, federal law also restricts generic drug manufacturers from initiating certain communications concerning product safety or contraindications with medical professionals. *See*, 21 U.S.C. § 355-l(i)(2) (directing that Secretary of Health and Human Services will implement any plan to communicate with healthcare providers in connection with risks possibly posed by generic drugs). The United States Supreme Court in *Mensing* held that **federal law does not permit generic manufacturers to unilaterally issue Dear Doctor letters**. *Mensing*, 546 U.S. at 615. That is so because Dear Doctor letters qualify as "labeling," thus "any such letters must be 'consistent with and not contrary to [the drug's] approved . . . labeling.'" *Id*. (quoting 21 C.F.R. § 201.100(d)(1)). As the U.S. Supreme Court recognized, if Defendants herein, as generic manufacturers and distributors, sent such letters as Plaintiffs suggest they should have, but the brand manufacturer did not, "that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id*. There is no allegation in the Complaint that the manufacturer of Diprivan sent any Dear Doctor letters after Defendants ANDA was approved. Thus, as explicitly set forth by the Supreme Court in *Mensing*, Defendants were prohibited by federal law from doing so.

4. Federal Law Preempts Plaintiffs' Attacks on the Dosage and Strength of Defendants' Generic Brand.

Plaintiffs attack the dosage levels or strength of Defendants' generic propofol by insinuating that Defendants should not have sold 50 mL vials to the Clinic. This claim is likewise preempted by the sameness doctrine. In addition to identical labeling requirements, federal law also requires that

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the "route of administration, dosage form, and strength" of the proposed generic drug be the **same as** those of the reference listed drug. 21 C.F.R. § 314.94(a)(6); *see also* 21 U.S.C. § 355(j)(2)(iii) (requiring the ANDA to include "information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug . . ."); *Bartlett*, 133 S. at 2475 ("[T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based.").

A drug's "dosage form" is defined as the "physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product." 21 C.F.R. § 314.3(b). The FDA examines the "physical appearance of the drug product; the physical form of the drug product prior to dispensing to the patient; the way the product is administered; and the design features that affect frequency of dosing" in comparing the generic to the brand drug. 21 C.F.R. § 314.3(b)(1)-(4). It is not entirely clear from their Complaint if Plaintiffs are attacking the dosage form of Defendants' generic product. Indeed, the lack of clarity simply underscores the Complaint's pleading deficiencies, discussed *infra*. To the extent they do attack the dosage form, however, Plaintiffs have not alleged—nor could they—that the complained of dosage form, i.e., 50 mL vials, that Defendants manufactured or distributed was different from that of the brand version, Diprivan.

Likewise, federal law preempts any attack on the strength of the propofol. The "strength" of a generic drug is defined as "the amount of drug substance contained in, delivered, or deliverable from a drug product." 21 C.F.R. § 314.3. Included in the definition is "the total quantity of drug substance in mass or units of activity in a dosage unit or container closure (e.g., weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure)" as well as "the concentration of the drug substance in mass or units of activity per unit volume of mass (e.g., weight/weight, weight/volume, or units/volume)." 21 C.F.R. § 314.3(b)(1)(i), (ii). Plaintiffs appear to complain primarily of the 50 mL vials manufactured by Defendants and essentially argue that the volume was "too much." *See,* Compl. at ¶ 45, 50. However, nowhere in the Complaint do Plaintiffs allege that the brand manufacturer did not *also* manufacture 50 mL vials.

Nor could they. To the contrary, the FDA expressly approved Defendants' generic propofol to be manufactured, marketed, and distributed in 50 mL single-patient vials in January 1999. *See,*

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Exhibit M (FDA Review Packet).[6] The FDA-approved package insert listed propofol as available in 20 mL, 50 mL, and 100 mL vials containing 10 mg/mL of propofol. *Id*. at 015 (emphasis added). The 50 mL vial labelling itself was stamped—literally—with the federal government's approval on January 4, 1999. *Id*. at Bates 024, 026. The Approval Summary clearly references approved labels and labeling for 50 mL containers and cartons (*id*. at 054) and discusses the amended application for 20 mL, 50 mL, and 100 mL vial sizes (*id*. at 059). The Review of Professional Labeling portion specifically notes that the Reference Listed Drug ("RLD"), Diprivan, is manufactured in 50 mL vials and 50 mL pre-filled syringes, and that the Abbreviated New Drug Application, *i.e.*, Defendants' generic propofol, is also manufactured in 50 mL vials. *Id*. at 076.

Clearly, then, the FDA approved the manufacturing, packaging, and distribution of the 50 mL single-use propofol that Plaintiffs seem to take issue with. And, as the total quantity per dosage unit of Defendants' generic propofol was identical to the brand Diprivan, as was required by federal law, Plaintiffs have not shown that Defendants deviated from the drug strength manufactured by the brand company. Indeed, the complete absence of any allegation that Defendants failed to adhere to the sameness doctrine with respect to drug strength is itself fatal to Plaintiffs' claim.

Nor can Plaintiffs proceed under their theory that Defendants should have ceased manufacturing or marketing propofol in 50 mL vials at any point. The United States Supreme Court has made clear that this "stop-selling" theory does not comport with principles of federal preemption. *See*, *Bartlett*, 570 U.S. at 475 ("The Court of Appeals' solution — that Mutual should simply have pulled Sulindac from the market in order to comply with both state and federal law — is no solution.

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[6] The New Drug Applications ("NDA") submitted by brand manufacturers, like Diprivan, and ANDA submitted by generic manufacturers, like Defendants, are publicly available on the FDA's online Approved Drug Products database: https://www.accessdata.fda.gov/scripts/cder/daf/. These federal records are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned" and are therefore subject to judicial notice. NRS 47.130(2)(b). As such, Defendants request that the Court take judicial notice of the NDA and ANDA pursuant to NRS 47.150(2) ("A judge or court shall take judicial notice if requested by a party and supplied with the necessary information."). Doing so does not convert this motion to dismiss into one for summary judgment. *See, e.g., Peck v. Nev. ex rel. 2nd Jud. Dist. Court*, 2017 Nev. Dist. LEXIS 2002, *4-5 (2d Dist. Ct. Jan. 10, 2017) ("The court may consider matters of public record, matters of judicial notice, and any exhibits attached to the complaint when ruling on a motion to dismiss.") (citing, *US v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003); *Breliant v. Preferred Equities Corp.*, 109 Nev. 842, 847, 858 P.2d 1258, 1261 (1993)). The direct link to **Exhibit M** is: https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/75102_propofol.pdf

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Rather, adopting the Court of Appeals' stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court's pre-emption case law.").

In sum, federal law completely preempts the state-law claims Plaintiffs allege, and federal law is clear that Defendants may not deviate from their obligation to ensure their generic propofol has the same labeling, route of administrate, dosage form, and strength as the brand product. Defendants did not stray from that responsibility in any respect. More importantly for purposes of the Rule 12(b)(5) stage, Plaintiffs have failed entirely to allege that Defendants did so.

Moreover, Plaintiffs should not be permitted to amend their Complaint in the event they seek to do so. The FDA approved the manufacturing of 50 mL vials. And, the FDA not allow generic manufacturers, like Defendants, to utilize the CBE process. State law cannot circumvent those federal regulations. To the extent Plaintiffs seek to place Defendants under a different burden imposed by any state laws that would require Defendants to alter their labeling in any manner, send Dear Doctor letters, issue warnings other than those issued by the brand-name, or cease distributing FDA-approved propofol in any manner, those state laws are preempted by federal law as described in *Mensing*, *Bartlett*, and their progeny. As such, any proposed amendment would be futile. *See Foman v. Davis*, 371 U.S. 178 (1962). Accordingly, Plaintiffs' claims should be dismissed with prejudice in their entirety.

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B. Plaintiffs' Claims as Plead Cannot be Proven Under Any Set of Facts

Even assuming *arguendo* that Plaintiffs' claims are not preempted by federal law, they must nevertheless be dismissed because they are insufficiently plead. Indeed, they cannot be proven under any set of facts even if leave to amend was given.

1. Strict Product Liability

Plaintiffs cannot prevail on their strict products liability claim because it is barred by the learned intermediary doctrine. As explained by the Nevada Supreme Court:

> [T]he learned-intermediary doctrine has been used to insulate drug manufacturers from liability in products-liability lawsuits. Under the learned-intermediary doctrine, a drug manufacturer is immune from liability to a patient taking the manufacturer's drug so long as the manufacturer has provided the patient's doctor with all relevant safety information for that drug. It is then up to the patient's doctor—who has the benefit of knowing the patient's specific situation—to convey to the patient any information that the doctor deems relevant.

Klasch v. Walgreen Co., 127 Nev. 832, 837, 264 P.3d 1155, 1158 (2011) (citations omitted).

The learned intermediary doctrine renders it impossible for Plaintiffs to prevail on their product defect claim under a failure-to-warn theory because the labels, package inserts, and packaging (again, all FDA approved and not subject to Defendants' unilateral change) **each specifically state, sometimes in multiple places, that the propofol is for "single patient use" only**. *See* **Exhibit M** at Bates 024 (container label for 20 mL, 50 mL, and 100 mL vials); *id*. at Bates 026 (packaging for 50 mL vial approved Jan. 4, 1999). The labeling also noted the potential for contamination, which could cause "fever, infection/sepsis, and/or other life-threating illness" and expressly directed physicians: "Do not use if contamination is suspected." *See id*. at Bates 026. These warnings were adequate as a matter of law given that the FDA approved them and it is the FDA, alone, that has the exclusive authority to regulate the contents of these warnings. It is impossible for Plaintiffs to prove otherwise because any claim that Nevada law required the warnings to state anything other than exactly what they did is federally preempted.

As the criminal convictions of Plaintiffs' medical providers prove, those individuals were acutely aware of the fact that multi-dosing was not permitted by the warnings attached to the propofol and that it could be, in fact, deadly. Yet, those medical providers ignored these express warnings for the specific purpose of multi-dosing patients in order to minimize waste and maximize their fraudulent insurance gains, all in furtherance of their criminal scheme. However, despite the medical providers' criminal acts, the fact remains that the warnings existed (and were approved and mandated by the FDA) but that the medical providers purposefully ignored them, cutting off causation. *See, e.g.*, *Mariscal v. Graco, Inc*., 52 F. Supp. 3d 973, 989 (N.D. Cal. 2014) ("Defendant is correct that a defendant is not liable to a plaintiff if the injury would have occurred even if the defendant had issued adequate warnings, such as when the person to whom the warning is directed does not read the warning [because, in that case,] there is no causation.") (internal quotations and citation omitted). As such, the learned intermediary doctrine bars Plaintiffs' strict liability claim to the extent they are proceeding under a failure to warn theory. *See, e.g.*, *Steinman v. Spinal Concepts, Inc*., 2011 U.S. Dist. LEXIS 107286, 2011 WL 4442836, at *9 (W.D.N.Y. Sept. 22, 2011) ("It is well settled with

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respect to prescription drugs and medical devices that a manufacturer's duty to warn is owed not [to] the patient, but to the treating physician as the 'learned intermediary.'") (alteration in original).

Nor can their claim proceed on a strict product liability defect theory.[7] To establish a claim for strict products liability, Plaintiffs must demonstrate that: (1) the product had a defect which rendered it unreasonably dangerous: (2) the defect existed at the time the product left the manufacturer; and (3) the defect caused the plaintiff's injury. *Asay v. Kolberg-Pioneer*, 2010 U.S. Dist. LEXIS 83105, *10, 2010 WL 3239006 (D. Nev. Aug. 13, 2010) (citing, *Fyssakis v. Knight Equipment Corp.*, 108 Nev. 212, 826 P.2d 570, 571 (Nev. 1992) (citations omitted)). Under Nevada law, a plaintiff who asserts a strict liability claim must establish that the defendant manufactured or sold the specific product that allegedly injured the plaintiff. *Baymiller v. Ranbaxy Pharms., Inc*., 894 F. Supp. 2d 1302, 1309, 2012 U.S. Dist. LEXIS 127285, *19-20, CCH Prod. Liab. Rep. P18, 917, 2012 WL 3929768 (citing, *Allison v. Merck & Co., Inc.*, 110 Nev. 762, 878 P.2d 948, 952 (Nev. 1994)).

While the Nevada Supreme Court has indicated an "acceptance of strict tort liability," it has also made clear that its acceptance "does not mean that the plaintiff is relieved of the burden of proving a case." *Shoshone Coca-Cola Bottling Co. v. Dolinski*, 82 Nev. 439, 443, 420 P.2d 855, 857-858 (1966). A plaintiff "must still establish that his injury was caused by a **defect in the product**, and that such defect existed when the product left the hands of the defendant." *Id*. (emphasis added). "The concept of strict liability does not prove causation, nor does it trace cause to the defendant." *Id*.

Here, Plaintiffs cannot prove any of the elements of a strict liability claim. First, they do not and cannot allege that there was a defect in the generic propofol medicine itself. Rather, they assert that third-party healthcare providers *may have* improperly reused vials of propofol when administering the anesthetic to them, and seek compensation for the resulting anxiety they allegedly suffered until they received negative test results. *See,* Compl. at ¶ 41, 48, 53, 56. By their own assertions, Plaintiffs' claims stem from the deliberate, criminal actions by individual tortfeasors not

[7] A theory that is, again, preempted by *Bartlett*. *See Bartlett*, 570 U.S. at 490 ("[W]e hold that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling.")

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named here and not from any alleged defect in the product. *Id*. at ¶ 7, 9, 12-14. Thus, they have not alleged, nor can they prove, any defect in the product and the corresponding causal link to Defendants, as opposed to deliberate actions by non-party criminal actors. *See, e.g., Duensing v. Gilbert*, 2013 U.S. Dist. LEXIS 47649, *22, 2013 WL 1316890 (D. Nev. Mar. 1, 2013) ("The plaintiff must demonstrate that the defect caused his injuries."); *Asay*, 2010 U.S. Dist. LEXIS 83105, *12, 2010 WL 3239006 ("Under strict liability, plaintiffs must demonstrate causation."). Any "defect" Plaintiffs allege was with the conduct at the Clinic, and not with the propofol, and thus Plaintiffs will not be able to prove that the chemical composition of the propofol, rather than the actions of the physicians, proximately caused their alleged injuries. Because they have failed to allege facts "show[ing] that [a] design defect in the product was a substantial factor in causing [Plaintiffs'] injury" their strict liability claim should be dismissed as a matter of law. *Price*, 111 Nev. 515, 893 P.2d at 370 (citation omitted).

2. Breach of Implied Warranty of Fitness for a Particular Purpose

Nevada law requires privity between the parties to pursue an implied warranty claim. *Long v. Flanigan Warehouse Co.*, 79 Nev. 241, 247, 382 P.2d 399, 402-03 (1963); *see also KB Home Nev., Inc. v. Dunrite Constr*., 2017 Nev. Unpub. LEXIS 813, *2-3, 402 P.3d 1253 (citing, *Soltani v. GP Indus.*, Docket No. 56114, 2011 Nev. Unpub. LEXIS 1362, at *2 ("Nevada law requires privity to pursue an implied warranty claim."). While Plaintiffs allege privity between Defendants Sicor and Baxter (Compl. at ¶ 43), they do not allege privity between themselves and any of the Defendants. Nor could they: by Plaintiffs' own admissions, Defendants sold propofol to *third-party medical providers*, who in turn entered into privity of contract with Plaintiffs vis-à-vis their visits to the Clinic. It is the third-party medical providers who directly contracted with Plaintiffs for the administration of propofol, which forms the basis of Plaintiffs' claims. As a matter of law, then, Plaintiffs cannot maintain a claim for breach of any implied warranty without privity of contract with the Defendants. *Shoshone Coca-Cola Bottling Co.*, 82 Nev. at 441, 420 P.2d at 857 (noting Court has rejected implied warranties in the absence of privity of contract) (citing, *Long*, 79 Nev. at 241, 382 P.2d at 399); *Amundsen v. Ohio Brass Co.*, 89 Nev. 378, 379-380, 513 P.2d 1234, 1234-1235 (1973) (same).

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3. Negligence

A plaintiff must satisfy four elements for a claim of negligence: (1) an existing duty of care, (2) breach, (3) legal causation, and (4) damages. *Turner v. Mandalay Sports Entertainment, LLC*, 124 Nev. 213, 180 P.3d 1172, 1175 (Nev. 2008). Plaintiffs cannot establish that Defendants owed them a duty of care beyond the duty to manufacture safe products, and the learned-intermediary doctrine forecloses any claim that Defendants had a duty to ensure that the propofol was being administered safely. Again, as explained by the Nevada Supreme Court:

> [T]he learned-intermediary doctrine has been used to insulate drug manufacturers from liability in products-liability lawsuits. Under the learned-intermediary doctrine, a drug manufacturer is immune from liability to a patient taking the manufacturer's drug so long as the manufacturer has provided the patient's doctor with all relevant safety information for that drug. It is then up to the patient's doctor—who has the benefit of knowing the patient's specific situation—to convey to the patient any information that the doctor deems relevant.

Klasch v. Walgreen Co., 127 Nev. 832, 837, 264 P.3d 1155, 1158 (2011) (citations omitted).

Apart from the duty to warn, a manufacturer has no further duty to ensure that a physician is appropriately administering its drug because "[i]t is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy." *Klasch*, 127 Nev. at fn. 9 (quoting *McKee v. American Home Products, Corp*., 113 Wn.2d 701, 782 P.2d 1045, 1050-51 (Wash. 1989)). As set forth above, Defendants' propofol contained the same labeling and warnings as the brand product, including that propofol is for "single patient" use only, which was approved and mandated by the FDA, and Plaintiffs do not allege otherwise. Moreover, Defendants did not have a legal duty to monitor the practices of the physicians who injected Plaintiffs because under Nevada law, "[g]enerally, no duty is owed to control the dangerous conduct of another." *Sparks v. Alpha Tau Omega Fraternity, Inc.*, 127 Nev. 287, 296 (2011) (quoting, *Sanchez v. Wal-Mart Stores*, 125 Nev. 818, 824, 221 P.3d 1276, 1280 (2009)).

Even assuming Plaintiffs can establish that Defendants owed them a state tort duty that does not conflict with their federally-imposed duties—which they cannot—they will still be unable to prove causation for two reasons, either of which is sufficient to defeat Plaintiffs' negligence claim. First, their claim is premised upon the fact that third-party physicians purposefully, improperly—and indeed, **criminally**—administered propofol to them. As set forth above, Defendants were prohibited

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by federal law from altering their warning labels. It cannot be disputed that the generic labels at issue were identical to the brand labels, as is required by federal law, and therefore had identical warnings, which included express warnings against multi-patient use. Plaintiffs do not allege otherwise. Clearly, then, the individual physicians that administered propofol to Plaintiffs either (a) did not read the warning labels; or (b) read but consciously disregarded the warnings.[8] In either situation, the physicians' failure to abide by the clear warnings against multi-patient use makes it impossible for Plaintiffs to prove causation as a matter of law.

For example, in *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804 (D. Nev. 2013), Judge Philip Pro held in dismissing the complaint against a manufacturer of medical products that "Plaintiff . . . offered no evidence that [the prescriber] ever reviewed the warnings that accompanied the product." *Id.* at *2. Judge Pro then found that a prescriber's failure to read the device warnings in question defeated causation:

> Plaintiff's implied warranty claim fails because Plaintiff has not presented evidence of proximate cause. Indeed the evidence shows that [the prescriber] reviewed no warnings which accompanied the . . . product at all, and there is no evidence that [he] would have done anything differently had the warnings accompanying Defendants' product been different.

Id.

Likewise, the purposeful failure of Desai and others to abide by the warnings on Defendants' propofol defeats causation here as a matter of law.

As a similar but additional ground, the criminal actions of Desai and his underlings serve as intervening causes, making it impossible for Plaintiffs to prove causation attributable to Defendants.[9] Under Nevada law, "[n]egligence is not actionable unless, without the intervention of an intervening cause, it proximately causes the harm for which complaint was made." *Thomas v. Bokelman*, 86 Nev. 10, 13, 462 P.2d 1020, 1022 (1970). "Proximate cause is any cause which in natural and continuous sequence, unbroken by an efficient intervening cause, produces the injury complained of and without

[8] In fact, the Complaint itself quotes and links to an article published by the Southern Nevada Health District which states, "[t]he vial, **which was not labeled for use on multiple patients**, was then used for a second patient . . ." Compl. at ¶ 14(c) (emphasis added).

[9] In their negligence claim, Plaintiffs errantly allege that Defendants sold propofol to the "Defendant Clinics." Compl. at ¶ 50. While they have not actually named any of the clinics as defendants—likely because they are defunct—Plaintiffs' Freudian slip is well-taken.

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which the result would not have occurred." *Taylor v. Silva*, 96 Nev. 738, 741 (1980). "An intervening cause means not a concurrent and contributing cause but a superseding cause which is itself the natural and logical cause of the harm." *Bokelman*, 86 Nev. at 13, 462 P.2d at 1022.

Here, Desai, Lakeman, Mathahs, and Rushing formulated an elaborate criminal scheme wherein they overbooked patients, raced through colonoscopy procedures, purposefully and knowingly reused syringes and propofol vials in blatant disregard of the express warnings, and abandoned all established safety standards, ethics, their training, and the law, all in a criminal effort to maximize profits. These are not mere allegations—these are **facts** that have been proven in both federal and state court, through guilty pleas and a jury trial, which facts this Court can and should take judicial notice of. The deliberate actions of these independent, third-party tortfeasors were committed in complete disregard of **the warning labels already on Defendants' propofol** and served as the "natural and continuous sequence" which lead to Plaintiffs' alleged injuries. *Taylor*, 96 Nev. at 741. But for the actions of these tortfeasors, "the result would not have occurred" and, therefore, Plaintiffs cannot prove that Defendants proximately caused their alleged injuries. *Id.*

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4. Deceptive Trade Practices Act

Plaintiffs' fourth claim for violation of Nevada Deceptive Trade Practices Act does nothing more than recite the statutory elements of claims brought pursuant to NRS Chapter 598. *See*, Compl. at ¶ 54-56. Plaintiffs make no effort to describe what alleged "false representations" were made by Defendants as to the generic drug's quality, ingredients, uses, benefits, alterations, quantities, or other characteristics. *Id.* As such, this claim fails to meet the minimum pleading standard of Nev. R. Civ. P. 8.[10]

[10] The Complaint alleges Defendants made "false representations in a transaction affecting Plaintiff Rader and others similarly-situated." Compl. at ¶ 55(c). There is no Plaintiff in this case named Rader; this portion of the Complaint appears to be a copy-paste from a previous lawsuit filed against these Defendants in 2010 in federal court, *Rader v. Teva*, case no. 2:10-cv-818-JCM-VCF. There, plaintiffs, brought the same claims against four of these same defendants based upon the same factual allegations. Judge Mahan initially rejected defendants' federal preemption argument, and in doing so relied upon the Ninth Circuit's decision in *Gaeta v. Perrigo Pharms. Co.*, 630 F.3d 1225 (9th Cir. 2011). Judge Mahan's decision in *Rader* was issued on June 20, 2011—three days before the United States Supreme Court issued its decision in *Mensing*. *Gaeta* was subsequently vacated by the United States Supreme Court for further consideration in light of *Mensing*. *See, L. Perrigo Co. v. Gaeta*, 565 U.S. 973, 132 S. Ct. 497, 181 L. Ed. 2d 343 (2011). Here, Plaintiffs' entire case theory has been completely and squarely foreclosed by *Mensing* and they have made no effort to retool their theory, instead apparently relying on prior success in *Rader*, which was decided on caselaw that has since been overturned.

Further, Plaintiffs have failed to meet the heightened pleading standard of Nev. R. Civ. P. 9(b). Violations of the Nevada Deceptive Trade Practices Act are considered claims for consumer fraud. *See*, NRS 41.600(2)(e) (defining "consumer fraud" as a deceptive trade practice as defined in NRS 598.0915 through 598.0925); *see also, Shlesinger v. Bank of Am., N.A.*, 2012 U.S. Dist. LEXIS 102030, *16-18, 2012 WL 2995698 (D. Nev. July 23, 2012) ("Consumer fraud includes a deceptive trade practice under Nevada's Deceptive Trade Practices Act."). Each of the subparts of Plaintiffs' claim for relief alleges violations of NRS 598.0915 through 598.0925. As based in fraud, claims brought under the Nevada Deceptive Trade Practices Act must be pled with particularity. NRCP 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."); *see also, Thomas v. Wachovia Mortg. FSB*, 2011 U.S. Dist. LEXIS 81758, at *7-8 (D. Nev. 2011); *Tucker v. JP Morgan Chase Bank, N.A.*, 2011 U.S. Dist. LEXIS 7179, at *5-6 (D. Nev. 2011); *Weinstein v. Home American Mortgage Corp*., 2010 U.S. Dist. LEXIS 139093, at *7-8 (D. Nev. 2010). Pleading fraud with particularity requires allegations regarding the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (quotation omitted). Further, "the plaintiff must set forth what is false or misleading about a statement, and why it is false." *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (quotation omitted).

Plaintiffs have failed to allege their consumer fraud claim with particularity. Averments of fraud must be specific enough to put a defendant on notice of the particular misconduct the defendant is alleged to have committed so that the defendant can properly defend against the allegations. *Vess v. Ciba-Geigy Corp., USA*, 317 F.3d 1097, 1104 (9th Cir. 2003). A plaintiff is required to plead facts as to time, place, and substance of the fraud, and specifically detail the defendant's allegedly wrongful acts, including when they occurred and who engaged in the misconduct. *See Cooper v. Pickett*, 137, F.3d 616, 627 (9th Cir. 1997). While Plaintiffs allege Defendants made "knowingly false representations," they do not clarify what those representations were, who made them, to whom they were made, or when they were made, nor do they explain how they were false. *See* Compl. at ¶ 55. And, Plaintiffs do not explain how this purported "fraud" led to their alleged injuries.

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In addition, in a case with multiple defendants, "Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." *Swartz*, 476 F.3d at 765-66 (internal quotations and citations omitted); *Minnick v. Wittman*, 2019 Nev. Dist. LEXIS 283, *9 (8th Jud. Dist. Mar. 20, 2019) ("Rather than supplying new specific fraud allegations against the Annuity Defendants, the Amended Complaint once again simply lumps the Annuity Defendants together with the Wittman defendants. Such a pleading tactic does not satisfy the Rule 9(b) standard."); *Pegasus Holdings v. Veterinary Centers of America, Inc.*, 38 F.Supp.2d 1158, 1163 (C.D. Cal. 1998) ("Where an action involves multiple defendants, a plaintiff must provide each and every defendant with enough information to enable them 'to know what misrepresentations are attributable to them and what fraudulent conduct they are charged with."). Further, in a fraud action against a corporation, courts have held that "a plaintiff must allege the names of the persons who made the allegedly fraudulent representation, their authority to speak, to whom they spoke, what they said or wrote, and when it was said or written." *Cisneros v. Instant Capital Funding Group, Inc.*, 2009 WL 3049209 at *6 (E.D. Cal. 2009) (quotations and citation omitted).

Here, Plaintiffs' fourth claim for relief is replete with vague and conclusory allegations that Defendants collectively made "false representations," without explanation. Compl. at ¶ 55. Plaintiffs fail to allege any facts regarding the time, place, substance or specific nature of Defendants' fraudulent words or acts. Plaintiffs also lump each Defendant together, and make no effort to describe how each individually participated in the alleged "fraud," whatever that might be. After reviewing Plaintiffs' Complaint, it is unclear what false representations Plaintiffs claim were made to them, or how those unidentified representations contributed to their alleged injuries. As such, this claim should be dismissed. *Swartz*, 476 F.3d at 766 (conclusory allegations of fraud "without any stated factual basis are insufficient as a matter of law"); *Shlesinger*, 2012 U.S. Dist. LEXIS 102030, *17, 2012 WL 2995698 ("Though Shlesinger lists numerous statutory provisions that Bank of America allegedly violated, he does not allege how the complained of conduct violates any of these provisions."); *Thomas*, 2011 U.S. Dist. LEXIS 81758, at *7-8 (dismissing for failing to allege with

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particularity what false representations were made and for lumping multiple defendants together without differentiating between them or the allegations against them).

5. Punitive Damages

Plaintiffs' eighth claim for punitive damages must be dismissed because punitive damages is not an independent claim for relief. *See, e.g., Sellen v. Lending*, 2013 Nev. Dist. LEXIS 3236 (Villani, M., Oct. 9, 2013) (dismissing claim for punitive damages because "[p]unitive damages is a remedy available only if a party prevails on another underlying cause of action.") (citing, *Sprouse v. Wentz*, 105 Nev. 597, 602 (1989)). Because punitive damages are not a standalone cause of action, but are instead a remedy derivative of Plaintiffs' substantive claims, which should be dismissed for the reasons above, Plaintiffs' claim for punitive damages must be dismissed as well.

Moreover, under Nevada law punitive damages are only available to a plaintiff who proves by clear and convincing evidence that the defendant is guilty of "oppression, fraud, or malice, express or implied." NRS 42.005; *Hughes v. Ethel M. Chocolates, Inc.*, 2013 U.S. Dist. LEXIS 60050, *19, 2013 WL 1792172 (D. Nev. Apr. 25, 2013). "[T]o justify punitive damages, the defendant's conduct must have exceeded 'mere recklessness or gross negligence.'" *Wyeth v. Rowatt*, 126 Nev. 446, 473, 244 P.3d 765, 783 (2010) (quoting, *Countrywide Home Loans v. Thitchener*, 124 Nev. 725, 739, 192 P.3d 243, 252 (2008)). Punitive damages are designed not to reward the victim but to punish the wrongdoer and deter fraudulent, malicious or oppressive conduct. *Turnbow v. Dep't of Human Resources, Welfare Div.*, 109 Nev. 293, 853 P.2d 97 (1993).

Per NRS 42.001, "'[m]alice, express or implied' means conduct which is intended to injure a person or despicable conduct which is engaged in with a **conscious disregard** of the rights or safety of others." *Thitchener*, 124 Nev. at 740 (emphasis in original). Similarly, "'[o]ppression' means despicable conduct that subjects a person to cruel and unjust hardship with **conscious disregard** of the rights of the person." *Id.* (emphasis in original). "Both definitions utilize conscious disregard of a person's rights as a common mental element, which in turn is defined as 'the knowledge of the probable harmful consequences of a wrongful act and a **willful and deliberate failure to act to avoid those consequences**.'" *Id.* (quoting NRS 42.001) (emphasis added).

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Plaintiffs do not allege that Defendants willfully and deliberately failed to act in order to avoid harm to them. Nor could they, as federal law expressly prohibited Defendants from acting in the manner the Complaint suggests they should have, whether they wished to or not. Awards of punitive damages are improper where the evidence fails to show either a willful wrong or the damage as an intended or necessary consequence. *American Excess Ins. Co. v. MGM Grand Hotels*, 102 Nev. 601, 729 P.2d 1352 (1986). And, Nevada follows the rule that proof of bad faith, by itself, does not establish liability for punitive damages. *United Fire Ins. Co. v. McClelland*, 105 Nev. 504, 780 P.2d 193 (1989). As such, Plaintiffs' claim for punitive damages should be dismissed.

III. CONCLUSION

Everything Plaintiffs claim Defendants should have done has been expressly prohibited not only by the United States Supreme Court, but also by dozens of state and federal courts throughout the country. These courts have acknowledged, either implicitly or explicitly, that the United States Supreme Court was aware of the consequences of its decisions by precluding these types of claims against Defendants and leaving potential plaintiffs without a remedy. In *Bartlett*, the United States Supreme Court was asked to re-evaluate its decision in *Mensing*, but rather than reversing it, the Court re-affirmed and expanded its decision to make clear that all of Plaintiffs' claims in this case are preempted.

Based upon the foregoing, it is clear that all of Plaintiffs' claims are preempted, and Defendants respectfully request that the Court dismiss Plaintiffs' Complaint in its entirety, with prejudice.

In the alternative, Plaintiffs have not—and cannot—establish the requisite causal link between Defendants' conduct and the alleged harm, because the criminal conduct of Desai and other third-party tortfeasors, proven beyond all reasonable doubt, served as an intervening cause in the chain of events. Thus, Plaintiffs cannot prove proximate cause as a matter of law, and their claims should be dismissed.

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Should the Court disagree, Plaintiffs' claims should alternatively be dismissed because that have not met the requisite pleading standard with respect to each claim, nor could they. Furthermore, Plaintiffs have not alleged they have suffered any legally cognizable injuries which may be redressed by this Court.

DATED this 25th day of September 2019.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of September 2019, a true and correct copy of the foregoing **MOTION TO DISMISS** was served electronically using the Odyssey eFileNV Electronic Filing system and serving all parties with an email address on record, pursuant to Administrative Order 14-2 and Rule 9 of the N.E.F.C.R.

/s/ Evelyn Escobar-Gaddi
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INDEX TO EXHIBITS TO MOTION TO DISMISS

Exhibit	Description
A	Federal Indictment in *USA v. Desai and Rushing*, Case No. 2:11-CR-166
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C	Federal Final Order of Forfeiture
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M	FDA Review Packet

Exhibit A

Federal Indictment in *USA v. Desai and Rushing*, case no. 2:11-cr-166

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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA
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UNITED STATES OF AMERICA, PLAINTIFF, VS. DIPAK DESAI, M.D., and TONYA RUSHING, DEFENDANTS.	CRIMINAL INDICTMENT 2:11-CR- 166 **VIOLATIONS:** 18 U.S.C. § 371 - Conspiracy 18 U.S.C. § 1347 - Health Care Fraud 18 U.S.C. § 982(a)(7) - Forfeiture

THE GRAND JURY CHARGES THAT:

At all times relevant:

Introduction

1. Defendant **DESAI**, a physician and the owner of the Endoscopy Center of Southern Nevada ("ECOSN"), schemed with defendant **RUSHING**, his Chief Operating Officer, to systematically overcharge the federal Medicare program and other health insurance companies for anesthesia billing. **DESAI** and **RUSHING** caused ECOSN to overstate significantly the amount of time its certified registered nurse anesthetists ("CRNAs") spent with patients on a given procedure.

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Persons and Entities

2. Defendant **DIPAK DESAI** ("**DESAI**") was a physician licensed by the state of Nevada, which license he voluntarily surrendered in February 2010. He specialized in gastroenterology, the branch of medicine that studies the digestive system and its disorders.

3. **DESAI** hired defendant **TONYA RUSHING** ("**RUSHING**") in January 2000 to help him run the business side of his medical practices. In 2005, **DESAI** promoted her to the position of Chief Operating Officer ("COO"). Together, **RUSHING** and **DESAI** jointly ran the practices' day-to-day operations.

4. The Gastroenterology Center of Nevada ("GCON") was a medical practice specializing in gastroenterology owned by **DESAI**. Its original and principal location was on Shadow Lane in Las Vegas.

5. ECOSN was an ambulatory surgical center, also owned by DESAI, at which gastroenterological procedures were performed. Procedures were performed at two locations: (1) the same building at Shadow Lane that housed GCON (the "Shadow Lane clinic"); and (2) a clinic located at Burnham Road in Las Vegas (the "Desert Shadow clinic"; collectively the clinics will be referred to as "ECOSN"). The fraud alleged to have taken place in this Indictment occurred at both of ECOSN"s locations.

6. Physicians primarily performed two procedures at the ECOSN clinics, an upper endoscopy and a colonoscopy. An upper endoscopy involves the insertion of a flexible video camera tube, about three feet long, through the patient's mouth, to inspect the esophagus, the stomach and the first section of the small intestine, known as the duodenum. A colonoscopy, the more complicated of the two procedures, is the insertion of a tube, longer and thicker than that used in an upper endoscopy, through the patient's rectum, to the end of the colon, looking for polyps, tumors or other indications of disease.

7. The federal Medicare program ("Medicare"), the state Medicaid program ("Medicaid") and Blue Cross / Blue Shield, Aetna, United Healthcare, Anthem, the Hotel and

Restaurant Employees International Union Welfare Fund ("Culinary Fund"), the Teamster's Security Fund for Southern Nevada, Regence Blue Cross and Pacificare (collectively "the Private Insurers") received and paid appropriate claims for reimbursement for the provision of care to their insureds. Medicare, Medicaid and the Private Insurers were health care benefit programs as that term is defined in Title 18, United States Code, Section 24, and as that term is used in Title 18, United States Code, Section 1347.

Propofol and the CRNA Model

8. Both an upper endoscopy and a colonoscopy require a dosage of a quick acting anesthetic known as Propofol (brand name - Diprivan).

9. At ECOSN, propofol was administered intravenously by a CRNA. A CRNA is an advance practice nurse, licensed by the State of Nevada, who has acquired special education and training in the field of anesthesia.

10. In approximately 2002, **DESAI** decided to hire CRNAs to practice at ECOSN. Prior to that time, he relied on anesthesiologists (medical doctors) for anesthesia services. DESAI sought two benefits from hiring CRNA's and eschewing the use of anesthesiologists: (1) ECOSN would not be limited to scheduling procedures only when the anesthesiologists were available; and (2) ECOSN could bill for the anesthesia services performed by the CRNAs.

11. From 2002 on, **DESAI** and **RUSHING** hired approximately eight CRNA's to work at ECOSN's two locations. They were paid a salary. Thus, to the extent insurance payments for anesthesia services performed by CRNAs exceeded their salaries, ECOSN, **DESAI** and **RUSHING** profited.

Billing Codes for Anesthesiology Services Attendant to Endoscopy Procedures

12. Medicare, Medicaid and the Private Insurers reimburse providers, such as GCON, for the administration of anesthesia attendant to upper endoscopies and colonoscopies.

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13. Current Procedural Terminology ("CPT") billing code 00740 relates to charges for anesthesia provided during upper endoscopy procedures. It is defined as "[a]nesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum."

14. CPT 00810 relates to charges for anesthesia provided during colonoscopies. It is defined as "[a]nesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum."

15. For both codes, CPT 00740 and CPT 00810, anesthesia is billed on the basis of how much face-to-face time the provider, such as a CRNA, spends with a patient. Anesthesia time begins when the provider, such as a CRNA begins to prepare the patient for the administration of anesthesia and ends when the provider, such as a CRNA, no longer is in the personal attendance of the patient.

16. Anesthesia time is calculated on the basis of fifteen (15) minute increments known as "units." For most insurers, time less than fifteen minutes is rounded up to the next whole unit. For most insurers, both codes, CPT 00740 and CPT 00810, include a base charge of 5.0 units, which is added to the time units to calculate the billed amount. (Nevada Medicaid includes a base charge of 6.0 units).

A. For example, for most insurers, if the CRNA spends 13 minutes with a patient, ECOSN is entitled to bill six (6) units - five base units plus one unit for time - for those anesthesia services.

B. On average, one unit is approximately $70, notwithstanding slight variations among Medicare, Medicaid and the Private Insurers.

C. Any payments for anesthesia services are made in addition to payments the Medicare, Medicaid and the Private Insurers may have made to the physician for performing the procedure itself.

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COUNT ONE
Conspiracy
(Title 18, United States Code, Sections 371)

17. The Grand Jury further charges and incorporates by reference the allegations of paragraphs 1 through 16 above as though fully set forth herein.

18. From in or about January 2005 and continuing through on or about February 2008, in the state and federal District of Nevada,

DIPAK DESAI, M.D., and
TONYA RUSHING,

defendants herein, knowingly and willfully conspired, confederated, and agreed with each other, and others known and unknown to the Grand Jury, to devise and participate in a scheme and artifice to defraud a health care benefit program, that is, Medicare, Medicaid and the Private Insurers, and to obtain by means of materially false and fraudulent pretenses, representations, and promises, money owned by and under the custody and control of Medicare, Medicaid and the Private Insurers, in connection with the delivery of, and payment for, health care benefits, items and services.

The Scheme and Artifice to Defraud

19. It was part of the scheme and artifice to defraud that **DESAI** and **RUSHING** caused fraudulent bills to be submitted to Medicare, Medicaid and the Private Insurers that falsely inflated the amount of anesthesia time spent by the CRNA's on the procedures performed at ECOSN.

20. As part of the scheme and artifice to defraud, **DESAI** and **RUSHING** instructed the CRNA's and caused them to be instructed to falsely and fraudulently list at least thirty-one (31) minutes of anesthesia time on the Anesthesia Record they maintained for each procedure, even though the CRNAs did not spend close to that amount face-to-face time with the patient, as **DESAI** and **RUSHING** then and there well knew.

A. **DESAI** imposed intense pressure on all ECOSN employees to schedule and treat as many patients as possible in a given day. CRNAs at ECOSN's Shadow Lane clinic regularly performed anesthesia on between sixty (60) and eighty (80) patients per day. As a result, the CRNAs

almost never spent thirty-one (31) or more minutes with a patient, and could not have possibly done so, given the number of patients each day they had to treat.

B. Due to **DESAI's** practice of performing colonoscopies and upper endoscopies in an unreasonably short amount of time, and his instruction to other physicians at ECOSN to do the same, he well knew that the CRNA's were spending less than thirty-one (31) minutes of face-to-face time with each patient.

21. As part of the scheme and artifice to defraud, **DESAI** and **RUSHING** instructed the individuals responsible for insurance billing to rely upon the CRNAs Anesthesia Record – the medical record **DESAI** and **RUSHING** had instructed the CRNA's to falsify – when preparing claims for reimbursement to be submitted to Medicare, Medicaid and the Private Insurers.

22. As part of the scheme and artifice to defraud, the CRNAs created and inserted false vital signs, including blood pressure and oxygen saturation, in their Anesthesia Records to make it appear as if they were spending at least thirty-one (31) minutes with each patient.

23. As part of the scheme and artifice to defraud, **DESAI** and **RUSHING** instituted a policy at ECOSN prohibiting the beneficiaries of one of the Private Insurers from being scheduled back to back on the same day. This Private Insurer required that the actual anesthesia time, or the time designated for anesthesia, be submitted along with the claims for reimbursement. **DESAI** and **RUSHING** instructed their employees not to schedule patients of this Private Insurer back-to-back in order to conceal from this Private Insurer the fact that each claim for reimbursement exceeded thirty-one (31) minutes.

24. As part of the scheme and artifice, **DESAI** and **RUSHING** created a separate company, owned by **RUSHING**, to handle the billing for anesthesia services rendered by the CRNAs. As a result, **RUSHING** simultaneously helped manage GCON and ECOSN and stood to profit handsomely from CRNA billings.

A. **RUSHING's** company received a percentage of all money collected for anesthesia services rendered by CRNAs, giving her a financial incentive to inflate anesthesia time.

B. **DESAI** and **RUSHING** concealed from the other GCON employees, including physicians in GCON's management structure, that they had formed this separate billing company.

C. **DESAI** solicited, and **RUSHING** paid, large sums of money earned by **RUSHING** for performing CRNA billing.

The Overt Acts

25. In furtherance of the conspiracy and in order to effect the objects thereof, defendants **DESAI, RUSHING**, and others known and unknown to the Grand Jury, committed and caused to be committed, the following overt acts, among others, in the District of Nevada and elsewhere:

A. In or about November 2003, **DESAI** and **RUSHING** caused the creation of Healthcare Business Solutions ("HBS"), to be owned by **RUSHING**, to handle the billing for anesthesia services rendered by the CRNAs. HBS received approximately 9% of all money collected for anesthesia services rendered by CRNAs and began billing for anesthesia services on January 1, 2004.

B. In or about January 2004, **RUSHING** prepared and circulated a memorandum to GCON employees instructing them that all the beneficiaries of one of the Private Insurers "are to be scheduled every other patient" and that the policy was "effective immediately." **RUSHING** copied **DESAI** on the memorandum.

C. On or about February 11, 2004, **RUSHING** instructed an HBS employee that "all claims [for anesthesia] needed (sic) 30 minutes or more."

D. Between in or about 2006 and in or about 2007, **RUSHING** paid **DESAI** approximately $185,000 out of money earned by **RUSHING** and HBS for billing fraudulent anesthesia services.

E. In or about July 2004, **DESAI** caused the physical expansion of the Shadow Lane clinic to add a second procedure room, to accommodate the treatment of more patients at

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ECOSN, consistent with the intense pressure he placed on GCON employees to schedule and perform more procedures.

F. In or about March 2006 and January 2007, **DESAI** circulated memoranda to GCON employees instructing them to increase "productivity." In one memorandum, addressed to **RUSHING**, **DESAI** stated, "I want you to understand my priority for the next one year is . . . to have a volume of 70 patients scheduled every day, I cannot afford on and off drops in that volume . . . I am very upset, I need to get something done for this."

G. Between 2002 and 2008, **DESAI** and **RUSHING** directly instructed the CRNA's working at ECOSN to list more than thirty (30) minutes of face-to-face anesthesia time on each patient's Anesthesia Record.

H. In February and March 2008, **DESAI** and **RUSHING** instructed the CRNAs and HBS's billers to cease their practice of listing and billing for more than thirty (30) minutes for each procedure. Instead, **DESAI** and **RUSHING** instructed the CRNAs and HBS's billers that anesthesia time was to begin when the CRNA first started talking to a patient and end when the patient left the procedure room. After this instruction, anesthesia times billed to Medicare, Medicaid and the Private Insurers by HBS plummeted.

I. All of the acts set forth in Counts Two through Twenty-Six below, hereby incorporated herein as overt acts.

All in violation of Title 18, United States Code, Section 371.

COUNTS TWO THROUGH TWENTY-SIX
Health Care Fraud
(Title 18, United States Code, Sections 1347 and 2)

26. The Grand Jury further charges and incorporates by reference the allegations of paragraphs 1 through 16 and 18 through 25, above, as though fully set forth herein.

27. On or about the date of each count listed below, in the District of Nevada and elsewhere,

DIPAK DESAI, M.D., and
TONYA RUSHING,

defendants herein, aided and abetted by each other, for the purposes of executing the scheme and artifice described above, knowingly and willfully submitted and caused to be submitted to Medicare, Medicaid and the Private Insurers, claims for reimbursement for anesthesia services which **DESAI** and **RUSHING** knew were overstated, and thereby obtained monies owned by and under the custody and control of Medicare, Medicaid and the Private Insurers as set forth below, with each submission constituting a separate violation of Title 18, United States Code, Sections 1347 and 2:

Count	Patient	Date of Service	CPT Code Billed	Insurer
2	R.C.	July 28, 2005	CPT 00740	Blue Cross / Blue Shield
3	H.S.	October 3, 2005	CPT 00810	Blue Cross / Blue Shield
4	C.M.	May 11, 2006	CPT 00740	Medicaid
5	L.G.	May 15, 2006	CPT 00810	United Healthcare
6	L.O	June 7, 2006	CPT 00810	United Healthcare
7	E.G.	October 26, 2006	CPT 00810	Medicaid
8	D.P.	November 1, 2006	CPT 00740	Teamsters Security Fund
9	S.C.	November 22, 2006	CPT 00810	Aetna
10	D.Mu.	April 2, 2007	CPT 00740	Anthem
11	N.D.	April 9, 2007	CPT 00740	Anthem
12	K.W.	May 9, 2007	CPT 00740	Medicare
13	T.P.	May 16, 2007	CPT 00810	Regence Blue Cross
14	R.M.	May 23, 2007	CPT 00810	Medicare
15	D.Ma.	May 24, 2007	CPT 00740	Culinary Fund
16	A.M.	June 5, 2007	CPT 00810	Aetna
17	R.D.	June 27, 2007	CPT 00810	United Healthcare

18	D.D.	July 9, 2007	CPT 00810	Medicaid
19	B.C.	September 10, 2007	CPT 00740	Medicare
20	M.R.	November 5, 2007	CPT 00810	Culinary Fund
21	D.A.	November 14, 2007	CPT 00740	Aetna
22	V.M.	November 19, 2007	CPT 00740	Blue Cross / Blue Shield
23	B.T	January 10, 2008	CPT 00740	Medicare
24	E.S.	January 29, 2008	CPT 00810	Medicare
25	R.H.	February 1, 2008	CPT 00740	Culinary Fund
26	C.C.	February 8, 2008	CPT 00740	Blue Cross / Blue Shield

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FORFEITURE ALLEGATION
Healthcare Fraud

1. The allegations contained in Counts One through Twenty-Six of this Criminal Indictment are hereby realleged and incorporated herein by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 982(a)(7).

2. Upon conviction of the felony offenses charged in Counts One Through Twenty-Six of this Criminal Indictment,

DIPAK DESAI, M.D., and
TONYA RUSHING,

defendants herein, shall forfeit to the United States of America, any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the violations of Title 18, United States Code, Sections 1347, or Title 18, United States Code, Section 371, conspiracy to violate such offenses, an *in personam* criminal forfeiture money judgment up to $8,100,000.00 in United States Currency.

3. If any property subject to forfeiture pursuant to Title 18, United States Code, Section 982(a)(2)(A), as a result of any act or omission of the defendants-

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property that cannot be divided without difficulty;

it is the intent of the United States of America, pursuant to Title 18, United States Code, Section 982(b)(1) and Title 21, United States Code, Section 853(p), to seek forfeiture of any properties of the defendants up to $8,100,000.00 in United States Currency.

. . .

All pursuant to Title 18, United States Code, Section 982(a)(7) and (b)(1); Title 18, United States Code, Section 1347 and 371; and Title 21, United States Code, Section 853(p).

DATED: this 27 day of April, 2011.

A TRUE BILL:

/s/
FOREPERSON OF THE GRAND JURY

DANIEL G. BOGDEN
United States Attorney

CRANE M. POMERANTZ
NANCY J. KOPPE
Assistant United States Attorneys

MARK KEMBERLING
Special Assistant United States Attorney

Exhibit B

Federal Amended Judgment of Conviction

AO 245C (Rev 09/11) Amended Judgment in a Criminal Case
Sheet 1

(NOTE: Identify Changes with Asterisks (*))

UNITED STATES DISTRICT COURT

District of Nevada

UNITED STATES OF AMERICA
v.
DIPAK DESAI, M.D

AMENDED JUDGMENT IN A CRIMINAL CASE

Case Number: 2:11-CR-166-LRH-CWH-1
USM Number: 46332-048

Date of Original Judgment: 7/10/15
(Or Date of Last Amended Judgment)

Richard Wright, Retained
Defendant's Attorney

Reason for Amendment:

☐ Correction of Sentence on Remand (18 U.S.C. § 3742(f)(1) and (2))

☐ Reduction of Sentence for Changed Circumstances (Fed. R. Crim. P. 35(b))

☐ Correction of Sentence by Sentencing Court (Fed. R. Crim. P. 35(a))

(X) Correction of sentence for Clerical Mistake (Fed. R. Crim. P. 36)

☐ Modification of Supervision Conditions (18 U.S.C. §§ 3563(c) or 3583(e))

☐ Modification of Imposed Term of Imprisonment for Extraordinary and Compelling Reasons (18 U.S.C. § 3582(c)(1))

☐ Modification of Imposed Term of Imprisonment for Retroactive Amendment(s) to the Sentencing Guidelines (18 U.S.C. § 3582(c)(2))

☐ Direct Motion to District Court Pursuant ☐ 28 U.S.C. § 2255 or ☐ 18 U.S.C. § 3559(c)(7)

☐ Modification of Restitution Order (18 U.S.C. § 3664)

THE DEFENDANT:

(X) pleaded guilty to count(s) 1 and 24 of the Indictment filed 4/27/11

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☐ was found guilty on count(s) _____ After a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. 371	Conspiracy to Commit Health Care Fraud	2/2008	1
18 U.S.C. 1347 and 2	Health Care Fraud, Aiding and Abetting	1/29/08	24

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s) _____

(X) Count(s) 2 - 23, 25, and 26 are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States Attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States Attorney of material changes in economic circumstances.

✓ FILED ____ RECEIVED
____ ENTERED ____ SERVED ON
COUNSEL/PARTIES OF RECORD

JUL 14 2015

CLERK US DISTRICT COURT
DISTRICT OF NEVADA
BY: DBN DEPUTY

7/9/15
Date of Imposition of Judgment

Signature of Judge
Larry R. Hicks, United States District Judge
Name and Title of Judge

7/14/15
Date

DEFENDANT: DIPAK DESAI, M.D.
CASE NUMBER: 2:11-CR-166-LRH-CWH-1

IMPRISONMENT

* The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of: **SIXTY (60) MONTHS AS TO COUNT 1; SEVENTY ONE (71) MONTHS AS TO COUNT 24, TO RUN CONCURRENT AND CONCURRENT TO Nevada state case No. C-265107; less 941 days time credit as so ordered by the Court pursuant to Sentencing Guideline 5G1.3(b).**

(X) The court makes the following recommendations to the Bureau of Prisons:

The Court recommends the defendant continue to serve his sentence at the state prison facility.

(X) The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on _____.

☐ as notified by the United States Marshal.

☐ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☐ before 2 p.m. on _____.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____ a _____

_____, with a certified copy of this judgment.

_____

UNITED STATES MARSHAL

By _____

DEPUTY UNTIED STATES MARSHAL

DEFENDANT: DIPAK DESAI, M.D.
CASE NUMBER: 2:11-CR-166-LRH-CWH-1

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of: **3 YEARS AS TO COUNT 1; AND 3 YEARS AS TO COUNT 24 TO RUN CONCURRENT.**

The defendant must report to the probation office in the district to which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state or local crime.

The defendant shall not unlawfully possess a controlled substance. The defendant shall refrain from any unlawful use of a controlled substance. The defendant shall submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court, not to exceed 104 tests annually.

(X) The above drug testing condition is suspended, based on the court's determination that the defendant poses a low risk of future substance abuse. *(Check, if applicable.)*

(X) The defendant shall not possess a firearm, ammunition, destructive device, or any other dangerous weapon. *(Check, if applicable.)*

(X) The defendant shall cooperate in the collection of DNA as directed by the probation officer. *(Check, if applicable.)*

☐ The defendant shall comply with the requirements of the Sex Offender Registration and Notification Act (42 U.S.C. § 16901, *et seq.*) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in which he or she resides, works, is a student, or was convicted of a qualifying offense. *(Check, if applicable.)*

☐ The defendant shall participate in an approved program for domestic violence. *(Check, if applicable.)*

If this judgment imposes a fine or restitution, it is a condition of supervised release that the defendant pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant must comply with the standard conditions that have been adopted by this court as well as with any additional conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

1) the defendant shall not leave the judicial district without the permission of the court or probation officer;
2) the defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
3) the defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
4) the defendant shall support his or her dependents and meet other family responsibilities;
5) the defendant shall work regularly at a lawful occupation, unless excused by the probation officer for schooling, training, or other acceptable reasons;
6) the defendant shall notify the probation officer at least ten days prior to any change in residence or employment;
7) the defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, or administer any controlled substance or any paraphernalia related to any controlled substances, except as prescribed by a physician;
8) the defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered;
9) the defendant shall not associate with any persons engaged in criminal activity and shall not associate with any person convicted of a felony, unless granted permission to do so by the probation officer;
10) the defendant shall permit a probation officer to visit him or her at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view of the probation officer;
11) the defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
12) the defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court; and
13) as directed by the probation officer, the defendant shall notify third parties of risks that may be occasioned by the defendant's criminal record or personal history or characteristics and shall permit the probation officer to make such notifications and to confirm the defendant's compliance with such notification requirement.

DEFENDANT: DIPAK DESAI, M.D.
CASE NUMBER: 2:11-CR-166-LRH-CWH-1

SPECIAL CONDITIONS OF SUPERVISION

1. Debt Obligation - The defendant shall be prohibited from incurring new credit charges, opening additional lines of credit, or negotiating or consummating any financial contracts, without the approval of the probation office.

2. Access to Financial Information - The defendant shall provide the probation office access to any requested financial information, including personal income tax returns, authorization for release of credit information, and any other business or financial information in which the defendant has a control or interest.

3. Employment Restriction - The defendant shall be restricted from engaging in employment, consulting, or any association with any medical business for a period of 3 years.

4. Warrantless Search - The defendant shall submit to the search of his person, and any property, residence, or automobile under his/her control by the probation office, or any other authorized person under the immediate and personal supervision of the probation office without a search warrant to ensure compliance with all conditions of release.

5. Possession of Weapon - The defendant shall not possess, have under his control, or have access to any firearm, explosive device, or other dangerous weapons, as defined by federal, state or local law.

6. Report to Probation Office After Release from Custody - The defendant shall report in person to the probation office in the District to which the defendant is released within 72 hours of release from custody.

Upon a finding of a violation of probation or supervised release, I understand that the court may (1) revoke supervision, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

These conditions have been read to me. I fully understand the conditions and have been provided a copy of them.

Defendant's signature _____ Date _____

Signature of the U.S. Probation Officer/Designated Witness _____ Date _____

DEFENDANT: DIPAK DESAI, M.D.
CASE NUMBER: 2:11-CR-166-LRH-CWH-1

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

		Assessment		Fine		Restitution
TOTALS	$	**100.00 (Count 1)** **100.00 (Count 24)** **Total: $200.00**	$	**WAIVED**	$	**2,213,550.00**

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage
FINAL RESTITUTION VICTIM LIST TO BE PROVIDED BY COUNSEL		$2,213,550.00	

Clerk, U.S. District Court
Attn: Financial Office
Case No. 2:11-CR-166-LRH-CWH-1
333 Las Vegas Boulevard, South
Las Vegas, NV 89101

TOTALS	$_____	$ 2,213,550.00

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: DIPAK DESAI, M.D.
CASE NUMBER: 2:11-CR-166-LRH-CWH-1

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A (X) Lump sum payment of $ 2,213,750.00 due immediately, balance due

☐ Not later than _____, or
☐ in accordance ☐ C, ☐ D, ☐ E, or (X) F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F (X) Special instructions regarding the payment of criminal monetary penalties:
Any unpaid balance shall be paid at a monthly rate of not less than 10% of any income earned during incarceration and/or gross income while on supervision, subject to adjustment by the Court based upon ability to pay.

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Defendant and Co-Defendant Names and Case Numbers *(including defendant number)*, Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

(X) The defendant shall forfeit the defendant's interest in the following property to the United States:
SEE ATTACHED

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	2:11-CR-166-LRH-(CWH)
	)	
DIPAK DESAI, M.D.,	)	
	)	
Defendant.	)	

FINAL ORDER OF FORFEITURE

This Court found that DIPAK DESAI, M.D., shall pay the criminal forfeiture money judgment of $2,213,550 in United States Currency, to be held jointly and severally liable with any codefendant, pursuant to Fed. R. Crim. P. 32.2(b)(1) and (2); Title 18, United States Code, Section 982(a)(7); and Title 21, United States Code, Section 853(p). Criminal Indictment, ECF No. 1; Change of Plea, ECF No. 85; Plea Memorandum, ECF No. 86; Order of Forfeiture, ECF No. 89.

THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the United States recover from DIPAK DESAI, M.D., the criminal forfeiture money judgment in the amount of $2,213,550 in United States Currency pursuant to Fed. R. Crim. P. 32.2(b)(4)(A) and (B); Title 18, United States Code, Section 982(a)(7); and Title 21, United States Code, Section 853(p).

DATED this 7 day of July, 2015.

UNITED STATES DISTRICT JUDGE

Exhibit C

Federal Final Order of Forfeiture

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, v. DIPAK DESAI, M.D., Defendant.	2:11-CR-166-LRH-(CWH)

FINAL ORDER OF FORFEITURE

This Court found that DIPAK DESAI, M.D., shall pay the criminal forfeiture money judgment of $2,213,550 in United States Currency, to be held jointly and severally liable with any codefendant, pursuant to Fed. R. Crim. P. 32.2(b)(1) and (2); Title 18, United States Code, Section 982(a)(7); and Title 21, United States Code, Section 853(p). Criminal Indictment, ECF No. 1; Change of Plea, ECF No. 85; Plea Memorandum, ECF No. 86; Order of Forfeiture, ECF No 89.

THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the United States recover from DIPAK DESAI, M.D., the criminal forfeiture money judgment in the amount of $2,213,550 in United States Currency pursuant to Fed. R Crim. P. 32.2(b)(4)(A) and (B); Title 18, United States Code, Section 982(a)(7); and Title 21, United States Code, Section 853(p).

DATED this 7 day of July, 2015.

UNITED STATES DISTRICT JUDGE

Exhibit D

Docket in *State of Nevada v. Desai*, case no. C-12-283381-1

REGISTER OF ACTIONS
CASE NO. C-12-283381-1

State of Nevada vs Dipak Desai

Case Type:	**Felony/Gross Misdemeanor**
Date Filed:	**08/10/2012**
Location:	**Department 21**
Cross-Reference Case Number:	**C283381**
Defendant's Scope ID #:	**1240942**
Grand Jury Case Number:	**09BGJ119**

RELATED CASE INFORMATION

Related Cases
10C265107-1 (Consolidated)
10C265107-2 (Consolidated)
10C265107-3 (Consolidated)
C-12-283381-2 (Multi-Defendant Case)
C-12-283381-3 (Multi-Defendant Case)

PARTY INFORMATION

Defendant	**Desai, Dipak Kantilal**	**Lead Attorneys** **Richard Allen Wright** *Retained* 7023824004(W)
Plaintiff	**State of Nevada**	**Steven B Wolfson** 702-671-2700(W)

CHARGE INFORMATION

Charges: Desai, Dipak Kantilal	Statute	Level	Date
1. INSURANCE FRAUD	686A.291	Felony	07/25/2007
2. PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM	202.595.2	Felony	07/25/2007
3. CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM	200.495.2b	Felony	07/25/2007
4. INSURANCE FRAUD	686A.291	Felony	07/25/2007
5. INSURANCE FRAUD	686A.291	Felony	09/21/2007
6. PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM	202.595.2	Felony	09/21/2007
7. CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM	200.495.2b	Felony	09/21/2007
8 INSURANCE FRAUD	686A.291	Felony	09/21/2007
9. PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM	202.595.2	Felony	09/21/2007
10. CRIMINAL NEGLECT OF PATIENT, RESULTING IN SUBSTANTIAL BODILY HARM	200.495 2b	Felony	09/21/2007
11. INSURANCE FRAUD	686A.291	Felony	09/21/2007
12. PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM	202.595.2	Felony	09/21/2007
13. CRIMINAL NEGLECT OF PATIENT, RESULTING IN SUBSTANTIAL BODILY HARM	200.495.2b	Felony	09/21/2007
14. INSURANCE FRAUD	686A 291	Felony	09/21/2007
15. INSURANCE FRAUD	686A.291	Felony	09/21/2007
16 PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM	202.595.2	Felony	09/21/2007
17 CRIMINAL NEGLECT OF PATIENT, RESULTING IN SUBSTANTIAL BODILY HARM	200.495 2b	Felony	09/21/2007
18. INSURANCE FRAUD	686A.291	Felony	09/21/2007
19. PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM	202.595 2	Felony	09/21/2007
20. CRIMINAL NEGLECT OF PATIENT, RESULTING IN SUBSTANTIAL BODILY HARM	200.495.2b	Felony	09/21/2007
21. INSURANCE FRAUD	686A.291	Felony	09/21/2007

22. PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM	202.595.2	Felony	09/21/2007
23. CRIMINAL NEGLECT OF PATIENT, RESULTING IN SUBSTANTIAL BODILY HARM	200.495.2b	Felony	09/21/2007
24. INSURANCE FRAUD	686A.291	Felony	09/20/2007
25. THEFT	205.0835.3	Felony	07/25/2007
26. OBTAINING MONEY UNDER FALSE PRETENSES	205.380.1a	Felony	09/20/2007
27. OBTAINING MONEY UNDER FALSE PRETENSES	205.380.1a	Felony	09/20/2007
28. MURDER, SECOND DEGREE	200.030.2	Felony	09/21/2007

EVENTS & ORDERS OF THE COURT

OTHER EVENTS AND HEARINGS

08/10/2012 **Indictment**
08/10/2012 **Grand Jury Indictment** (11:45 AM) (Judicial Officer Bell, Linda Marie)
Parties Present
Minutes
Result: Matter Heard
08/16/2012 **Order**
to Seal Grand Jury exhibits
08/16/2012 **Order**
Order To Seal Grand Jury Exhibits
08/21/2012 **Reporters Transcript**
Reporters Transcript of Proceedings - Grand Jury August 10, 2012
08/21/2012 **Media Request and Order**
Media Request and Order Allowing Camera Access to Court Proceedings
08/21/2012 **Media Request and Order**
Media Request and Order for Camera Access to Court Proceedings
08/22/2012 **Initial Arraignment** (9:30 AM) (Judicial Officer Miley, Stefany)
Minutes
Result: Plea Entered
08/22/2012 **Bail Set**
$250,000.00
08/23/2012 **Receipt for Grand Jury Transcript**
08/28/2012 **Media Request and Order**
Media Request and Order for Camera Access to Court Proceedings
09/04/2012 **Recorders Transcript of Hearing**
Transcript of Proceedings Re: Arraignment (All) Defendant's Motion for Bail on Order Shortening Time (Mathahs) Deft's Motion to Stay Proceedings Pending Resolution of Writ Proceedings Pursuant to NRAP 8(A) August 22, 2012
09/07/2012 **Reporters Transcript**
Reporters Transcript of Proceedings - Grand Jury Instructions August 10, 2012
09/11/2012 **Receipt for Grand Jury Transcript**
09/19/2012 **Status Check: Trial Setting** (9:30 AM) (Judicial Officer Miley, Stefany)
Minutes
Result: Trial Date Set
09/24/2012 **Motion to Consolidate**
Defendant Desai's Motion to Consolidate Related Cases
10/02/2012 **All Pending Motions** (9:30 AM) (Judicial Officer Adair, Valerie)
10/02/2012, 10/04/2012
Defendant Desai's Motion to Consolidate C265107 with C283381
Parties Present
Minutes
Result: Matter Heard
10/15/2012 **Notice of Department Reassignment**
10/29/2012 **Petition**
Petition for Writ of Habeas Corpus
10/30/2012 **Memorandum**
Defendant Desai's Memorandum in Support of Petition for Wit of Habeas Corpus and Alternative Motion to Dismiss Murder Indictment
11/01/2012 **Status Check** (9:30 AM) (Judicial Officer Adair, Valerie)
11/01/2012, 01/08/2013
Experts/Trial Readiness
Minutes
Result: Matter Continued
11/05/2012 **Certificate of Service**
Certificate of Service
11/05/2012 **Order**
Order to Issue Writ of Habeas Corpus
11/05/2012 **Writ**
Writ of Habeas Corpusd
11/13/2012 **Petition for Writ of Habeas Corpus** (9:30 AM) (Judicial Officer Adair, Valerie)
11/13/2012, 12/11/2012
Parties Present
Minutes

	Result: Briefing Schedule Set
12/04/2012	**Reply**
	Defendant Desai's Reply to State's Return to Writ of Habeas Corpus Regarding the Murder Indictment
12/11/2012	**All Pending Motions** (9:30 AM) (Judicial Officer Adair, Valerie)
12/19/2012	**Decision** (3:00 PM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Denied in Part
12/21/2012	**Motion**
	Defendant's Desai's Motion and Notice of Motion for Competency Evaluation
01/08/2013	*CANCELED* **Status Check** (9:30 AM) (Judicial Officer Adair, Valerie)
	Vacated - On in Error
	Experts
01/08/2013	**Motion** (9:30 AM) (Judicial Officer Adair, Valerie)
	Defendant's Desai's Motion and Notice of Motion for Competency Evaluation
01/11/2013	**Recorders Transcript of Hearing**
	Recorder's Transcript of Hearing re: Defendant's Petition for Writ of Habeas Corpus (Desai)(Both)Defendant Keith Mathahs' Petition for Writ of Habeas Corpus or in the Alternative, Motion to Dismiss Indictment (Both), Defendant Ronald Lakeman's Petition and Joinder, Tuesday, December 11, 2012
01/11/2013	**Recorders Transcript of Hearing**
	Recorder's Transcript of Hearing Re: Defendant Desai's Motion for Competency Evaluation, Status Check: Experts/Trial Readiness (All), Tuesday, January 8, 2013
03/11/2013	**Opposition to Motion**
	Defendant Desai's Opposition to State's Motion to Admit Foreign Documents Relating to Rodolfo Meana
04/11/2013	**Amended Indictment**
	Fourth Amended Indictment
04/16/2013	**Calendar Call** (9:30 AM) (Judicial Officer Adair, Valerie)
	Minutes
	04/16/2013 Reset by Court to 04/16/2013
04/17/2013	**Reporters Transcript**
	Calendar Call (All), State's Motion to Admit Evidence of Other Crimes, Tuesday, April 16, 2013
04/19/2013	**Reporters Transcript**
	Transcript Re: Status Check: Experts (All) Thursday, march 7, 2013
04/22/2013	**Jury Trial** (9:30 AM) (Judicial Officer Adair, Valerie)
04/26/2013	**Jury Trial** (9:30 AM) (Judicial Officer Adair, Valerie)
04/29/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
04/30/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
05/01/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
05/03/2013	**Jury Trial** (10:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Matter Heard
05/06/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
05/06/2013	**Jury List**
05/07/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
05/07/2013	**Amended Indictment**
	Fifth Amended Indictment
05/08/2013	**Jury Trial** (9:30 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/08/2013	**Amended Jury List**
05/09/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/10/2013	**Jury Trial** (9:30 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/13/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/14/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/15/2013	**Jury Trial** (12:30 PM) (Judicial Officer Adair, Valerie)
05/16/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/17/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/20/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/21/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
05/22/2013	**Jury Trial** (12:30 AM) (Judicial Officer Adair, Valerie)
05/23/2013	**Jury Trial** (10:30 AM) (Judicial Officer Adair, Valerie)
05/24/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/28/2013	*CANCELED* **Petrocelli Hearing** (9:30 AM) (Judicial Officer Adair, Valerie)

	Vacated
05/28/2013	**Jury Trial** (12:30 PM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/29/2013	**Petrocelli Hearing** (9:00 AM) (Judicial Officer Adair, Valerie) **05/29/2013, 06/06/2013**
	Minutes
	Result: Matter Continued
05/29/2013	**Jury Trial** (12:30 PM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/30/2013	**Jury Trial** (9:45 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
05/31/2013	**Jury Trial** (9:30 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
06/03/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
06/03/2013	**Reporters Transcript** *Excerpt of Jury Trial - Day 13, Continued Testimony of Keith Mathahs, Monday, May 13, 2013*
06/04/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
06/05/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
06/06/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
06/06/2013	*CANCELED* **Petrocelli Hearing** (9:00 AM) (Judicial Officer Adair, Valerie) *Vacated - On In Error*
06/07/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
06/10/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Trial Continues
06/11/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/12/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/13/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/14/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/17/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/18/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/19/2013	**Jury Trial** (10:30 AM) (Judicial Officer Adair, Valerie)
06/20/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/20/2013	**Minute Order** (11:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Matter Heard
06/21/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/24/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/25/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/26/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/26/2013	**Proposed Jury Instructions Not Used At Trial**
06/27/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
06/27/2013	**Amended Jury List** *Second Amended Jury List*
06/27/2013	**Jury Instructions** *Defendant Desai's Proposed Special Jury Instructions*
06/28/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
07/01/2013	**Jury Trial** (9:00 AM) (Judicial Officer Adair, Valerie)
	Minutes
	Result: Verdict
07/01/2013	**Jury Verdict**
07/01/2013	**Jury Instructions**
10/23/2013	*CANCELED* **Calendar Call** (9:30 AM) (Judicial Officer Miley, Stefany) *Vacated*
10/28/2013	*CANCELED* **Jury Trial** (1:00 PM) (Judicial Officer Miley, Stefany) *Vacated*
11/05/2013	**Criminal Order to Statistically Close Case** *Criminal Order to Statistically Close Case*

FINANCIAL INFORMATION

	Defendant Desai, Dipak Kantilal			
	Total Financial Assessment			171.00
	Total Payments and Credits			171.00
	Balance Due as of 08/10/2018			**0.00**
08/16/2012	Transaction Assessment			4.00
08/16/2012	Payment (Window)	Receipt # 2012-103159-CCCLK	NATIONWIDE LEGAL NEVADA	(4.00)
05/13/2013	Transaction Assessment			72.00
05/13/2013	Payment (Window)	Receipt # 2013-58599-CCCLK	SNELL & WILMER LLP	(72.00)
07/02/2013	Transaction Assessment			87.00
07/02/2013	Payment (Window)	Receipt # 2013-80310-CCCLK	WEINBERG, WHEELER, HUDGINGS	(87.00)
07/09/2013	Transaction Assessment			8.00
07/09/2013	Payment (Window)	Receipt # 2013-82481-CCCLK	Taylor Fong	(8.00)

Exhibit E

Keith Mathahs' Plea Agreement

ORIGINAL

FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT

DEC 10 2012

BY LOUISA GARCIA, DEPUTY

GPA
STEVEN B. WOLFSON
Clark County District Attorney
Nevada Bar #001565
MICHAEL V. STAUDAHER
Chief Deputy District Attorney
Nevada Bar #008273
200 Lewis Avenue
Las Vegas, NV 89155-2212
(702) 671-2500
Attorney for Plaintiff

DISTRICT COURT
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,
Plaintiff,

-vs-

KEITH H. MATHAHS,
#2753191
Defendant.

CASE NO: 10C265107-3

DEPT NO: XXI

GUILTY PLEA AGREEMENT

I hereby agree to plead guilty to: **COUNT 1 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN DEATH (Category B Felony - NRS 0.060, 200.495); COUNT 2 - CRIMINAL NEGLECT OF PATIENTS (Category B Felony - NRS 0.060, 200.495); COUNT 3 - INSURANCE FRAUD (Category D Felony - NRS 686A.2815); COUNT 4 - OBTAINING MONEY UNDER FALSE PRETENSES (Category B Felony - NRS 205.265, 205.380)** and **COUNT 5 - CONSPIRACY TO COMMIT RACKETEERING (Gross Misdemeanor - NRS 199.480, 199.490, 207.350, 207.360, 207.370, 207.380, 207.390, 207.400)**, as more fully alleged in the charging document attached hereto as Exhibit "1".

My decision to plead guilty is based upon the plea agreement in this case which is as follows:

The State will retain the right to argue at sentencing within the parameters set forth hereinafter, but will not oppose concurrent time between the counts. Defendant agrees to

testify truthfully and completely about matters in the instant case at the trial of co-defendants, Dipak Desai and/or Ronald E. Lakeman. Defendant further agrees that he is subject to the jurisdiction of Nevada if he is physically outside of Nevada at the time of the issuance of any subpoena for such purposes. The State and Defendant agree that the sentencing of Defendant will be postponed until after the State trial and/or plea and/or sentencing of co-defendants, Dipak Desai and/or Ronald E. Lakeman. Defendant expressly agrees to waive defects, if any, in the pleadings and to withdraw any petition(s) to the Nevada Supreme Court that he may have filed or joined in for this matter. In exchange for Defendant's plea, the State agrees not to prosecute the Defendant for the murder of victim, Rodolfo Meana. The State further agrees not to argue for greater than a twenty-eight (28) to seventy-two (72) month maximum term on Count 1 related to Rodolfo Meana. The State further agrees to dismiss all remaining charges contained in the Second Amended Indictment. Defendant agrees to pay appropriate restitution, if any, to the named victim(s), in all counts contained in the Third Amended Indictment. The parties agree that restitution shall be strictly contingent upon proof adduced at a separate hearing prior to sentencing and shall not duplicate any amounts paid as civil awards or settlement agreements.

If the Court elects not to follow this negotiation, the State agrees that the Defendant may withdraw his plea and proceed to trail on the original charges contained in the Second Amended Indictment. At the time of the entry of change of plea pursuant to this Agreement, the parties shall place on the record in open court that this Agreement contemplates that the Court shall retain the discretion to reject the sentencing limitations consistent with the State's right to argue, as set forth above, and therefore refuse to accept the Defendant's change of plea, but that should the Court determine to accept the Defendant's change of plea and elect not to sentence the Defendant consistent with the limitations of the State's right to argue, as set forth above, the Defendant shall be permitted to withdraw his plea of guilty.

I agree to the forfeiture of any and all weapons or any interest in any weapons seized and/or impounded in connection with the instant case and/or any other case negotiated in whole or in part in conjunction with this plea agreement.

I understand and agree that, if I fail to interview with the Department of Parole and Probation, fail to appear at any subsequent hearings in this case, or an independent magistrate, by affidavit review, confirms probable cause against me for new criminal charges including reckless driving or DUI, but excluding minor traffic violations, that the State will have the unqualified right to argue for any legal sentence and term of confinement allowable for the crime(s) to which I am pleading guilty, including the use of any prior convictions I may have to increase my sentence as an habitual criminal to five (5) to twenty (20) years, life without the possibility of parole, life with the possibility of parole after ten (10) years, or a definite twenty-five (25) year term with the possibility of parole after ten (10) years.

Otherwise I am entitled to receive the benefits of these negotiations as stated in this plea agreement.

CONSEQUENCES OF THE PLEA

I understand that by pleading guilty I admit the facts which support all the elements of the offense(s) to which I now plead as set forth in Exhibit "1".

As to Count 1 - I understand that as a consequence of my plea of guilty the Court must sentence me to imprisonment in the Nevada Department of Corrections for a minimum term of not less than ONE (1) year and a maximum term of not more than TWENTY (20) years. The minimum term of imprisonment may not exceed forty percent (40%) of the maximum term of imprisonment.

As to Count 2 - I understand that as a consequence of my plea of guilty the Court must sentence me to imprisonment in the Nevada Department of Corrections for a minimum term of not less than ONE (1) year and a maximum term of not more than SIX (6) years. The minimum term of imprisonment may not exceed forty percent (40%) of the maximum term of imprisonment. I understand that I may also be fined up to $5,000.00.

As to Count 3 - I understand that as a consequence of my plea of guilty the Court must sentence me to imprisonment in the Nevada Department of Corrections for a minimum term of not less than ONE (1) year and a maximum term of not more than FOUR (4) years. The minimum term of imprisonment may not exceed forty percent (40%) of the maximum

term of imprisonment. I understand that I may also be fined up to $5,000.00.

As to Count 4 - I understand that as a consequence of my plea of guilty the Court must sentence me to imprisonment in the Nevada Department of Corrections for a minimum term of not less than ONE (1) year and a maximum term of not more than SIX (6) years. The minimum term of imprisonment may not exceed forty percent (40%) of the maximum term of imprisonment. I understand that I may also be fined up to $10,000.00.

As to Count 5 - I understand that as a consequence of my plea of guilty the Court must sentence me to imprisonment in the Nevada Department of Corrections for a minimum term of not less than ONE (1) year and a maximum term of not more than SIX (6) years. The minimum term of imprisonment may not exceed forty percent (40%) of the maximum term of imprisonment. I understand that I may also be fined up to $5,000.00.

I understand that the law requires me to pay an Administrative Assessment Fee. I understand that, if appropriate, I will be ordered to make restitution to the victim of the offense(s) to which I am pleading guilty and to the victim of any related offense which is being dismissed or not prosecuted pursuant to this agreement. I will also be ordered to reimburse the State of Nevada for any expenses related to my extradition, if any.

I understand that I am eligible for probation for the offense(s) to which I am pleading guilty. I understand that, except as otherwise provided by statute, the question of whether I receive probation is in the discretion of the sentencing judge.

I also understand that I must submit to blood and/or saliva tests under the Direction of the Division of Parole and Probation to determine genetic markers and/or secretor status.

I further understand that if I am pleading guilty to charges of Burglary, Invasion of the Home, Possession of a Controlled Substance with Intent to Sell, Sale of a Controlled Substance, or Gaming Crimes, for which I have prior felony conviction(s), I will not be eligible for probation and may receive a higher sentencing range.

I understand that if more than one sentence of imprisonment is imposed and I am eligible to serve the sentences concurrently, the sentencing judge has the discretion to order the sentences served concurrently or consecutively.

I also understand that information regarding charges not filed, dismissed charges, or charges to be dismissed pursuant to this agreement may be considered by the judge at sentencing.

I have not been promised or guaranteed any particular sentence by anyone. I know that my sentence is to be determined by the Court within the limits prescribed by statute.

I understand that if my attorney or the State of Nevada or both recommend any specific punishment to the Court, the Court is not obligated to accept the recommendation.

I understand that if the offense(s) to which I am pleading guilty was committed while I was incarcerated on another charge or while I was on probation or parole that I am not eligible for credit for time served toward the instant offense(s).

I understand that if I am not a United States citizen, any criminal conviction will likely result in serious negative immigration consequences including but not limited to:

1. The removal from the United States through deportation;
2. An inability to reenter the United States;
3. The inability to gain United States citizenship or legal residency;
4. An inability to renew and/or retain any legal residency status; and/or
5. An indeterminate term of confinement, with the United States Federal Government based on my conviction and immigration status.

Regardless of what I have been told by any attorney, no one can promise me that this conviction will not result in negative immigration consequences and/or impact my ability to become a United States citizen and/or a legal resident.

I understand that the Division of Parole and Probation will prepare a report for the sentencing judge prior to sentencing. This report will include matters relevant to the issue of sentencing, including my criminal history. This report may contain hearsay information regarding my background and criminal history. My attorney and I will each have the opportunity to comment on the information contained in the report at the time of sentencing. Unless the District Attorney has specifically agreed otherwise, the District Attorney may also comment on this report.

WAIVER OF RIGHTS

By entering my plea of guilty, I understand that I am waiving and forever giving up the following rights and privileges:

1. The constitutional privilege against self-incrimination, including the right to refuse to testify at trial, in which event the prosecution would not be allowed to comment to the jury about my refusal to testify.

2. The constitutional right to a speedy and public trial by an impartial jury, free of excessive pretrial publicity prejudicial to the defense, at which trial I would be entitled to the assistance of an attorney, either appointed or retained. At trial the State would bear the burden of proving beyond a reasonable doubt each element of the offense(s) charged.

3. The constitutional right to confront and cross-examine any witnesses who would testify against me.

4. The constitutional right to subpoena witnesses to testify on my behalf.

5. The constitutional right to testify in my own defense.

6. The right to appeal the conviction with the assistance of an attorney, either appointed or retained, unless specifically reserved in writing and agreed upon as provided in NRS 174.035(3). I understand this means I am unconditionally waiving my right to a direct appeal of this conviction, including any challenge based upon reasonable constitutional, jurisdictional or other grounds that challenge the legality of the proceedings as stated in NRS 177.015(4). However, I remain free to challenge my conviction through other post-conviction remedies including a habeas corpus petition pursuant to NRS Chapter 34.

VOLUNTARINESS OF PLEA

I have discussed the elements of all of the original charge(s) against me with my attorney and I understand the nature of the charge(s) against me.

I understand that the State would have to prove each element of the charge(s) against me at trial.

I have discussed with my attorney any possible defenses, defense strategies and circumstances which might be in my favor.

All of the foregoing elements, consequences, rights, and waiver of rights have been thoroughly explained to me by my attorney.

I believe that pleading guilty and accepting this plea bargain is in my best interest, and that a trial would be contrary to my best interest.

I am signing this agreement voluntarily, after consultation with my attorney, and I am not acting under duress or coercion or by virtue of any promises of leniency, except for those set forth in this agreement.

I am not now under the influence of any intoxicating liquor, a controlled substance or other drug which would in any manner impair my ability to comprehend or understand this agreement or the proceedings surrounding my entry of this plea.

My attorney has answered all my questions regarding this guilty plea agreement and its consequences to my satisfaction and I am satisfied with the services provided by my attorney.

DATED this 10 day of December, 2012.

KEITH H. MATHAHS
Defendant

AGREED TO BY:

MICHAEL V. STAUDAHER
Chief Deputy District Attorney
Nevada Bar #008273

CERTIFICATE OF COUNSEL:

I, the undersigned, as the attorney for the Defendant named herein and as an officer of the court hereby certify that:

1. I have fully explained to the Defendant the allegations contained in the charge(s) to which guilty pleas are being entered.

2. I have advised the Defendant of the penalties for each charge and the restitution that the Defendant may be ordered to pay.

3. I have inquired of Defendant facts concerning Defendant's immigration status and explained to Defendant that if Defendant is not a United States citizen any criminal conviction will most likely result in serious negative immigration consequences including but not limited to:

   a. The removal from the United States through deportation;

   b. An inability to reenter the United States;

   c. The inability to gain United States citizenship or legal residency;

   d. An inability to renew and/or retain any legal residency status; and/or

   e. An indeterminate term of confinement, by with United States Federal Government based on the conviction and immigration status.

   Moreover, I have explained that regardless of what Defendant may have been told by any attorney, no one can promise Defendant that this conviction will not result in negative immigration consequences and/or impact Defendant's ability to become a United States citizen and/or legal resident.

4. All pleas of guilty offered by the Defendant pursuant to this agreement are consistent with the facts known to me and are made with my advice to the Defendant.

5. To the best of my knowledge and belief, the Defendant:

   a. Is competent and understands the charges and the consequences of pleading guilty as provided in this agreement,

   b. Executed this agreement and will enter all guilty pleas pursuant hereto voluntarily, and

   c. Was not under the influence of intoxicating liquor, a controlled substance or other drug at the time I consulted with the Defendant as certified in paragraphs 1 and 2 above.

Dated: This 10 day of December, 2012.

ATTORNEY FOR DEFENDANT

sam-MVU

AIND
STEVEN B. WOLFSON
Clark County District Attorney
Nevada Bar #001565
MICHAEL V. STAUDAHER
Chief Deputy District Attorney
Nevada Bar #008273
200 Lewis Avenue
Las Vegas, Nevada 89155-2212
(702) 671-2500
Attorney for Plaintiff

DISTRICT COURT

CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

KEITH H. MATHAHS, #2753191

Defendant.

Case No. 10C265107-3
Dept. No. XXI

THIRD AMENDED INDICTMENT

STATE OF NEVADA)
) ss.
COUNTY OF CLARK)

The Defendant(s) above named, KEITH H. MATHAHS accused by the Clark County Grand Jury of the crime(s) of **CRIMINAL NEGLECT OF PATIENTS RESULTING IN DEATH (Category B Felony - NRS 0.060, 200.495); CRIMINAL NEGLECT OF PATIENTS (Category B Felony - NRS 0.060, 200.495); INSURANCE FRAUD (Category D Felony - NRS 686A.2815); OBTAINING MONEY UNDER FALSE PRETENSES (Category B Felony - NRS 205.265, 205.380)** and **CONSPIRACY TO COMMIT RACKETEERING (Gross Misdemeanor - NRS 199.480, 199.490, 207.350, 207.360, 207.370, 207.380, 207.390, 207.400)**, committed at and within the County of Clark, State of Nevada, on or between June 3, 2005, and May 5, 2008, as follows:

EXHIBIT "1"

P:\WPDOCS\IND\003\00379305-3.doc

COUNT 1 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN DEATH

Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI, being professional caretakers of RODOLFO MEANA, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said RODOLFO MEANA, resulting in the death of RODOLFO MEANA, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, by performing one or more of the following acts: (1) by directly or indirectly instructing employees of the Endoscopy Center of Southern Nevada, (ECSN) to administer one or more doses of the anesthetic drug Propofol from a single use vial to more than one patient contrary to the express product labeling of said drug and in violation of universally accepted safety precautions for the administration of said drug; and/or (2) by creating an employment environment in which said employees were pressured to administer one or more doses of the anesthetic drug Propofol from a single use vial to more than one patient contrary to the express product labeling of said drug and in violation of universally accepted safety precautions for the administration of said drug; and/or (3) by directly or indirectly instructing said employees, and/or creating an employment environment in which said employees were pressured to reuse syringes and/or needles and/or biopsy forceps and/or snares and/or bite blocks contrary to the express product labeling of said items, and/or in violation of universally accepted safety precautions for the use of said items; and/or (4) by directly or indirectly instructing said employees, and/or creating an employment environment in which said employees were pressured to limit the use of medical supplies necessary to conduct safe endoscopic procedures; and/or (5) by directly or indirectly instructing said employees, and/or creating an

employment environment in which said employees were pressured to falsely prechart patient records and/or rush patients through said endoscopy center and/or rush patient procedures at the expense of patient safety and/or well being; and/or (6) by directly or indirectly scheduling and/or treating an unreasonable number of patients per day which resulted in substandard care and/or jeopardized the safety and/or well being of said patients; and/or (7) by directly or indirectly instructing said employees, and/or creating an employment environment in which said employees were inadequately trained and/or pressured to provide endoscopy scopes for patient procedures that were not adequately cleaned and/or prepared contrary to the express manufacturers guidelines for the handling and processing of said endoscopy scopes, and/or in violation of universally accepted safety precautions for the use of said scopes; and/or (8) by methods unknown; for the purpose of enhancing the financial profit of ECSN, said act(s) or omission(s) causing the transmission of Hepatitis C virus from patient KENNETH RUBINO to patient RODOLFO MEANA, who was not previously infected with the Hepatitis C virus; Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 2 - CRIMINAL NEGLECT OF PATIENTS

Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI, being professional caretakers of MICHAEL WASHINGTON and/or STACY HUTCHINSON and/or PATTY ASPINWALL and/or SONIA ORELLANA-RIVERA and/or CAROLE GRUESKIN and/or GWENDOLYN MARTIN, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said MICHAEL

WASHINGTON and/or STACY HUTCHINSON and/or PATTY ASPINWALL and/or SONIA ORELLANA-RIVERA and/or CAROLE GRUESKIN and/or GWENDOLYN MARTIN, resulting in substantial bodily harm to MICHAEL WASHINGTON and/or STACY HUTCHINSON and/or PATTY ASPINWALL and/or SONIA ORELLANA-RIVERA and/or CAROLE GRUESKIN and/or GWENDOLYN MARTIN, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, by performing one or more of the following acts: (1) by directly or indirectly instructing employees of the Endoscopy Center of Southern Nevada, (ECSN) to administer one or more doses of the anesthetic drug Propofol from a single use vial to more than one patient contrary to the express product labeling of said drug and in violation of universally accepted safety precautions for the administration of said drug; and/or (2) by creating an employment environment in which said employees were pressured to administer one or more doses of the anesthetic drug Propofol from a single use vial to more than one patient contrary to the express product labeling of said drug and in violation of universally accepted safety precautions for the administration of said drug; and/or (3) by directly or indirectly instructing said employees, and/or creating an employment environment in which said employees were pressured to reuse syringes and/or needles and/or biopsy forceps and/or snares and/or bite blocks contrary to the express product labeling of said items, and/or in violation of universally accepted safety precautions for the use of said items; and/or (4) by directly or indirectly instructing said employees, and/or creating an employment environment in which said employees were pressured to limit the use of medical supplies necessary to conduct safe endoscopic procedures; and/or (5) by directly or indirectly instructing said employees, and/or creating an employment environment in which said employees were pressured to falsely

prechart patient records and/or rush patients through said endoscopy center and/or rush patient procedures at the expense of patient safety and/or well being; and/or (6) by directly or indirectly scheduling and/or treating an unreasonable number of patients per day which resulted in substandard care and/or jeopardized the safety and/or well being of said patients; and/or (7) by directly or indirectly instructing said employees, and/or creating an employment environment in which said employees were inadequately trained and/or pressured to provide endoscopy scopes for patient procedures that were not adequately cleaned and/or prepared contrary to the express manufacturers guidelines for the handling and processing of said endoscopy scopes, and/or in violation of universally accepted safety precautions for the use of said scopes; and/or (8) by methods unknown; for the purpose of enhancing the financial profit of ECSN, said act(s) or omission(s) causing the transmission of Hepatitis C virus from patient SHARRIEFF ZIYAD to patient MICHAEL WASHINGTON, and/or said act(s) or omission(s) causing the transmission of Hepatitis C virus from patient KENNETH RUBINO to patient STACY HUTCHINSON and/or said act(s) or omission(s) causing the transmission of Hepatitis C virus from patient KENNETH RUBINO to patient PATTY ASPINWALL, and/or said act(s) or omission(s) causing the transmission of Hepatitis C virus from patient KENNETH RUBINO to patient SONIA ORELLANA-RIVERA and/or said act(s) or omission(s) causing the transmission of Hepatitis C virus from patient KENNETH RUBINO to patient CAROLE GRUESKIN and/or said act(s) or omission(s) causing the transmission of Hepatitis C virus from patient KENNETH RUBINO to patient GWENDOLYN MARTIN, who was not previously infected with the Hepatitis C virus; Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this

crime.

COUNT 3 - INSURANCE FRAUD

Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI, did knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to ANTHEM BLUE CROSS AND BLUE SHIELD that the billed anesthesia time and/or charges for the endoscopic procedure performed on SHARRIEFF ZIYAD and/or by falsely representing to VETERANS ADMINISTRATION that the billed anesthesia time and/or charges for the endoscopic procedure performed on MICHAEL WASHINGTON and/or by falsely representing to ANTHEM BLUE CROSS AND BLUE SHIELD that the billed anesthesia time and/or charges for the endoscopic procedure performed on KENNETH RUBINO and/or by falsely representing to HEALTH PLAN OF NEVADA that the billed anesthesia time and/or charges for the endoscopic procedure performed on STACY HUTCHINSON and/or by falsely representing to SECURE HORIZONS and/or PACIFICARE that the billed anesthesia time and/or charges for the endoscopic procedure performed on RODOLFO MEANA and/or by falsely representing to ANTHEM BLUE CROSS AND BLUE SHIELD that the billed anesthesia time and/or charges for the endoscopic procedure performed on PATTY ASPINWALL and/or by falsely representing to CULINARY WORKERS HEALTH FUND that the billed anesthesia time and/or charges for the endoscopic procedure performed on SONIA ORELLANA-RIVERA and/or by falsely representing to HEALTH PLAN OF NEVADA/SENIOR DIMENSIONS that the billed anesthesia time and/or charges for the

endoscopic procedure performed on CAROLE GRUESKIN and/or by falsely representing to PACIFICARE that the billed anesthesia time and/or charges for the endoscopic procedure performed on GWENDOLYN MARTIN were more than the actual anesthetic times and/or charges, said false representation resulting in the payment of money to Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI and/or their medical practice and/or the racketeering enterprise which exceeded that which would have normally been allowed for said procedure; Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 4 - OBTAINING MONEY UNDER FALSE PRETENSES

Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI, did with intent to cheat and defraud, wilfully, unlawfully, feloniously, knowingly, designedly, and by use of false pretenses, obtain $250.00, or more, lawful money of the United States from GWENDOLYN MARTIN, SONIA ORELLANA-RIVERA, STACY HUTCHINSON, KENNETH RUBINO, PATTY ASPINWALL, SHARRIEFF ZIYAD, MICHAEL WASHINGTON, CAROLE GRUESKIN and RODOLFO MEANA, and/or PACIFICARE, CULINARY WORKERS HEALTH FUND, ANTHEM BLUE CROSS AND BLUE SHIELD, HEALTH PLAN SOLUTIONS, HEALTH PLAN OF NEVADA/SENIOR DIMENSIONS, HEALTHCARE PARTNERS OF NEVADA, UNITED HEALTH SERVICES, HEALTH PLAN OF NEVADA, VETERANS ADMINISTRATION and SECURE HORIZONS within Las Vegas, Clark County, Nevada, in the following manner, to-wit: by falsely representing that the billed anesthesia times and/or charges for the endoscopic procedures performed on GWENDOLYN MARTIN, SONIA ORELLANA-

RIVERA, STACY HUTCHINSON, KENNETH RUBINO, PATTY ASPINWALL, SHARRIEFF ZIYAD, MICHAEL WASHINGTON, CAROLE GRUESKIN and RODOLFO MEANA were more than the actual anesthetic times and/or charges, said false representation resulting in the payment of money to Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI and/or the medical practice and/or the racketeering enterprise, which exceeded that which would have normally been allowed for said procedures Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 5 – CONSPIRACY TO COMMIT RACKETEERING

Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI, did then and there meet with each other and between themselves, and each of them with the other, wilfully and unlawfully conspire and agree to commit a crime, to-wit: racketeering, and in furtherance of said conspiracy, Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI, did then and there, within Clark County, Nevada knowingly, willfully and feloniously while employed by or associated with an enterprise, conduct or participate directly or indirectly in racketeering activity through the affairs of said enterprise; and/or with criminal intent receive any proceeds derived, directly or indirectly, from racketeering activity to use or invest, whether directly or indirectly, any part of the proceeds from racketeering activity; and/or through racketeering activity to acquire or maintain, directly or indirectly, any interest in or control of any enterprise; and/or intentionally organize, manage, direct, supervise or finance a criminal syndicate; and/or did conspire to engage in said acts, to-wit: by directly or indirectly causing and/or pressuring the employees and/or agents of the Endoscopy Center of Southern Nevada to falsify patient anesthesia

records from various endoscopic procedures; and/or to commit insurance fraud by directly or indirectly submitting said false anesthesia records to various insurance companies for the purpose of obtaining money under false pretenses from said insurance companies and/or patients; said fraudulent submissions resulting in the payment of monies to Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI and/or their medical practice and/or the enterprise, which exceeded the legitimate reimbursement amount allowed for said procedures; Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendant with RONALD ERNEST LAKEMAN and DIPAK KANTILAL DESAI acting with the intent to commit said crime.

DATED this 7th day of December, 2012.

STEVEN B. WOLFSON
Clark County District Attorney
Nevada Bar #001565

BY 
MICHAEL V. STAUDAHER
Chief Deputy District Attorney
Nevada Bar #008273

09BGJ049C/10F03793C/sam-MVU
LVMPD EV #0802292576
(TK11)

Exhibit F

Mathahs' Judgment of Conviction

Electronically Filed
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CLERK OF THE COURT

JOCP

DISTRICT COURT

CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

KEITH H. MATHAHS
#2753191

Defendant.

CASE NO. C265107-3

DEPT. NO. XXI

JUDGMENT OF CONVICTION

(PLEA OF GUILTY)

The Defendant previously appeared before the Court with counsel and entered a plea of guilty to the crimes of COUNT 1 – CRIMINAL NEGLECT OF PATIENTS RESULTING IN DEATH (Category B Felony), in violation of NRS 0.060, 200.495; COUNT 2 – CRIMINAL NEGLECT OF PATIENTS (Category B Felony), in violation of NRS 0.060, 200.495; COUNT 3 – INSURANCE FRAUD (Category D Felony), in violation of NRS 686A.2815; COUNT 4 – OBTAINING MONEY UNDER FALSE PRETENSES (Category B Felony), in violation of NRS 205.265, 205.380; and COUNT 5 – CONSPIRACY TO COMMIT RACKETEERING (Gross Misdemeanor), in violation of NRS 199.480, 199.490, 207.350, 207.360, 207.370, 207.380, 207.390, 207.400; thereafter, on the 31ST day of October, 2013, the Defendant was present in court for sentencing with his counsel, MICHAEL CRISTALLI, ESQ., and good cause appearing,

THE DEFENDANT IS HEREBY ADJUDGED guilty of said offenses and, in addition to the $25.00 Administrative Assessment Fee, and $150.00 DNA Analysis Fee including testing to determine genetic markers, the Defendant is sentenced as follows: AS TO COUNT 1 - TO A MAXIMUM of SEVENTY-TWO (72) MONTHS with a MINIMUM parole eligibility of TWENTY-EIGHT (28) MONTHS in the Nevada Department of Corrections (NDC); AS TO COUNT 2 - TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM parole eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 2 to run CONCURRENT with COUNT 1; AS TO COUNT 3 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM parole eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 3 to run CONCURRENT with COUNT 2; AS TO COUNT 4 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM parole eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 4 to run CONCURRENT with COUNT 3; and AS TO COUNT 5 – TWELVE (12) MONTHS in the Clark County Detention Center (CCDC), COUNT 5 to run CONCURRENT with COUNT 4; with TWO (2) DAYS credit for time served.

DATED this 8 day of November, 2013

Valerie Adair

VALERIE ADAIR
DISTRICT JUDGE

Exhibit G

Fifth Superseding Indictment in
State of Nevada v. Depak Desai and Ronald Lakeman
Case No. C-12-383381-1

ORIGINAL

AIND
STEVEN B. WOLFSON
Clark County District Attorney
Nevada Bar #001565
MICHAEL V. STAUDAHER
Chief Deputy District Attorney
Nevada Bar #008273
200 Lewis Avenue
Las Vegas, Nevada 89155-2212
(702) 671-2500
Attorney for Plaintiff

FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT
MAY 16 2013
BY, Denise Husted
DEPUTY
Denise Husted

DISTRICT COURT
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

DIPAK KANTILAL DESAI, #1240942
RONALD ERNEST LAKEMAN, #2753504

Defendant(s).

CASE NO: **10C265107-1 / C-12-283381-1**

DEPT NO: XXI

FIFTH AMENDED INDICTMENT

STATE OF NEVADA)
) ss.
COUNTY OF CLARK)

The Defendant(s) above named, DIPAK KANTILAL DESAI and RONALD ERNEST LAKEMAN accused by the Clark County Grand Jury of the crime(s) of **INSURANCE FRAUD (Category D Felony - NRS 686A.2815); PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Category C Felony - NRS 0.060, 202.595); CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Category B Felony - NRS 0.060, 200.495); THEFT (Category B Felony – NRS 205.0832, 205.0835); OBTAINING MONEY UNDER FALSE PRETENSES (Category B Felony - NRS 205.265, 205.380)** and **MURDER (SECOND DEGREE) (Category A Felony - NRS 200.010, 200.020, 200.030, 200.070, 202.595, 200.495)**, committed at and

within the County of Clark, State of Nevada, on or between June 3, 2005, and April 27, 2012, as follows:

COUNT 1 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about July 25, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to ANTHEM BLUE CROSS – BLUE SHIELD that the billed anesthesia time and/or charges for the endoscopic procedure performed on SHARRIEFF ZIYAD were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to the Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

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COUNT 2 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS did on or about July 25, 2007, then and there willfully and unlawfully perform acts in willful or wanton disregard of the safety of persons or property resulting in substantial bodily harm to MICHAEL WASHINGTON, to wit: transmitting the Hepatitis C virus to MICHAEL WASHINGTON, in the following manner, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of MICHAEL WASHINGTON which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said MICHAEL WASHINGTON; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of MICHAEL WASHINGTON and/or (3) pursuant to a conspiracy to commit this

crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 3 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS on or about July 25, 2007, being professional caretakers of MICHAEL WASHINGTON, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said MICHAEL WASHINGTON, resulting in substantial bodily harm to MICHAEL WASHINGTON, to wit: transmitting the Hepatitis C virus to MICHAEL WASHINGTON, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of MICHAEL WASHINGTON which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said MICHAEL WASHINGTON; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and

KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of MICHAEL WASHINGTON and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 4 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about July 25, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to VETERANS ADMINISTRATION that the billed anesthesia time and/or charges for the endoscopic procedure performed on MICHAEL WASHINGTON were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other

in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 5 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement conccaled or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to ANTHEM BLUE CROSS AND BLUE SHIELD that the billed anesthesia time and/or charges for the endoscopic procedure performed on KENNETH RUBINO were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

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COUNT 6 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS did on or about September 21, 2007, then and there willfully and unlawfully perform acts in willful or wanton disregard of the safety of persons or property resulting in substantial bodily harm to STACY HUTCHINSON, to wit: transmitting the Hepatitis C virus to STACY HUTCHINSON, in the following manner, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of STACY HUTCHINSON which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said STACY HUTCHINSON; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of STACY HUTCHINSON and/or (3) pursuant to a conspiracy to commit this crime,

Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 7 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS on or about September 21, 2007, being professional caretakers of STACY HUTCHINSON, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said STACY HUTCHINSON, resulting in substantial bodily harm to STACY HUTCHINSON, to wit: transmitting the Hepatitis C virus to STACY HUTCHINSON, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of STACY HUTCHINSON which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said STACY HUTCHINSON; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform

said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of STACY HUTCHINSON and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 8 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to HEALTH PLAN OF NEVADA that the billed anesthesia time and/or charges for the endoscopic procedure performed on STACY HUTCHINSON were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of

the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 9 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS did on or about September 21, 2007, then and there willfully and unlawfully perform acts in willful or wanton disregard of the safety of persons or property resulting in substantial bodily harm to RUDOLFO MEANA, to wit: transmitting the Hepatitis C virus to RUDOLFO MEANA, in the following manner, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of RUDOLFO MEANA which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said RUDOLFO MEANA; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he obtained the medical supplies, and/or drugs utilized in the treatment of KENNETH

RUBINO and RODOLFO MEANA which were subsequently contaminated with the Hepatitis C virus and thereafter directly or indirectly shared, exchanged or transferred said contaminated medical supplies, and/or drugs between himself and KEITH MATHAHS and/or between treatment rooms before, during or after the endoscopic procedure performed on KENNETH RUBINO which resulted in the transmission of the Hepatitis C virus into the body of RODOLFO MEANA and others and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 10 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS on or about September 21, 2007, being professional caretakers of RUDOLFO MEANA, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said RUDOLFO MEANA, resulting in substantial bodily harm to RUDOLFO MEANA, to wit: transmitting the Hepatitis C virus to RUDOLFO MEANA, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of RUDOLFO MEANA which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or

supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said RUDOLFO MEANA; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he obtained the medical supplies, and/or drugs utilized in the treatment of KENNETH RUBINO and RODOLFO MEANA which were subsequently contaminated with the Hepatitis C virus and thereafter directly or indirectly shared, exchanged or transferred said contaminated medical supplies, and/or drugs between himself and KEITH MATHAHS and/or between treatment rooms before, during or after the endoscopic procedure performed on KENNETH RUBINO which resulted in the transmission of the Hepatitis C virus into the body of RODOLFO MEANA and others and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 11 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title

57 of the Nevada Revised Statutes, by falsely representing to SECURE HORIZONS and/or PACIFICARE that the billed anesthesia time and/or charges for the endoscopic procedure performed on RUDOLFO MEANA were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 12 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS did on or about September 21, 2007, then and there willfully and unlawfully perform acts in willful or wanton disregard of the safety of persons or property resulting in substantial bodily harm to PATTY ASPINWALL, to wit: transmitting the Hepatitis C virus to PATTY ASPINWALL, in the following manner, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said PATTY ASPINWALL; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform

said acts and created a work environment where DEFENDANT LAKEMAN, KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of PATTY ASPINWALL and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 13 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS on or about September 21, 2007, being professional caretakers of PATTY ASPINWALL, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said PATTY ASPINWALL, resulting in substantial bodily harm to PATTY ASPINWALL, to wit: transmitting the Hepatitis C virus to PATTY ASPINWALL, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number

of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said PATTY ASPINWALL; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of PATTY ASPINWALL and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 14 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to ANTHEM BLUE CROSS AND BLUE SHIELD that the billed anesthesia time and/or charges for the endoscopic procedure performed on PATTY ASPINWALL were more than the actual anesthetic time

and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 15 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to UNITED HEALTH SERVICES that the billed anesthesia time and/or charges for the endoscopic procedure performed on PATTY ASPINWALL were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing,

or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 16 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS did on or about September 21, 2007, then and there willfully and unlawfully perform acts in willful or wanton disregard of the safety of persons or property resulting in substantial bodily harm to SONIA ORELLANA-RIVERA, to wit: transmitting the Hepatitis C virus to SONIA ORELLANA-RIVERA, in the following manner, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of SONIA ORELLANA-RIVERA which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said SONIA ORELLANA-RIVERA; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he obtained the medical supplies, and/or drugs utilized in the treatment of KENNETH RUBINO and SONIA ORELLANA-RIVERA

which were subsequently contaminated with the Hepatitis C virus and thereafter directly or indirectly shared, exchanged or transferred said contaminated medical supplies, and/or drugs between himself and KEITH MATHAHS and/or between treatment rooms before, during or after the endoscopic procedure performed on KENNETH RUBINO which resulted in the transmission of the Hepatitis C virus into the body of SONIA ORELLANA-RIVERA and others and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 17 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS on or about September 21, 2007, being professional caretakers of SONIA ORELLANA-RIVERA, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said SONIA ORELLANA-RIVERA, resulting in substantial bodily harm to SONIA ORELLANA-RIVERA, to wit: transmitting the Hepatitis C virus to SONIA ORELLANA-RIVERA, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, to wit: by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of SONIA ORELLANA-RIVERA which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly

or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said SONIA ORELLANA-RIVERA; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he obtained the medical supplies, and/or drugs utilized in the treatment of KENNETH RUBINO AND SONIA ORELLANA-RIVERA which were subsequently contaminated with the Hepatitis C virus and thereafter directly or indirectly shared, exchanged or transferred said contaminated medical supplies, and/or drugs between himself and KEITH MATHAHS and/or between treatment rooms before, during or after the endoscopic procedure performed on KENNETH RUBINO which resulted in the transmission of the Hepatitis C virus into the body of SONIA ORELLANA-RIVERA and others and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 18 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title

57 of the Nevada Revised Statutes, by falsely representing to CULINARY WORKERS HEALTH FUND that the billed anesthesia time and/or charges for the endoscopic procedure performed on SONIA ORELLANA-RIVERA were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 19 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS did on or about September 21, 2007, then and there willfully and unlawfully perform acts in willful or wanton disregard of the safety of persons or property resulting in substantial bodily harm to CAROLE GRUESKIN, to wit: transmitting the Hepatitis C virus to CAROLE GRUESKIN, in the following manner, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said CAROLE GRUESKIN; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform

said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of CAROLE GRUESKIN and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 20- CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS on or about September 21, 2007, being professional caretakers of CAROLE GRUESKIN, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said CAROLE GRUESKIN, resulting in substantial bodily harm to CAROLE GRUESKIN, to wit: transmitting the Hepatitis C virus to CAROLE GRUESKIN, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number

of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said CAROLE GRUESKIN; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he limited the use of medical supplies, and/or drugs and rushed patients, and/or patient procedures which in turn allowed DEFENDANT DESAI to directly or indirectly treat and/or perform an unreasonable number of patient procedures in a single day all at the expense of patient safety and well being, and which resulted in substandard care and jeopardized the safety of CAROLE GRUESKIN and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 21 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or about September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to HEALTH PLAN OF NEVADA that the billed anesthesia time and/or charges for the endoscopic procedure performed on CAROLE GRUESKIN were more than the actual anesthetic time and/or

charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 22 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS did on or about September 21, 2007, then and there willfully and unlawfully perform acts in willful or wanton disregard of the safety of persons or property resulting in substantial bodily harm to GWENDOLYN MARTIN, to wit: transmitting the Hepatitis C virus to GWENDOLYN MARTIN, in the following manner, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable nnmber of patients per day, and/or rushed patients or patient procedures, Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said GWENDOLYN MARTIN; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against

universally accepted standards of medical care, that he obtained the medical supplies, and/or drugs utilized in the treatment of KENNETH RUBINO and GWENDOLYN MARTIN which were subsequently contaminated with the Hepatitis C virus and thereafter directly or indirectly shared, exchanged or transferred said contaminated medical supplies, and/or drugs between himself and KEITH MATHAHS and/or between treatment rooms before, during or after the endoscopic procedure performed on KENNETH RUBINO which resulted in the transmission of the Hepatitis C virus into the body of GWENDOLYN MARTIN and others and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 23 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM

Defendants and KEITH MATHAHS on or about September 21, 2007, being professional caretakers of GWENDOLYN MARTIN, did act or omit to act in an aggravated, reckless or gross manner, failing to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of said GWENDOLYN MARTIN, resulting in substantial bodily harm to GWENDOLYN MARTIN, to wit: transmitting the Hepatitis C virus to GWENDOLYN MARTIN, said acts or omissions being such a departure from what would be the conduct of an ordinarily prudent, careful person under the same circumstances that it is contrary to a proper regard for danger to human life or constitutes indifference to the resulting consequences, said consequences of the negligent act or omission being reasonably foreseeable; said danger to human life not being the result of inattention, mistaken judgment or misadventure, but the natural and probable result of said aggravated reckless or grossly negligent act or omission, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures,

Defendants and KEITH MATHAHS acting with the intent to commit said crime in order to fraudulently increase the insurance billing and/or money reimbursement for the medical procedure performed on the said GWENDOLYN MARTIN; specifically, as to DEFENDANT DESAI, that he directly or indirectly both instructed DEFENDANT LAKEMAN, and KEITH MATHAHS and said others to perform said acts and created a work environment where DEFENDANT LAKEMAN, and KEITH MATHAHS and others were pressured to commit the said acts described above; specifically, as to DEFENDANT LAKEMAN, engaging in conduct against universally accepted standards of medical care, that he obtained the medical supplies, and/or drugs utilized in the treatment of KENNETH RUBINO and GWENDOLYN MARTIN which were subsequently contaminated with the Hepatitis C virus and thereafter directly or indirectly shared, exchanged or transferred said contaminated medical supplies, and/or drugs between himself and KEITH MATHAHS and/or between treatment rooms before, during or after the endoscopic procedure performed on KENNETH RUBINO which resulted in the transmission of the Hepatitis C virus into the body of GWENDOLYN MARTIN and others and/or (3) pursuant to a conspiracy to commit this crime, Defendants and KEITH MATHAHS acting in concert throughout.

COUNT 24 - INSURANCE FRAUD

Defendants and KEITH MATHAHS did on or between September 20, 2007 and September 21, 2007, knowingly and willfully present, or cause to be presented a statement as a part of, or in support of, a claim for payment or other benefits under a policy of insurance issued pursuant to Title 57 of the Nevada Revised Statutes, knowing that the statement concealed or omitted facts, or contained false or misleading information concerning a fact material to said claim; and/or did assist, abet, solicit or conspire to present or cause to be presented a statement to an insurer, a reinsurer, a producer, a broker or any agent thereof, knowing that said statement concealed or omitted facts, or did contain false or misleading information concerning a fact material to a claim for payment or other benefits under such policy issued pursuant to Title 57 of the Nevada Revised Statutes, by falsely representing to PACIFIC CARE that the billed anesthesia time and/or charges for the

endoscopic procedure performed on GWENDOLYN MARTIN were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice which exceeded that which would have normally been allowed for said procedure; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 25 – THEFT

Defendants and KEITH MATHAHS did between July 25, 2007 and December 31, 2007, then and there knowingly, feloniously, and without lawful authority, commit theft by obtaining personal property in the amount of $250.00, or more, lawful money of the United States, from STACY HUTCHINSON, KENNETH RUBINO, PATTY ASPINWALL, SHARRIEFF ZIYAD, MICHAEL WASHINGTON, CAROLE GRUESKIN and RODOLFO MEANA, and/or ANTHEM BLUE CROSS AND BLUE SHIELD, HEALTHCARE PARTNERS OF NEVADA, UNITED HEALTH SERVICES, VETERANS ADMINISTRATION and SECURED HORIZONS, by a material misrepresentation with intent to deprive those persons of the property, in the following manner, to-wit: by falsely representing that the billed anesthesia time and/or charges for the endoscopic procedure performed on STACY HUTCHINSON, KENNETH RUBINO, PATTY ASPINWALL, SHARRIEFF ZIYAD, MICHAEL WASHINGTON, CAROLE GRUESKIN and RODOLFO MEANA, were more than the actual anesthetic time and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or their medical practice, which exceeded that which would have normally been allowed for said procedure, thereby obtaining said personal property by a material misrepresentation with intent to deprive them of the property, Defendants and KEITH MATHAHS being

responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 26 - OBTAINING MONEY UNDER FALSE PRETENSES

Defendants and KEITH MATHAHS did on or between September 20, 2007, and December 31, 2007, with intent to cheat and defraud, wilfully, unlawfully, feloniously, knowingly, designedly, and by use of false pretenses, obtain $250.00, or more, lawful money of the United States from GWENDOLYN MARTIN and/or PACIFICARE, within Las Vegas, Clark County, Nevada, in the following manner, to-wit: by falsely representing that the billed anesthesia times and/or charges for the endoscopic procedures performed on GWENDOLYN MARTIN were more than the actual anesthetic times and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or the medical practice, which exceeded that which would have normally been allowed for said procedures Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

COUNT 27 - OBTAINING MONEY UNDER FALSE PRETENSES

Defendants and KEITH MATHAHS did on or between September 21, 2007, and December 31, 2007, with intent to cheat and defraud, wilfully, unlawfully, feloniously, knowingly, designedly, and by use of false pretenses, obtain $250.00, or more, lawful money of the United States from SONIA ORELLANA-RIVERA and/or CULINARY WORKERS

HEALTH FUND, within Las Vegas, Clark County, Nevada, in the following manner, to-wit: by falsely representing that the billed anesthesia times and/or charges for the endoscopic procedures performed on SONIA ORELLANA-RIVERA were more than the actual anesthetic times and/or charges, said false representation resulting in the payment of money to Defendants and KEITH MATHAHS and/or the medical practice, which exceeded that which would have normally been allowed for said procedures Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said acts; and/or (2) aiding or abetting each other in the commission of the crime by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to commit said acts, Defendants and KEITH MATHAHS acting with the intent to commit said crime, and/or (3) pursuant to a conspiracy to commit this crime.

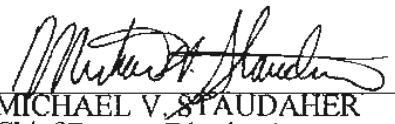
COUNT 28 – MURDER (SECOND DEGREE)

Defendants and KEITH MATHAHS did on or between September 21, 2007 and April 27, 2012, then and there willfully, feloniously, without authority of law, and with malice aforethought, kill RODOLFO MEANA, a human being, by introducing Hepatitis C virus into the body of RODOLFO MEANA, based upon the following principles of criminal liability, to-wit: (1) by the killing occurring under circumstances showing an abandoned and malignant heart; and/or (2) during the commission of an unlawful act, to-wit: criminal neglect of patients, and/or performance of an unlawful act in reckless disregard of persons or property, which in its consequences, naturally tends to destroy the life of a human being; and/or (3) the killing being committed in the prosecution of a felonious intent, to-wit: criminal neglect of patients, and/or performance of an act in reckless disregard of persons or property, which in its consequences, naturally tends to destroy the life of a human being, by directly or indirectly using and/or introducing contaminated medical instruments, supplies, and/or drugs upon or into the body of RODOLFO MEANA which were contaminated with the Hepatitis C virus; Defendants and KEITH MATHAHS being responsible under one or more of the following principles of criminal liability, to wit: (1) by directly committing said

acts; and/or (2) by aiding or abetting each other and/or others including uncharged confederates in the commission of the crime(s) of criminal neglect of patients, and/or performance of an act in reckless disregard of persons or property by directly or indirectly counseling, encouraging, hiring, commanding, inducing, or procuring each other, and/or others to utilize a patient care delivery system which directly or indirectly limited the use of medical instruments, and/or supplies, and/or drugs; scheduled and/or treated an unreasonable number of patients per day, and/or rushed patients or patient procedures all at the expense of patient safety and/or well being, and which resulted in substandard care and/or jeopardized the safety of RODOLFO MEANA, Defendants and KEITH MATHAHS acting with the intent to commit the crime(s) of criminal neglect of patients, and/or performance of an act in reckless disregard of persons or property; and/or (3) pursuant to a conspiracy to commit the crime(s) of criminal neglect of patients, and/or performance of an act in reckless disregard of persons or property, Defendants and KEITH MATHAHS acting in concert throughout.

DATED this 6th day of May, 2013.

STEVEN B. WOLFSON
DISTRICT ATTORNEY
Nevada Bar #001565

BY 
MICHAEL V. STAUDAHER
Chief Deputy District Attorney
Nevada Bar #008273

Names of witnesses testifying before the Grand Jury:

ARMOUR, PATRICIA, NV. HEALTH DISTRICT

ASPINWALL, PATTY

BAGANG, MAYNARD, LVMPD

CAMPBELL, LYNETTE, RN

CAROL, CLIFFORD

CARRERA, HILARIO

CERDA, RYAN, HEALTH CARE BUSINESS SOLUTIONS

DESAI, SAEHAL

DROBENINE, JAN, CDC LAB SUPERVISOR

DUENAS, YERENY, INSURANCE CLAIMS

GONZALES, PATRICIA, BLUE CROSS DIRECTOR DEPT.

GRUESKIN, CAROLE

HAWKINS, MELVIN

HUTCHINSON, STACY

KALKA, KATIE, UNITED HEALTH GROUP INV.

KHUDYAKOV, YURY, CDC

KRUEGER, JEFFREY ALEN, RN

LABUS, BRIAN, NV HEALTH DISTRICT

LANGLEY, GAYLE, CDC PHYSICIAN

LOBIANBO, ANNAMARIE, CRNA

MARTIN, GWENDOLYN

MEANA, RODOLFO

MYERS, ELAINE, CLAIMS DIRECTOR

NEMEC, FRANK, GASTROENTEROLOGIST

OLSON, ALANE, MEDICAL EXAMINER

RIVERA, SONIA ORELLONO

RUBINO, KENNETH

RUSHING, TONYA, OFFICE MGR.
SAGENDORF, VINCENT, CRNA
SAMPSON, NANCY, LVMPD
SAMS, JOANNE, VET ADMIN. CODER
SCHAEFER, MELISSA, CDC PHYSICIAN
SHARMA, SATISH, ANESTHESIOLOGIST
SIMS, DOROTHY, BUREAU OF LICENSING AND CERTIFICATION
SPAETH, CORRINE, CLAIMS DIRECTOR
VANDRUFF, MARION, MEDICAL ASSISTANT
WASHINGTON, MICHAEL
YEE, THOMAS, ANESTHESIOLOGIST
YOST, ANNE, NURSE
ZIYAD, SHARRIEFF

Additional witnesses known to the District Attorney at time of filing the Indictment:
ALFARO-MARTINEZ, SAMUEL
ANWAR, JAVAID, 3006 MARYLAND PKWY #400, LVN 89109
ARBOREEN, DAVE, LVMPD
ARMENI, PAOLA
ARNONE, ANTHONY, LVMPD
ASHANTE, DR.
BAILEY, PAULINE, 3416 MONTE CARLO DR., LVN 89121
BARCLAY, DR. ROBERT
BIEN, KATHY, 3800 DALECREST DR. #1117, LVN 89129
BLEMINGS, RENATE, 2100 PLAIN ST., PAHRUMP, NV 89060
BROWN, DAVID
BUI, DR.
BUNIN, DANIEL

BURKIN, JERALD, FBI SA

CALVALHO, DANIEL CARRERA

CARAWAY, ANTOINETTE, 1407 BAREBACK CT., HNV 89014

CARRERA, ELADIO, 612 CANYON GREENS DR., LVN 89144

CARROLL, CLIFFORD, 10313 ORKINEY DR., LVN 89144

CASTLEMAN, DR. STEPHANIE

CAVETT, JOSHUA, 7829 TATTERSALL FLAG ST., LVN 89139

CHAFFEE, ROD, 9303 GILCREASE #1080, LVN 89149

CLEMMER, DANA MARIE, 4913 FERRELL ST., NLVN 89034

COE, DANIEL, LVMPD

COHAN, DR. CHARLES, POB 4144, SAYLORSBURG, PA

COOK, KATIE, FBI S/A

COOPER, DOUG, CHIEF INV., NV. ST. BOARD OF ME

CRANE, AUSA

CREMEN, FRANK

DESAI, DIPAK, 3093 RED ARROW, LVN 89135

DESAI, KUSAM, MD

DIAZ, ALLEN, LVMPD INTERPRETER

DIBUDUO, CHARLES

DORAME, JOHN

DRURY, JANINE

ECKERT, PHYSICIAN ASST.

ELLEN, DIANE

FALZONE, LISA, 8024 PEACEFUL WOODS STREET, LVN 89143

FARIS, FRANK

FIGLER, DAYVID

FISHCHER, GAYLE, 1600 CLIFTON MAIL STOP #G37, ATLANTA, GA. 30333

FORD, MIKE, LVMPD

FRANKS, LISA, PHYSICIAN ASST.

GASKILL, SARA

GENTILE, DOMINIC

GLASS-SERAN, BARBARA, CRNA

GRAY, WARREN, LVMPD

GREER, MARY, 3462 SHAMROCK AVE., LVN 89120

GREGORY, MARTHA

HAHN, JASON, LVMPD

HANCOCK, L., LVMPD #7083

HANSEN, IDA

HARPER, TIFFANY

HARRIS, ORELENA (HOLLEMAN), 2816 DESERT SONG, LVN 89106

HERRERO, CARMELO, 1864 WOODHAVEN DR., HNV 89074

HIGGINS, HEATHER, INV. NV. ST. BOARD OF ME

HIGUERA, LILIA, 3504 FLOWER, NLVN 89030

HITTI, DR. MIRANDA

HOWARD, NADINE, HEALTH FACILITIES SURVEYOR

HUBBARD, LINDA, 515 PARK ROYAL DR., NLVN 89031

HUGHES, LAURA, AG INV.

HUYNH, NGUYEN, 3004 HAZY MEADOW LN., LVN 89108

IRVIN, JOHNNA

JOHNSON, SHONNA S., 22 VIA DE LUCCIA, HNV 89074

JONES, LISA, CHIEF NSB OF LICENSURE AND CERTIFICATION (BLC)

JURANI, DR.

KIRCH, MARLENE

KAUL, DR.

KAUSHAL, DR. DHAN

KELLEY, J., LVMPD #3716

KHAN, IKRAM, 3006 S. MARYLAND PKWY, #465 LVN 89109
KNOWLES, DR.
KOSLOY, LESLEE, RN, HEALTH FACILITIES SURVEYOR
LAKEMAN, RONALD, 700 SHADOW LN #165B, LVN 89106
LATHROP, CAROL, 1741 AUGUSTA ST., PAHRUMP, NV 89048
LATHROP, WILLIAM
LEWIS, DR. DANIEL
LOBIONDA, CRNA
LOPEZ, J. JULIAN, 7106 SMOKE RANCH RD. #120 LVN 89128
LUKENS, JOHN
MAANOA, PETER, RN
MALEY, KATIE, 4275 BURNHAM #101, LVN
MALMBERG, GEORGE
MANTHEI, PETER, 7066 AZURE BEACH AZURE ST., LVN 89148
MANUEL, DR. DAVID
MARTIN, LOVEY
MASON, ALBERT
MATHAHS, KEITH, 10220 BUTTON WILLOW DR., LVN 89134
MCDOWELL, RALPH, 388 SANTA CANDIDA ST., LVN 89138
MCGOWAN, SHANNON, 5420 CARNATION MEADOW ST., LVN 89130
MCILROY, ROBIN, FBI
MILLER, JAMES
MIONE, VINCENT, 2408 W. EL CAMPO GRANDE AVE., NLVN 89031
MOORE, DAVID
MUKHERJEE, RANADER, MD
MURPHY, MAGGIE, 10175 W. SPRING MTN RD. #2012 LVN 89117
NAYYAR, SANJAY, MD
NAZAR, WILLIAM

NAZARIO, DR. BRUNILDA
OM, HARI, LLC MGR
O'REILLY, JOHN
O'REILLY, TIM
PAGE-TAYLOR, LESLIE, CDC
PATEL, DR.
PENSAKOVIC, JOAN
PETERSON, KAREN, 2138 FT. SANDERS ST., HNV
PHELPS, LISA, 784 MORMON PEAK ST., OVERTON, NV 89040
POMERANZ, AUSA
PRESTON, LAWRENCE, 801 S. RANCHO DR., STE C-1, LVN
QUANNAH, LAKOTA
REXFORD, KEVIN
RICHVALSKY, KAREN, 3325 NIGUL WAY, LVN 89117
ROSEL, LINDA, FBI SA
RUSSOM, RUTA, 4854 MONTERREY AVE., LVN 89121
SAGENDORF, VINCENT
SAMEER, DR. SHEIKH
SAPP, BETSY, PHLEBOTOMIST
SCAMBIO, JEAN, 2920 YUKON FLATS CT., NLVN 89031
SCHULL, JERRY, 5413 SWEET SHADE ST., LVN
SENI, DR.
SHARMA, DR. SATISH
SHARMA, VISHVINDER, DR. 3212 CEDARDALE PL., LVN 89134
SHEFNOFF, NEIL, 755 E. MCDOWELL RD., PHOENIX, AZ 85006
SMITH, CHARNESSA
SOOD, RAJAT
STURMAN, GLORIA

SUKHDEO, DANIEL, 3925 LEGEND HILLS ST. #203, LVN 89129

TAGLE, PEGGY, RN

TERRY, JENNIFER, LVMPD INTERPRETER

TONY, DR.

VAZIRI, DR.

WAHID, SHAHID, MD

WEBB, KAREN, 1459 S. 14TH ST., OMAHA, NE

WHITAKER, GERALDINE, 701 CARPICE DR. #17B, BOULDER CITY, NV 89005

WHITELY, R. LVMPD

WILLIAMS, SKLAR, RESIDENT AGENT, 8363 W. SUNSET RD. #300, LVN 89113

WISE, PATTY

YAMPOLSKY, MACE

ZIMMERMAN, MARILYN, 550 SEASONS PKWY, BELVIDERE, IL 89040

09BGJ049A-C/10F03793A-C/09BGJ119A-C /sam-MVU
LVMPD EV #0802292576
(TK11)

Exhibit H

Jury Verdict Against Depak Desai in
State of Nevada v. Desai, case no. 10-C-265107-1

VER

ORIGINAL

FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT

JUL 01 2013
5:44 pm

BY, KATRINA HERNANDEZ, DEPUTY

DISTRICT COURT

CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

DIPAK KANTILAL DESAI,

Defendant.

CASE NO: 10-C-265107-1

DEPT NO: XXI

VERDICT

We, the jury in the above entitled case, find the Defendant DIPAK KANTILAL DESAI, as follows:

COUNT 1 - INSURANCE FRAUD (Anthem Blue Cross-Blue Shield/Sharrieff Ziyad)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 2 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Michael Washington)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 3 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Michael Washington)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 4 – OMITTED

COUNT 5 - INSURANCE FRAUD (Anthem Blue Cross/Blue Shield/Kenneth Rubino)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 6 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Stacy Hutchinson)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 7 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Stacy Hutchinson)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

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COUNT 8 - INSURANCE FRAUD (Health Plan of Nevada/Stacy Hutchinson)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 9 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Rodolfo Meana)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 10 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Rodolfo Meana)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Death

☐ Not Guilty

COUNT 11 - INSURANCE FRAUD (PacificCare/Rodolfo Meana)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

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COUNT 12 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 13 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 14 - INSURANCE FRAUD (Anthem Blue Cross Blue Shield/Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 15 - INSURANCE FRAUD (United Health Services/Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

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COUNT 16 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Sonia Orellana-Rivera)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 17 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Sonia Orellana-Rivera)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 18 - INSURANCE FRAUD (Culinary Workers Health Fund/Sonia Orellana Rivera)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 19 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Carole Grueskin)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

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COUNT 20- CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Carole Grueskin)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 21 - INSURANCE FRAUD (Health Plan of Nevada/Carole Grueskin)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 22 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Gwendolyn Martin)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 23 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Gwendolyn Martin)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

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COUNT 24 - INSURANCE FRAUD (PacificCare/Gwendolyn Martin)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 25 – THEFT (Stacy Hutchinson, Kenneth Rubino, Patty Aspinwall, Sharrieff Ziyad, Michael Washington, Carole Grueskin, Rodolfo Meana and/or Anthem Blue Cross and Blue Shield, Healthcare Partners of Nevada, United Health Services, Veterans Administration and Secured Horizons)

(please check the appropriate box, select only one)

☐ Guilty of Theft $250.00 or over

☑ Guilty of Theft under $250

☐ Not Guilty

COUNT 26 - OBTAINING MONEY UNDER FALSE PRETENSES (Gwendolyn Martin and/or PacificCare)

(please check the appropriate box, select only one)

☐ Guilty of Obtaining Money Under False Pretenses $250 or over

☑ Guilty of Obtaining Money Under False Pretenses under $250

☐ Not Guilty

COUNT 27 - OBTAINING MONEY UNDER FALSE PRETENSES (Sonia Orellana-Rivera and/or Culinary Workers Health Fund)

(please check the appropriate box, select only one)

☐ Guilty of Obtaining Money Under False Pretenses $250 or over

☑ Obtaining Money Under False Pretenses under $250

☐ Not Guilty

///

COUNT 28 – MURDER (SECOND DEGREE) (Rodolfo Meana)

(please check the appropriate box, select only one)

☑ Guilty of Second Degree Murder

☐ Not Guilty

DATED this 1ST day of ~~June~~ JULY, 2013

FOREPERSON

Exhibit I

Jury Verdict Against Ronald Lakeman in
State of Nevada v. Lakeman, case no. 10-C-265107-2

VER

ORIGINAL

FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT
5:44 PM
JUL 01 2013
BY, KATRINA HERNANDEZ, DEPUTY

DISTRICT COURT

CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

RONALD ERNEST LAKEMAN,

Defendant.

CASE NO: 10-C-265107-2

DEPT NO: XXI

VERDICT

We, the jury in the above entitled case, find the Defendant RONALD ERNEST LAKEMAN, as follows:

COUNT 1 - INSURANCE FRAUD (Anthem Blue Cross-Blue Shield/Sharrieff Ziyad)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 2 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Michael Washington)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 3 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Michael Washington)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 4 – OMITTED

COUNT 5 - INSURANCE FRAUD (Anthem Blue Cross/Blue Shield/Kenneth Rubino)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☑ Not Guilty

COUNT 6 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Stacy Hutchinson)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 7 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Stacy Hutchinson)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

///

///

COUNT 8 - INSURANCE FRAUD (Health Plan of Nevada/Stacy Hutchinson)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 9 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Rodolfo Meana)

(please check the appropriate box, select only one)

☐ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☑ Not Guilty

COUNT 10 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Rodolfo Meana)

(please check the appropriate box, select only one)

☐ Guilty of Criminal Neglect of Patients Resulting in Death

☑ Not Guilty

COUNT 11 - INSURANCE FRAUD (PacificCare/Rodolfo Meana)

(please check the appropriate box, select only one)

☐ Guilty of Insurance Fraud

☑ Not Guilty

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COUNT 12 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 13 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 14 - INSURANCE FRAUD (Anthem Blue Cross Blue Shield/Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 15 - INSURANCE FRAUD (United Health Services/Patty Aspinwall)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

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COUNT 16 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Sonia Orellana-Rivera)

(please check the appropriate box, select only one)

☐ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☑ Not Guilty

COUNT 17 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Sonia Orellana-Rivera)

(please check the appropriate box, select only one)

☐ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☑ Not Guilty

COUNT 18 - INSURANCE FRAUD (Culinary Workers Health Fund/Sonia Orellana Rivera)

(please check the appropriate box, select only one)

☐ Guilty of Insurance Fraud

☑ Not Guilty

COUNT 19 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Carole Grueskin)

(please check the appropriate box, select only one)

☑ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☐ Not Guilty

///

///

COUNT 20- CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Carole Grueskin)

(please check the appropriate box, select only one)

☑ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☐ Not Guilty

COUNT 21 - INSURANCE FRAUD (Health Plan of Nevada/Carole Grueskin)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 22 - PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Gwendolyn Martin)

(please check the appropriate box, select only one)

☐ Guilty of Performance of Act in Reckless Disregard of Persons or Property Resulting in Substantial Bodily Harm

☑ Not Guilty

COUNT 23 - CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Gwendolyn Martin)

(please check the appropriate box, select only one)

☐ Guilty of Criminal Neglect of Patients Resulting in Substantial Bodily Harm

☑ Not Guilty

///

///

COUNT 24 - INSURANCE FRAUD (PacificCare/Gwendolyn Martin)

(please check the appropriate box, select only one)

☑ Guilty of Insurance Fraud

☐ Not Guilty

COUNT 25 – THEFT (Stacy Hutchinson, Kenneth Rubino, Patty Aspinwall, Sharrieff Ziyad, Michael Washington, Carole Grueskin, Rodolfo Meana and/or Anthem Blue Cross and Blue Shield, Healthcare Partners of Nevada, United Health Services, Veterans Administration and Secured Horizons)

(please check the appropriate box, select only one)

☐ Guilty of Theft $250.00 or over

☑ Guilty of Theft under $250

☐ Not Guilty

COUNT 26 - OBTAINING MONEY UNDER FALSE PRETENSES (Gwendolyn Martin and/or PacificCare)

(please check the appropriate box, select only one)

☐ Guilty of Obtaining Money Under False Pretenses $250 or over

☑ Guilty of Obtaining Money Under False Pretenses under $250

☐ Not Guilty

COUNT 27 - OBTAINING MONEY UNDER FALSE PRETENSES (Sonia Orellana-Rivera and/or Culinary Workers Health Fund)

(please check the appropriate box, select only one)

☐ Guilty of Obtaining Money Under False Pretenses $250 or over

☐ Obtaining Money Under False Pretenses under $250

☑ Not Guilty

///

COUNT 28 – MURDER (SECOND DEGREE) (Rodolfo Meana)

(please check the appropriate box, select only one)

☐ Guilty of Second Degree Murder

☑ Not Guilty

DATED this 1st day of ~~June~~ July, 2013

FOREPERSON

Exhibit J

Judgment of Conviction Against Ronald Lakeman in
State of Nevada v. Lakeman, case no. 10-C-265107-2

Electronically Filed
11/13/2013 10:58:25 AM

CLERK OF THE COURT

JOC

DISTRICT COURT

CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

RONALD ERNEST LAKEMAN
#2753504

Defendant.

CASE NO. C265107-2

DEPT. NO. XXI

JUDGMENT OF CONVICTION

(JURY TRIAL)

The Defendant previously entered a plea of not guilty to the crimes of COUNTS 1, 4, 5, 8, 11, 14, 15, 18, 21, and 24 – INSURANCE FRAUD (Category D Felony), in violation of NRS 686A.2815; COUNTS 2, 6, 9, 12, 16, 19, and 22 – PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Category C Felony), in violation of NRS 0.060, 202.595; COUNTS 3, 7, 10, 13, 17, 20, and 23 – CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Category B Felony), in violation of NRS 0.060, 200.495; COUNT 25 – THEFT (Category B Felony), in violation of NRS 205.0832, 205.0835; COUNTS 26 and 27 – OBTAINING MONEY UNDER FALSE PRETENSES (Category B Felony), in violation of NRS 205.265, 205.380; and COUNT

28 – MURDER (SECOND DEGREE) (Category A Felony), in violation of NRS 200.010, 200.020, 200.030, 200.070, 202.595, 200.495; and the matter having been tried before a jury and the Defendant having been found guilty of the crimes of COUNTS 1, 8, 14, 15, 21, and 24 – INSURANCE FRAUD (Category D Felony), in violation of NRS 686A.2815; COUNTS 2, 6, 12, and 19 – PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Category C Felony), in violation of NRS 0.060, 202.595; COUNTS 3, 7, 13, and 20 – CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Category B Felony), in violation of NRS 0.060, 200.495; COUNT 25 – THEFT UNDER $250.00 (Misdemeanor); and COUNT 26 – OBTAINING MONEY UNDER FALSE PRETENSES UNDER $250.00 (Misdemeanor); thereafter, on the 24TH day of October, 2013, the Defendant was present in court for sentencing with his counsel, FREDERICK SANTACROCE, ESQ., and good cause appearing,

THE DEFENDANT IS HEREBY ADJUDGED guilty of said offense(s) and, in addition to the $25.00 Administrative Assessment Fee, $150.00 DNA Analysis Fee including testing to determine genetic markers, and $1,861.73 Extradition Fee, the Defendant is SENTENCED as follows: AS TO COUNT 1 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC); AS TO COUNT 2 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 2 to run CONCURRENT with COUNT 1; AS TO COUNT 3 - TO A MAXIMUM of SEVENTY-TWO (72) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada

Department of Corrections (NDC), COUNT 3 to run CONCURRENT with COUNT 2; AS TO COUNT 6 – TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 6 to run CONCURRENT with COUNT 3; AS TO COUNT 7 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 7 to run CONSECUTIVE to COUNT 6; AS TO COUNT 8 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 8 to run CONCURRENT with COUNT 7; AS TO COUNT 12 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 12 to run CONCURRENT with COUNT 8; AS TO COUNT 13 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 13 to run CONSECUTIVE to COUNT 12; AS TO COUNT 14 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 14 to run CONCURRENT with COUNT 13; AS TO COUNT 15 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 15 to run CONCURRENT with COUNT 14; AS TO COUNT 19 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 19 to run CONCURRENT with COUNT 15; AS TO COUNT 20 - TO A MAXIMUM of SIXTY

(60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 20 to run CONSECUTIVE to COUNT 19; AS TO COUNT 21 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 21 to run CONCURRENT with COUNT 20; AS TO COUNT 24 - TO A MAXIMUM of THIRTY (30) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 24 to run CONCURRENT with COUNT 21; AS TO COUNT 25 – SIX (6) MONTHS in the Clark County Detention Center (CCDC), COUNT 25 to run CONCURRENT with other Counts; and AS TO COUNT 26 – SIX (6) MONTHS in the Clark County Detention Center (CCDC); COUNT 26 to run CONCURRENT with other Counts; with ONE HUNDRED SEVENTEEN (117) DAYS Credit for Time Served.

FURTHER, COUNT 4 is OMITTED and COUNTS 5, 9, 10, 11, 16, 17, 18, 22, 23, 27 and 28 Defendant is found NOT GUILTY.

DATED this 8 day of November, 2013

Valerie Adair

VALERIE ADAIR
DISTRICT JUDGE

Exhibit K

Amended Judgment of Conviction Against Depak Desai in
State of Nevada v. Desai, case no. 10-C-265107-1

Electronically Filed
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CLERK OF THE COURT

AJOC

DISTRICT COURT

CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

DIPAK KANTILAL DESAI
#1240942

Defendant.

CASE NO. C265107-1

DEPT. NO. XXI

AMENDED JUDGMENT OF CONVICTION

(JURY TRIAL)

The Defendant previously entered a plea of not guilty to the crimes of COUNTS 1, 4, 5, 8, 11, 14, 15, 18, 21, and 24 – INSURANCE FRAUD (Category D Felony), in violation of NRS 686A.2815; COUNTS 2, 6, 9, 12, 16, 19, and 22 – PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Category C Felony), in violation of NRS 0.060, 202.595; COUNTS 3, 7, 10, 13, 17, 20, and 23 – CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Category B Felony), in violation of NRS 0.060, 200.495; COUNT 25 – THEFT (Category B Felony), in violation of NRS 205.0832, 205.0835; COUNTS 26 and 27 – OBTAINING MONEY UNDER FALSE PRETENSES (Category B Felony), in violation of NRS 205.265, 205.380; and COUNT

28 – MURDER (SECOND DEGREE) (Category A Felony), in violation of NRS 200.010, 200.020, 200.030, 200.070, 202.595, 200.495; and the matter having been tried before a jury and the Defendant having been found guilty of the crimes of COUNTS 1, 5, 8, 11, 14, 15, 18, 21, and 24 – INSURANCE FRAUD (Category D Felony), in violation of NRS 686A.2815; COUNTS 2, 6, 9, 12, 16, 19, and 22 – PERFORMANCE OF ACT IN RECKLESS DISREGARD OF PERSONS OR PROPERTY RESULTING IN SUBSTANTIAL BODILY HARM (Category C Felony), in violation of NRS 0.060, 202.595; COUNTS 3, 7, 10, 13, 17, 20, and 23 – CRIMINAL NEGLECT OF PATIENTS RESULTING IN SUBSTANTIAL BODILY HARM (Category B Felony), in violation of NRS 0.060, 200.495; COUNT 25 – THEFT UNDER $250.00 (Misdemeanor); COUNTS 26 and 27 – OBTAINING MONEY UNDER FALSE PRETENSES UNDER $250.00 (Misdemeanor); and COUNT 28 – MURDER (SECOND DEGREE) (Category A Felony), in violation of NRS 200.010, 200.020, 200.030, 200.070, 202.595, 200.495; thereafter, on the 24TH day of October, 2013, the Defendant was present in court for sentencing with his counsels, RICHARD WRIGHT, ESQ., and MARGARET STANISH, ESQ., and good cause appearing,

THE DEFENDANT IS HEREBY ADJUDGED guilty of said offense(s) and, in addition to the $25.00 Administrative Assessment Fee, and $150.00 DNA Analysis Fee including testing to determine genetic markers, the Defendant is SENTENCED as follows: AS TO COUNT 1 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC); AS TO COUNT 2 - TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada

Department of Corrections (NDC), COUNT 2 to run CONCURRENT with COUNT 1; AS TO COUNT 3 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 3 to run CONCURRENT with COUNT 2; AS TO COUNT 5 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 5 to run CONCURRENT with COUNT 3; AS TO COUNT 6 – TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 6 to run CONCURRENT with COUNT 5; AS TO COUNT 7 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 7 to run CONSECUTIVE to COUNT 6; AS TO COUNT 8 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 8 to run CONCURRENT with COUNT 7; AS TO COUNT 9 - TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 9 to run CONCURRENT with COUNT 8; AS TO COUNT 10 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 10 to run CONSECUTIVE to COUNT 9; AS TO COUNT 11 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 11 to run CONCURRENT with COUNT 10; AS TO

COUNT 12 - TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 12 to run CONCURRENT with COUNT 11; AS TO COUNT 13 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 13 to run CONCURRENT with COUNT 12; AS TO COUNT 14 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 14 to run CONCURRENT with COUNT 13; AS TO COUNT 15 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 15 to run CONCURRENT with COUNT 14; AS TO COUNT 16 - TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 16 to run CONCURRENT with COUNT 15; AS TO COUNT 17 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 17 to run CONCURRENT with COUNT 16; AS TO COUNT 18 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 18 to run CONCURRENT with COUNT 17; AS TO COUNT 19 - TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 19 to run CONCURRENT with COUNT 17; AS TO COUNT 20 - TO A MAXIMUM of SIXTY (60)

MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 20 to run CONCURRENT with COUNT 18; AS TO COUNT 21 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 21 to run CONCURRENT with COUNT 21; AS TO COUNT 22 - TO A MAXIMUM of FORTY-EIGHT (48) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 22 to run CONCURRENT with COUNT 20; AS TO COUNT 23 - TO A MAXIMUM of SIXTY (60) MONTHS with a MINIMUM Parole Eligibility of TWENTY-FOUR (24) MONTHS in the Nevada Department of Corrections (NDC), COUNT 23 to run CONSECUTIVE to COUNT 21; AS TO COUNT 24 - TO A MAXIMUM of THIRTY-FOUR (34) MONTHS with a MINIMUM Parole Eligibility of TWELVE (12) MONTHS in the Nevada Department of Corrections (NDC), COUNT 24 to run CONCURRENT with COUNT 23; AS TO COUNT 25 – SIX (6) MONTHS in the Clark County Detention Center (CCDC), COUNT 25 to run CONCURRENT with other Counts; and AS TO COUNT 26 – SIX (6) MONTHS in the Clark County Detention Center (CCDC); COUNT 26 to run CONCURRENT with other Counts; AS TO COUNT 27 - SIX (6) MONTHS in the Clark County Detention Center (CCDC); COUNT 27 to run CONCURRENT with other Counts; and AS TO COUNT 28 – LIFE with a MINIMUM Parole Eligibility of ONE HUNDRED TWENTY (120) MONTHS in the Nevada Department of Corrections (NDC), COUNT 28 to run CONSECUTIVE to COUNT 24; with THREE HUNDRED NINETEEN (319) DAYS Credit for Time Served.

FURTHER, COUNT 4 is OMITTED.

THEREAFTER, on the 18th day of November, 2013, pursuant to COURTS REVIEW, sentence is amended as follows: COUNT 21 to run CONCURRENT with Count 20.

DATED this 18th day of November, 2013

Valerie Adair

VALERIE ADAIR
DISTRICT JUDGE

Exhibit L

Decision in *Desai v. State of Nevada*, no. 64591
133 Nev. Adv. Op. 48 (July 27, 2017)

133 Nev., Advance Opinion 48

IN THE SUPREME COURT OF THE STATE OF NEVADA

KUSUM DESAI, AS PERSONAL REPRESENTATIVE FOR DIPAK KANTILAL DESAI,
Appellant,
vs.
THE STATE OF NEVADA,
Respondent.

No. 64591

FILED

JUL 27 2017

ELIZABETH A. BROWN
CLERK OF SUPREME COURT
BY
CHIEF DEPUTY CLERK

Appeal from a judgment and amended judgment of conviction, pursuant to a jury verdict, of nine counts of insurance fraud, seven counts of performance of an act in reckless disregard of persons or property resulting in substantial bodily harm, seven counts of criminal neglect of patients resulting in substantial bodily harm, theft, two counts of obtaining money under false pretenses, and second-degree murder. Eighth Judicial District Court, Clark County; Valerie Adair, Judge.

Affirmed in part and reversed in part.

Franny A. Forsman, Las Vegas; Wright, Stanish & Winckler and Richard A. Wright, Las Vegas,
for Appellant.

Adam Paul Laxalt, Attorney General, Carson City; Steven B. Wolfson, District Attorney, and Michael V. Staudaher and Ryan J. MacDonald, Deputy District Attorneys, Clark County,
for Respondent.

BEFORE THE COURT EN BANC.[1]

OPINION

By the Court, HARDESTY, J.:

A jury convicted appellant Dipak Kantilal Desai of, among other things, seven counts of performance of an act in reckless disregard of persons or property resulting in substantial bodily harm pursuant to NRS 202.595(2), and seven counts of criminal neglect of patients resulting in substantial bodily harm pursuant to NRS 200.495(1), collectively characterized in this opinion as the endangerment crimes. In this appeal, we are asked to determine whether a defendant can aid and abet a negligent or reckless crime, such as the endangerment crimes at issue here. We conclude that a defendant can be convicted of aiding and abetting a negligent or reckless crime upon sufficient proof that the aider and abettor possessed the necessary intent to aid in the act that caused the harm. Because the State presented sufficient evidence to show that Desai acted with awareness of the reckless or negligent conduct and with the intent to promote or further that conduct in the endangerment crimes for which he was convicted, we affirm his convictions for those crimes.

Desai also challenges the sufficiency of the evidence to convict him of second-degree murder. Because there were intervening causes between Desai's actions and the victim's death, we conclude that the State

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[1]The Honorable Ron D. Parraguirre, Justice, voluntarily recused himself from participation in the decision of this matter. The Honorable Lidia S. Stiglich, Justice, did not participate in the decision of this matter.

presented insufficient evidence to convict Desai of second-degree murder. Accordingly, we reverse Desai's second-degree murder conviction.[2]

FACTS AND PROCEDURAL HISTORY

Desai was the original founding member and managing partner of the Endoscopy Center of Southern Nevada and other ambulatory surgical centers (collectively, the clinic) in Las Vegas. Desai made all decisions regarding the clinic, including the ordering and use of supplies and scheduling of patients. He was also in charge of the certified registered nurse anesthetists.

On July 25, 2007, the clinic's first patient of the day informed Desai that he had hepatitis C before his procedure began. Later that day, Michael Washington had a procedure performed at the clinic. Washington was later diagnosed with hepatitis C. On September 21, 2007, the clinic's first patient of the day informed a nurse that he had hepatitis C before his procedure began. Later that day, Sonia Orellana Rivera, Gwendolyn Martin, Patty Aspinwall, Stacy Hutchinson, and Rodolfo Meana had procedures performed at the clinic. All five patients were later diagnosed

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[2]Desai also challenges his convictions on several other grounds: (1) his right to confrontation was violated because he was precluded from adequately cross-examining victim Rodolfo Meana prior to his death, a surrogate testified regarding Meana's autopsy report, and Meana's death certificate was improperly admitted; (2) the State committed prosecutorial misconduct; (3) the district court was required to order another competency evaluation and hold another hearing after Desai suffered a new series of strokes; and (4) his convictions for reckless disregard of persons and criminal neglect of patients must be reversed because they are lesser-included offenses of second-degree felony murder. After careful consideration, we determine that these arguments are without merit and do not warrant discussion.

with hepatitis C. Meana received some treatment following his diagnosis, but failed to adequately complete any treatment and eventually died as a result of the disease.

After learning that multiple patients contracted hepatitis C at the clinic, the Southern Nevada Health District initiated an investigation. Blood samples of the infected patients were sent to the Centers for Disease Control and Prevention (CDC). The CDC determined that the sources for the strains of hepatitis C contracted by Washington, Orellana Rivera, Martin, Aspinwall, Hutchinson, and Meana were the patient seen first at the clinic on July 25, 2007, and the patient seen first at the clinic on September 21, 2007. The CDC also concluded that the outbreak was the result of the clinic's nurse anesthetists reentering vials of propofol after injecting a patient and then reusing those vials of propofol on a subsequent patient.

Desai, along with Ronald Lakeman and Keith Mathahs, who were both nurse anesthetists at the clinic, were indicted. Desai and Lakeman were charged with ten counts of insurance fraud, seven counts of performance of an act in reckless disregard of persons or property resulting in substantial bodily harm, seven counts of criminal neglect of patients resulting in substantial bodily harm, theft, two counts of obtaining money under false pretenses, and second-degree murder. Mathahs agreed to testify against Desai and Lakeman after pleading guilty to criminal neglect of patients resulting in death, criminal neglect of patients resulting in substantial bodily harm, obtaining money under false pretenses, insurance fraud, and conspiracy. A jury found Desai guilty of

all counts except one omitted count of insurance fraud. Desai now appeals.[3]

DISCUSSION

There was sufficient evidence to convict Desai of the endangerment crimes

On appeal, Desai argues that there is insufficient evidence to convict him of the endangerment crimes because he did not have the required intent for aiding and abetting. To resolve this issue, we must first determine whether one can aid and abet a negligent or reckless crime.

Aiding and abetting a negligent or reckless crime

Desai argues that there was insufficient evidence to convict him of the endangerment crimes because he did not possess the intent required to prove that he aided and abetted Lakeman and Mathahs. We disagree.[4] When reviewing a challenge to the sufficiency of the evidence,

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[3]We note that appellant Dipak Kantilal Desai passed away on April 10, 2017. On June 6, 2017, Kusum Desai filed a motion to substitute as the personal representative for appellant Desai, deceased, pursuant to NRAP 43(a)(1), arguing that this court should resolve the appeal because it raises important issues of first impression, some of which are constitutional in nature. The State did not oppose the motion, and on June 14, 2017, this court granted the motion to substitute. *See Brass v. State*, 129 Nev. 527, 530, 306 P.3d 393, 395 (2013) ("[W]hen a criminal defendant dies after a notice of appeal has been filed, a personal representative must be substituted for the decedent within 90 days of his death being suggested upon the record . . . .").

[4]The indictment charged Desai with committing the endangerment crimes under three theories of liability: Desai directly committed the act, aided and abetted the principal in committing the act, or conspired with the principal in committing the act. Indictments are allowed to present "alternat[ive] theories of liability as long as there is evidence in support of those theories." *Walker v. State*, 116 Nev. 670, 673, 6 P.3d 477, 479 (2000);

continued on next page . . .

we must determine "whether, after viewing the evidence in the light most favorable to the prosecution, *any* rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt." *McNair v. State*, 108 Nev. 53, 56, 825 P.2d 571, 573 (1992) (qnoting *Jackson v. Virginia*, 443 U.S. 307, 319 (1979)).

The criminal offenses at issue here are set forth in NRS 202.595 and NRS 200.495. NRS 202.595 prohibits a person from "perform[ing] any act or neglect[ing] any duty imposed by law in willful or wanton disregard of the safety of persons or property." NRS 200.495(1) punishes "[a] professional caretaker who fails to provide such service, care or supervision as is reasonable and necessary to maintain the health or safety of a patient." And NRS 195.020 provides that a person who aids and abets in the commission of a crime shall be punished as a principal. However, we have not previously determined whether one can aid and abet a reckless or negligent crime.

Some jurisdictions have determined that a defendant cannot be convicted of aiding and abetting a reckless or negligent crime because "it is logically impossible to intend to aid" another in acting recklessly or

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. . . *continued*

see also NRS 173.075(2). Because we conclude that there was sufficient evidence to convict Desai under an aiding and abetting theory of liability, we do not discuss the other two theories of liability. *See State v. Kirkpatrick*, 94 Nev. 628, 630, 584 P.2d 670, 671-72 (1978) ("Where . . . a single offense may be committed by one or more specified means, and those means are charged alternatively, the state need only prove one of the alternative means in order to sustain a conviction.").

negligently.[5] Audrey Rogers, *Accomplice Liability for Unintentional Crimes: Remaining Within the Constraints of Intent*, 31 Loy. L.A. L. Rev. 1351, 1383 (1998). These jurisdictions opine that "[a]pplying accomplice liability [to reckless or negligent crimes] raises troubling questions about whether the complicity doctrine is being stretched beyond its proper limits merely to find a means of punishing the [secondary actor]." *Id.* at 1353.

It appears, however, that courts are moving away from this rule, *see id.* at 1352 (explaining that "a growing number of courts have found secondary actors responsible for another individual's unintentional crime"), because "giving assistance or encouragement to one it is known will thereby engage in conduct dangerous to life should suffice for accomplice liability." Wayne R. LaFave, *Criminal Law* § 13.2(e) (5th ed. 2010). We are persuaded by the rationale for this approach and thus decline to completely excuse an aider and abettor of a reckless or negligent crime from liability. Although NRS 195.020 provides that an aider and abettor shall be punished as a principal, the statute "does not specify what

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[5]*See, e.g., Fight v. State*, 863 S.W.2d 800, 805 (Ark. 1993) (agreeing with the New Hampshire Supreme Court "that an accomplice's liability ought not to extend beyond the criminal purposes that he or she shares" (quoting *State v. Etzweiler*, 480 A.2d 870, 874 (N.H. 1984), *superseded by statute on other grounds as stated in State v. Anthony*, 861 A.2d 773, 775-76 (N.H. 2004))); *People v. Marshall*, 106 N.W.2d 842, 844 (Mich. 1961) (determining that an owner of a vehicle who gave his keys to an intoxicated individual who killed another could not be found guilty of manslaughter because "the killing of [the victim] was not counselled by him, accomplished by another acting jointly with him, nor did it occur in the attempted achievement of some common enterprise"); *Etzweiler*, 480 A.2d at 874-75 (holding that the aider and abettor "could [not] intentionally aid [the principal] in a crime that [the principal] was unaware that he was committing").

mental state is required to be convicted as an aider or abettor." *Sharma v. State*, 118 Nev. 648, 653, 56 P.3d 868, 870 (2002). Thus, we must determine what mental state is required to convict an aider and abettor of a reckless or negligent crime.

In *Sharma*, the appellant challenged his conviction for aiding and abetting attempted murder, arguing that the jury was improperly instructed on the necessary elements of the crime. *Id.* at 650, 56 P.3d at 869. This court held "that in order for a person to be held accountable for the *specific intent crime* of another under an aiding or abetting theory of principal liability, the aider or abettor must have knowingly aided the other person with the intent that the other person commit the charged crime." *Id.* at 655, 56 P.3d at 872 (emphasis added). The mental state articulated in *Sharma* for specific intent crimes leaves open the question as to the mental state required for reckless or negligent crimes. Consistent, however, with our reasoning in *Sharma*, we conclude that an aider and abettor must act with awareness of the reckless or negligent conduct and with the intent to promote or further that conduct.

This holding is consistent with how other jurisdictions have held. *See, e.g.*, *People v. Wheeler*, 772 P.2d 101, 105 (Colo. 1989) ("[T]he complicitor must be *aware* that the principal is engaging in [negligent] conduct." (emphasis added)); *State v. Foster*, 522 A.2d 277, 284 (Conn. 1987) ("[A] person may be held liable as an accessory to a criminally negligent act if he . . . intentionally aids another in the crime."); *Commonwealth v. Bridges*, 381 A.2d 125, 128 (Pa. 1977) ("[A]n accomplice's conduct must, with the intent to promote or facilitate, aid one whose conduct does causally result in the criminal offense."); *State v. McVay*, 132 A. 436, 439 (R.I. 1926) (determining that the defendant could

be charged as an aider and abettor because he "recklessly and willfully advised, counseled, and commanded [the principals] to take a chance by negligent action or failure to act").

Having concluded that Desai can be charged as an aider and abettor in a negligent or reckless crime, we must now determine whether there was sufficient evidence presented to show that Desai possessed the necessary intent to aid and abet in the endangerment crimes for which he was convicted.

There was sufficient evidence to show that Desai intended to aid and abet in the endangerment crimes

Desai argues that the State did not sufficiently prove that he had knowledge that Mathahs' and Lakeman's injection practices violated a standard of patient care or that he intended for them to violate a standard of patient care. Desai also argues that the State failed to prove that he had knowledge of the lack of availability and reuse of supplies at the clinic.

According to a CDC medical officer, unsafe injection practices result when a nurse anesthetist administers to a patient one dose of propofol using a needle and syringe and places that same syringe back into a vial of propofol—even if the needle is changed—which is then later used on a second patient. There is a risk that any blood in the syringe from the first patient will be transferred to the propofol vial that is later used on a second patient.

When the State questioned Mathahs about reentering a propofol vial in order to redose a patient, Mathahs testified that he would replace the needle before reentering the vial. Mathahs further testified on direct examination as follows:

[STATE]: Are you aware that there is at least a risk of potential contamination even changing out the needle in that situation?

[MATHAHS]: Yes, there is.

[STATE]: Did you ever express your concerns about doing this to Dr. Desai?

[MATHAHS]: Yes.

[STATE]: What was his response?

[MATHAHS]: It's to save money, just go ahead and do it.

[STATE]: So he instructed you to do it even though you made him aware of the risk?

[MATHAHS]: Yes.

This line of questioning occurred again on redirect examination:

[STATE]: Did you not testify on direct examination that when Desai told you to do this, reuse stuff that you had never done before, that you expressed the risk to him and that he told you to do it anyway?

[MATHAHS]: I don't remember the exact conversation but, yes, I'm sure it was had, yes.

[STATE]: So you expressed—just so we're clear, in whatever words, you expressed that there was a risk in doing that to Dr. Desai and he ordered you to do it anyway and you did it.

[MATHAHS]: Yes.

Further, Gayle Langley, a CDC medical officer, testified that she observed Mathahs reenter a vial of propofol with the same syringe.

Mathahs testified that Desai checked the disposal containers and, if he found any unused propofol remaining in the syringes or vials of propofol, he would yell at the responsible nurse anesthetist for being wasteful. Mathahs "guess[ed]" that Desai wanted any unused propofol to

be used on a subsequent patient and testified that he would likely be fired if Desai found a discarded vial still containing propofol.

The State also called Nancy Sampson, an analyst with the Las Vegas Metropolitan Police Department (LVMPD), to testify regarding charts she prepared that summarized patient records from the clinic. Sampson testified that the clinic's 2007 records indicated that it did not have adequate supplies to use a new vial of propofol on each patient and a new syringe for each injection.

Clinic employees testified that Desai complained that the nurse anesthetists used too many supplies, told employees that supplies should not be wasted, told a nurse anesthetist that he used too much propofol, and promised the nurse anesthetists a bonus if they brought the cost of propofol down. There was further testimony that Desai admonished other doctors if they changed their used gown after a procedure, Desai yelled if a nurse put a sheet on a patient, and materials were cut in half. Jeffrey Krueger, a nurse at the clinic, testified that a technician informed him that Desai had instructed her to reuse disposable forceps. When Krueger explained to Desai that they had "gone over this [issue], that we have plenty of them, there is no need to reprocess, they're single use, we know the risks of it," Desai said, "I know, I know, okay, okay."

Finally, Ralph McDowell, a nurse anesthetist at the clinic, testified that Desai told him to pretend that he did not know what a multiuse vial was if he was asked. And an LVMPD detective testified that

a nurse anesthetist told him that Desai told her to inject patients "the way [Lakeman] did it."[6]

"Intention is manifested by the circumstances connected with the perpetration of the offense," NRS 193.200, and the jury is tasked with determining intent, *see State v. McNeil*, 53 Nev. 428, 435, 4 P.2d 889, 890 (1931) (stating that the "question of intent . . . must be left to the jury"). The State presented evidence that the clinic lacked adequate supplies to safely inject patients with propofol and Desai was more concerned with curbing waste of supplies than with patient comfort or safety. Additionally, Mathahs testified that he was aware of the risks of reusing the same needle and expressed his concerns to Desai, and that Desai encouraged the nurse anesthetists to reuse propofol vials if there was any remaining propofol following a procedure. The evidence further demonstrated that Desai was not concerned when nurse anesthetists failed to follow proper procedures, and Desai requested that nurse anesthetists conceal unsafe injection practices.

Viewing the evidence adduced at trial in a light most favorable to the prosecution, we conclude that any rational trier of fact could have found beyond a reasonable doubt that Desai was guilty of the endangerment crimes. While there was conflicting testimony and other evidence regarding clinic injection practices, the availability of supplies, and Desai's knowledge of supply reuse at the clinic, it was the jury's duty

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[6]Another CDC medical officer testified that Lakeman told her that reentering a vial of propofol with the same syringe "was not the safest practice, but that he would keep pressure on the plunger to . . . try to prevent backflow of anything into the syringe from the patient."

to weigh the evidence and assess the credibility of the witnesses. *See McNair v. State*, 108 Nev. 53, 56, 825 P.2d 571, 573 (1992) ("[I]t is the jury's function, not that of the court, to assess the weight of the evidence and determine the credibility of witnesses.").

Thus, we conclude that the State presented sufficient evidence for the jury to find that Desai possessed the necessary intent to aid and abet in the endangerment crimes, and we thus affirm Desai's convictions for these crimes.

There was insufficient evidence to convict Desai of second-degree murder

Desai challenges the sufficiency of the evidence to convict him of second-degree murder. According to the instructions given to the jury, there were two theories of liability under which the jury could convict Desai of second-degree murder: second-degree felony murder or murder in the second degree. The verdict form listed "Count 28 – MURDER (SECOND DEGREE) (Rodolfo Meana)" and had two boxes below the count titled "Guilty of Second Degree Murder" and "Not Guilty." There is no way to tell whether the jury found Desai guilty of second-degree felony murder or murder in the second-degree. Thus, we discuss both theories of liability.

Second-degree felony murder

Second-degree felony murder requires an inherently dangerous felony and "an immediate and direct causal relationship between the" defendant's actions and victim's death. *Sheriff v. Morris*, 99 Nev. 109, 118, 659 P.2d 852, 859 (1983). "[I]mmediate" is defined as "without the intervention of some other source or agency." *Ramirez v. State*, 126 Nev. 203, 206, 235 P.3d 619, 622 (2010) (internal quotation marks omitted).

Meana contracted hepatitis C on September 21, 2007, from the unsafe injection practice of a nurse anesthetist at the clinic. Meana died from the hepatitis C infection over four years later on April 27, 2012. During those four years, Meana was told to seek medical treatment by at least two doctors. Although both doctors told Meana that treatment could cure his hepatitis C infection, Meana voluntarily declined full treatment.

We conclude that the link between Desai's reckless and negligent conduct of encouraging unsafe injection techniques is sufficiently attenuated from Meana's death. Meana did not die as an immediate and direct consequence of Desai's actions. Rather, his failure to pursue treatment broke any such direct causal connection. Moreover, the improper act did not have an immediate relationship to Meana's death because over four years passed between the two occurrences, and Meana refused any medical treatment that may have cured the disease that caused his death. *See Morris*, 99 Nev. at 118, 659 P.2d at 859 (expressing specific limitations to the rule's application to attenuate the "potential for untoward prosecutions"). We conclude that any rational trier of fact could not have found beyond a reasonable doubt the essential elements of second-degree felony murder. *See McNair*, 108 Nev. at 56, 825 P.2d at 573.

Murder in the second degree

First-degree murder is a "willful, deliberate and premeditated killing." NRS 200.030(1)(a). Second-degree murder "is all other kinds of murder," NRS 200.030(2), and requires a finding of implied malice without premeditation and deliberation, *see Labastida v. State*, 115 Nev. 298, 307, 986 P.2d 443, 449 (1999). Implied malice is demonstrated when the defendant "commit[s] an[ ] affirmative act that harm[s] [the victim]." *Id.*; *see also* NRS 193.190 (requiring unity of act and intent to constitute the

crime charged); NRS 200.020(2) ("Malice shall be implied when no considerable provocation appears, or when all the circumstances of the killing show an abandoned and malignant heart.").

While Desai aided and abetted the nurse anesthetists to act recklessly and negligently when injecting patients, the nurse anesthetist who improperly injected Meana "commit[ted] [the] affirmative act that harmed" Meana. *Labastida*, 115 Nev. at 307, 986 P.2d at 449. Because Desai's conduct was a step removed from the act that caused the harm, we conclude that any rational trier of fact could not have found beyond a reasonable doubt the essential elements of murder in the second degree. *See McNair*, 108 Nev. at 56, 825 P.2d at 573; *Labastida*, 115 Nev. at 307-08, 986 P.2d at 449.

Although it is unclear under which theory of liability Desai was found guilty, we conclude that there was insufficient evidence to convict him under either theory, and we thus reverse Desai's conviction for second-degree murder.[7]

[7]Desai also argues that the third element of second-degree felony murder was omitted from the jury instructions, the trial court failed to instruct the jury on the merger doctrine, and this court should abrogate the second-degree felony-murder rule. Because we reverse Desai's second-degree murder conviction due to insufficient evidence, we need not address these other arguments.

Accordingly, for the reasons set forth above, we affirm the district court's judgment of conviction except for Desai's second-degree murder conviction, which we reverse.

_____, J.
Hardesty

We concur:

_____, C.J.
Cherry

_____, J.
Douglas

_____, J.
Gibbons

_____, J.
Pickering

Exhibit M

FDA Review Packet

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-102

Approval Letter

001

APP0955

ANDA 75-102

Gensia Sicor Pharmaceuticals, Inc.
Attention: Rosalie A. Lowe
17 Hughes
Irvine, CA 92618

JAN 4 1999

Dear Madam:

This is in reference to your abbreviated new drug application dated March 31, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Propofol Injectable Emulsion 1% (10 mg/mL).

Reference is also made to your amendments dated May 20, and December 3, 1997; and January 16, February 11, March 12, April 13, May 27, August 24, October 16, November 10, December 14, December 15, December 21, and December 28, 1998.

The listed drug referenced in your application is subject to a period of patent protection which expires on March 22, 2015 (patents 5,714,520 [the '520 patent], 5,731,355 and 5,731,356). Your application contains certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on any of the listed patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of this application shall be made effective immediately unless an action is brought for infringement of one or more of the patents which are the subject of the certifications before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified the Agency that Zeneca Limited initiated a patent infringement suit within the forty-five day period involving the '520 patent in the United States District Court for the District of Delaware (Zeneca Limited v. Gensia Sicor Pharmaceuticals, Inc. [Civil Action No. 98-170 (JJF)]). You have also notified the Agency that on April 17, 1998, Zeneca Limited dismissed the suit against Gensia Sicor Pharmaceuticals, Inc. without prejudice.

The listed drug referenced in your application is also subject to a period of new product (NP) market exclusivity expiring on June 11, 1999, for Propofol Injectable Emulsion, 10 mg/mL, formulated with EDTA as a preservative. As the drug product provided for in the current abbreviated new drug application is formulated using sodium metabisulfite as the preservative in place of EDTA, you have informed the Agency that the current exclusivity is not applicable to your drug product.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Propofol Injectable Emulsion 1% (10 mg/mL) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Diprivan Injectable Emulsion 1% of Zeneca Ltd.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/ 1/99

Roger L. Williams, M.D.
Deputy Center Director for Pharmacuetical Science
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-102

FINAL PRINTED LABELING

004

APP0958

Y36-204-201
Package Insert

GensiaSicor PHARMACEUTICALS

Propofol

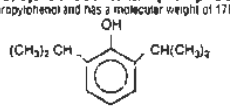
Injectable Emulsion 1%
200 mg/20 mL (10 mg/mL) propofol

Contains a Sulfite

For I.V. Administration

DESCRIPTION

Propofol injectable emulsion is a sterile, nonpyrogenic emulsion containing 10 mg/mL of propofol suitable for intravenous administration. Propofol is chemically described as 2,6-Diisopropylphenol and has a molecular weight of 178.28. The structural and molecular formulas are:



$C_{12}H_{18}O$

Propofol is very slightly soluble in water and, thus, is formulated in a white oil-in-water emulsion. The pKa is 11. The octanol/water partition coefficient for propofol is 6761:1 at a pH of 6-8.5. In addition to the active component, propofol, the formulation also contains soybean oil (100 mg/mL), glycerol (22.5 mg/mL), egg yolk phospholipid (12 mg/mL), and sodium metabisulfite (0.25 mg/mL) with sodium hydroxide to adjust pH. The propofol injectable emulsion is isotonic and has a pH of 4.5-6.4.

STRICT ASEPTIC TECHNIQUE MUST ALWAYS BE MAINTAINED DURING HANDLING. PROPOFOL INJECTABLE EMULSION IS A SINGLE-USE PARENTERAL PRODUCT WHICH CONTAINS SODIUM METABISULFITE (0.25 mg/mL) TO RETARD THE RATE OF GROWTH OF MICROORGANISMS IN THE EVENT OF ACCIDENTAL EXTRINSIC CONTAMINATION. HOWEVER, PROPOFOL INJECTABLE EMULSION CAN STILL SUPPORT THE GROWTH OF MICROORGANISMS AS IT IS NOT AN ANTIMICROBIALLY PRESERVED PRODUCT UNDER USP STANDARDS. ACCORDINGLY, STRICT ASEPTIC TECHNIQUE MUST STILL BE ADHERED TO. DO NOT USE IF CONTAMINATION IS SUSPECTED. DISCARD UNUSED PORTIONS AS DIRECTED WITHIN THE REQUIRED TIME LIMITS (SEE DOSAGE AND ADMINISTRATION, HANDLING PROCEDURES). THERE HAVE BEEN REPORTS IN WHICH FAILURE TO USE ASEPTIC TECHNIQUE WHEN HANDLING PROPOFOL INJECTABLE EMULSION WAS ASSOCIATED WITH MICROBIAL CONTAMINATION OF THE PRODUCT AND WITH FEVER, INFECTION/SEPSIS, OTHER LIFE-THREATENING ILLNESS, AND/OR DEATH.

CLINICAL PHARMACOLOGY

General

Propofol injectable emulsion is an intravenous sedative-hypnotic agent for use in the induction and maintenance of anesthesia or sedation. Intravenous injection of a therapeutic dose of propofol produces hypnosis rapidly with minimal excitation, usually within 40 seconds from the start of an injection (the time for one arm-brain circulation). As with other rapidly acting intravenous anesthetic agents, the half-time of the blood-brain equilibration is approximately 1 to 3 minutes, and this accounts for the rapid induction of anesthesia.

Pharmacodynamics

Pharmacodynamic properties of propofol are dependent upon the therapeutic blood propofol concentrations. Steady state propofol blood concentrations are generally proportional to infusion rates, especially within an individual patient. Undesirable side effects such as cardiorespiratory depression are likely to occur at higher blood concentrations which result from bolus dosing or rapid increase in infusion rate. An adequate interval (3 to 5 minutes) must be allowed between clinical dosage adjustments in order to assess drug effects.

The hemodynamic effects of propofol during induction of anesthesia vary, if spontaneous ventilation is maintained, the major cardiovascular effects are arterial hypotension (sometimes greater than a 30% decrease) with little or no change in heart rate and no appreciable decrease in cardiac output. If ventilation is assisted or controlled (positive pressure ventilation), the degree and incidence of decrease in cardiac output are accentuated. Addition of a potent opioid (e.g., fentanyl) when used as a premedicant further decreases cardiac output and respiratory drive.

If anesthesia is continued by infusion of propofol, the stimulation of endotracheal intubation and surgery may return arterial pressure towards normal. However, cardiac output may remain depressed. Comparative clinical studies have shown that the hemodynamic effects of propofol during induction of anesthesia are generally more pronounced than with other IV induction agents traditionally used for this purpose.

Clinical and preclinical studies suggest that propofol is rarely associated with elevation of plasma histamine levels.

Induction of anesthesia with propofol is frequently associated with apnea in both adults and children. In 1573 adult patients who received propofol (2 to 2.5 mg/kg), apnea lasted less than 30 seconds in 7% of patients, 30-60 seconds in 24% of patients, and more than 60 seconds in 12% of patients. In the 213 pediatric patients between the ages of 3 and 12 years assessable for apnea who received propofol (1 to 3.5 mg/kg), apnea lasted less than 30 seconds in 12% of patients, 30-60 seconds in 10% of patients, and more than 60 seconds in 5% of patients.

During maintenance, propofol causes a decrease in ventilation usually associated with an increase in carbon dioxide tension which may be marked depending upon the rate of administration and other concurrent medications (e.g., opioids, sedatives, etc.).

During monitored anesthesia care (MAC) sedation, attention must be given to the cardiorespiratory effects of propofol. Hypotension, oxyhemoglobin desaturation, apnea, airway obstruction, and/or oxygen desaturation can occur, especially following a rapid bolus of propofol. During initiation of MAC sedation, slow infusion or slow injection techniques are preferable over rapid bolus administration; and during maintenance of MAC sedation, a variable rate infusion is preferable over intermittent bolus administration in order to minimize undesirable cardiorespiratory effects. In the elderly, debilitated, or ASA III/IV patients, rapid (single or repeated) bolus dose administration should not be used for MAC sedation. (See WARNINGS.) Propofol is not recommended for MAC sedation in children because safety and effectiveness have not been established.

Clinical studies in humans and studies in animals show that propofol does not suppress the adrenal response to ACTH.

Preliminary findings in patients with normal intracranial pressure indicate that propofol anesthesia produces a decrease in intraocular pressure which may be associated with a concomitant decrease in systemic vascular resistance.

Animal studies and limited experience in susceptible patients have not indicated any propensity of propofol to induce malignant hyperthermia.

Studies to date indicate that propofol when used in combination with hypocarbia increases cerebrovascular resistance and decreased cerebral blood flow, cerebral metabolic oxygen consumption, and intracranial pressure. Propofol does not affect cerebrovascular reactivity to changes in arterial carbon dioxide tension. (See Clinical Trials - Neuroanesthesia.)

Pharmacokinetics

The proper use of propofol injectable emulsion requires an understanding of the disposition and elimination characteristics of propofol.

The pharmacokinetics of propofol are well described by a three compartment linear model with compartments representing the plasma, rapidly equilibrating tissues, and slowly equilibrating tissues.

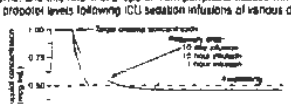
Following an I.V. bolus dose, there is a rapid equilibration between the plasma and the highly perfused tissue of the brain, thus accounting for the rapid onset of anesthesia. Plasma levels initially decline rapidly as a result of both rapid distribution and high metabolic clearance. Distribution accounts for about half of this decline following a bolus of propofol.

However, distribution is not constant over time but decreases as body tissues equilibrate with plasma and become saturated. The rate at which equilibration occurs is a function of the rate and duration of the infusion. When equilibration occurs, there is no longer a net transfer of propofol between tissues and plasma.

Discontinuation of the recommended doses of propofol after the maintenance of anesthesia for approximately one hour, or for sedation in the ICU for one day, results in a prompt decrease in blood propofol concentrations and rapid awakening. Longer infusions (10 days of ICU sedation) result in accumulation of significant tissue stores of propofol, such that the reduction in circulating propofol is slowed and the time to awakening is increased.

By daily titration of propofol dosage to achieve only the minimum effective therapeutic concentration, rapid awakening within 10 to 15 minutes will occur even after long-term administration. However, higher than necessary infusion levels have been maintained for a long time, propofol will be redistributed from fat and muscle to the plasma, and the return of propofol from peripheral tissues will slow recovery.

The figure below illustrates the fall of plasma propofol levels following ICU sedation infusions of various durations.



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APP0959

NICS. Propofol is not recommended for MAC sedation in children because safety and effectiveness have not been established.

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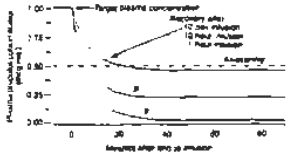
However, distribution is not constant over time but decreases as body tissues equilibrate with plasma and become saturated. The rate at which equilibration occurs is a function of the rate and duration of the infusion. When equilibration occurs, there is no longer a net transfer of propofol between tissues and plasma.

Discontinuation of the recommended doses of propofol after the maintenance of anesthesia for approximately one hour, or for sedation in the ICU for one day, results in a prompt decrease in blood propofol concentrations and rapid awakening. Longer infusions (30 days of ICU sedation) result in accumulation of significant tissue stores of propofol, such that the reduction in circulating propofol is slowed and the time to awakening is increased.

By daily titration of propofol dosage to achieve only the minimum effective therapeutic concentration, rapid awakening (within 10 to 15 minutes) will occur even after long-term administration. If, however, higher than necessary infusion levels have been maintained for a long time, propofol will be redistributed from fat and muscle to the plasma; and this return of propofol from peripheral tissues will slow recovery.

The figure below illustrates the fall of plasma propofol levels following ICU sedation infusions of various durations.



The large contribution of distribution (about 50%) to the fall of propofol plasma levels following brief infusions means that after very long infusions (at steady state) about half the usual rate will maintain the same plasma levels. Failure to reduce the infusion rate in patients receiving propofol for extended periods may result in excessively high blood concentrations of the drug. Thus, titration to clinical response and daily evaluation of sedation levels are important during use of propofol infusion for ICU sedation, especially of long duration.

Adults: Propofol clearance ranges from 23-50 mL/kg/min (1.6 to 3.4 L/min in 70 kg adults). It is chiefly eliminated by hepatic conjugation to inactive metabolites which are excreted by the kidney. A glucuronide conjugate accounts for about 50% of the administered dose. Propofol has a steady state volume of distribution (10-day infusion) approaching 60 L/kg in healthy adults. A difference in pharmacokinetics due to gender has not been observed. The terminal half-life of propofol after a 10-day infusion is 1 to 3 days.

Geriatrics: With increasing patient age, the dose of propofol needed to achieve a defined anesthetic end point (dose-requirement) decreases. This does not appear to be an age-related change of pharmacodynamics or brain sensitivity, as measured by EEG burst suppression. With increasing patient age, pharmacokinetic changes are such that for a given I.V. bolus dose, higher peak plasma concentrations occur, which can explain the decreased dose requirement. These higher peak plasma concentrations in the elderly can predispose patients to cardiorespiratory effects including hypotension, apnea, airway obstruction, and/or oxygen desaturation. The higher plasma levels reflect an age-related decrease in volume of distribution and reduced intercompartmental clearance. Lower doses are thus recommended for initiation and maintenance of sedation/anesthesia in elderly patients. (See CLINICAL PHARMACOLOGY - Individualization of Dosage.)

Pediatrics: The pharmacokinetics of propofol were studied in 53 children between the ages of 3 and 12 years who received propofol for periods of approximately 1-2 hours. The observed distribution and clearance of propofol in these children were similar to adults.

Organ Failure: The pharmacokinetics of propofol do not appear to be different in people with chronic hepatic cirrhosis or chronic renal impairment compared to adults with normal hepatic and renal function. The effects of acute hepatic or renal failure on the pharmacokinetics of propofol have not been studied.

Clinical Trials

Anesthesia and Monitored Anesthesia Care (MAC) Sedation

Propofol was compared to intravenous and inhalational anesthetic or sedative agents in 91 trials involving a total of 5,135 patients. Of these, 3,351 received propofol and comprised the overall safety database for anesthesia and MAC sedation. Fifty-five of these trials (20 for anesthesia induction and 35 for induction and maintenance of anesthesia or MAC sedation) were carried out in the US or Canada and provided the basis for dosage recommendations and the adverse event profile during anesthesia or MAC sedation.

Pediatric Anesthesia

Propofol was compared to standard anesthetic agents in 12 clinical trials involving 534 patients receiving propofol. Of these, 349 were from US/Canadian clinical trials and comprised the overall safety database for pediatric anesthesia.

TABLE 1. PEDIATRIC ANESTHESIA CLINICAL TRIALS
Patients Receiving Propofol Median and (Range)

	Induction Only	Induction and Maintenance
Number of Patients*	240	105
Induction Bolus Dosages	2.5 mg/kg (1-3.5)	3 mg/kg (2-3.6)
Injection Duration	20 sec (6-45)	
Maintenance Dosage		181 mcg/kg/min (107-318)
Maintenance Duration		78 min (29-268)

*Body weight not recorded for one patient

Neuroanesthesia
Propofol was studied in 58 patients undergoing craniotomy for supratentorial tumors in two clinical trials. The mean lesion size (anterior/posterior and lateral) was 31 mm and 32 mm in one trial and 55 mm and 42 mm in the other trial, respectively.

TABLE 2. NEUROANESTHESIA CLINICAL TRIALS
Patients Receiving Propofol Median and (Range)

Patient Type	No. of Patients	Induction Bolus Dosages (mg/kg)	Maintenance Dosage (mcg/kg/min)	Maintenance Duration (min)
Craniotomy patients	50	1.35 (0.9-6.9)	146 (68-425)	285 (48-622)

In ten of these patients, propofol was administered by infusion in a controlled clinical trial to evaluate the effect of propofol on cerebrospinal fluid pressure (CSFP). The mean arterial pressure was maintained relatively constant over 25 minutes with a change from baseline of -4% ± 17% (mean ± SD), whereas the percent change in cerebrospinal fluid pressure (CSFP) was -46% ± 14%. As CSFP is an indirect measure of intracranial pressure (ICP), when given by infusion or slow bolus, propofol, in combination with hypocarbia, is capable of decreasing ICP independent of changes in arterial pressure.

Intensive Care Unit (ICU) Sedation
Propofol was compared to benzodiazepines and/or opioids in 14 clinical trials involving a total of 550 ICU patients. Of these, 302 received propofol and comprise the overall safety database for ICU sedation. Six of these studies were carried out in the US or Canada and provide the basis for dosage recommendations and the adverse event profile.

Information from 193 literature reports of propofol used for ICU sedation in over 930 patients and information from the clinical trials are summarized below:

TABLE 3. ICU SEDATION CLINICAL TRIALS AND LITERATURE
Patients Receiving Propofol Median and (Range)

ICU Patient Type	Number of Patients: Trials	Number of Patients: Literature	Sedation Dose: mcg/kg/min	Sedation Dose: mg/kg/h	Sedation Duration: Hours
Post-CABG	41		11 (0.1-30)	0.66 (0.006-1.8)	10 (2-14)
	-	334	(5-100)	(0.3-6)	(4-24)
Post-Surgical	60	-	20 (8-53)	1.2 (0.4-3.2)	18 (0.3-187)
		142	(23-82)	(1.4-4.9)	(5-96)
Neuro/Head Trauma	?	-	25 (13-37)	1.5 (0.8-2.2)	168 (112-282)
	-	184	(8.3-67)	(0.5-5.2)	(8 hr-5 days)
Medical	49	-	41 (9-131)	2.5 (0.5-7.9)	72 (0.4-337)
		76	(3.3-62)	(0.2-3.7)	(4-96)
Special Patients					
ARDS/Resp. Failure		56	(10-142)	(0.6-6.5)	(1 hr-8 days)
COPD/Asthma	-	49	(17-75)	(1-4.5)	(1-8 days)
Status Epilepticus	-	15	(25-157)	(1.5-10)	(1-21 days)
Tetanus	-	11	(5-100)	(0.3-6)	(1-25 days)

Trials (individual patients from clinical studies)
Literature (individual patients from published reports)
CABG (Coronary Artery Bypass Graft)
ARDS (Adult Respiratory Distress Syndrome)

Cardiac Anesthesia
Propofol was evaluated in 3 clinical trials conducted in the US and Canada, involving a total of 569 patients undergoing coronary artery bypass graft (CABG). Of these, 301 patients received propofol. They comprise the safety database for cardiac anesthesia and provide the basis for dosage recommendations in this patient population, in conjunction with reports in the published literature.

Individualization of Dosage
General: STRICT ASEPTIC TECHNIQUE MUST ALWAYS BE MAINTAINED DURING HANDLING. PROPOFOL INJECTABLE EMULSION IS A SINGLE-USE PARENTERAL PRODUCT WHICH CONTAINS SODIUM METABISULFITE (0.25 mg/mL) TO RETARD THE RATE OF GROWTH OF MICROORGANISMS IN THE EVENT OF ACCIDENTAL EXTRINSIC CONTAMINATION. HOWEVER, PROPOFOL INJECTABLE EMULSION CAN STILL SUPPORT THE GROWTH OF MICROORGANISMS AS IT IS NOT AN ANTIMICROBIALLY PRESERVED PRODUCT UNDER USP STANDARDS. ACCORDINGLY, STRICT ASEPTIC TECHNIQUE MUST STILL BE ADHERED TO. DO NOT USE IF CONTAMINATION IS SUSPECTED. DISCARD UNUSED PORTIONS AS DIRECTED WITHIN THE REQUIRED TIME LIMITS (SEE DOSAGE AND ADMINISTRATION, HANDLING PROCEDURES). THERE HAVE BEEN REPORTS IN WHICH FAILURE TO USE ASEPTIC TECHNIQUE WHEN HANDLING PROPOFOL INJECTABLE EMULSION WAS ASSOCIATED WITH MICROBIAL CONTAMINATION OF THE PRODUCT AND WITH FEVER, INFECTION/SEPSIS, OTHER LIFE-THREATENING ILLNESS, AND/OR DEATH.

Propofol blood concentrations at steady state are generally proportional to infusion rates, especially in individual patients. Undesirable effects such as cardiorespiratory depression are likely to occur at higher blood concentrations which result from bolus dosing or rapid increases in the infusion rate. An adequate interval (3 to 5 minutes) must be allowed between clinical dosage adjustments in order to assess drug effects.

When administering propofol by infusion, syringe pumps or volumetric pumps are recommended to provide controlled infusion rates. When infusing propofol to patients undergoing magnetic resonance imaging, metered control devices may be required if mechanical pumps are impractical.

Changes in vital signs (increases in pulse rate, blood pressure, sweating, and/or tearing) that indicate a response to surgical stimulation or lightening of anesthesia may be controlled by the administration of propofol 25 mg (2.5 mL) to 50 mg (5 mL) incremental boluses and/or by increasing the infusion rate.

For minor surgical procedures (e.g., body surface), nitrous oxide (60%-70%) can be combined with a variable rate propofol infusion to provide satisfactory anesthesia. With more stimulating surgical procedures (e.g., intra-abdominal), or if supplementation with nitrous oxide is not provided, administration rate(s) of propofol and/or opioids should be increased in order to provide adequate anesthesia.

Infusion rates should always be titrated downward in the absence of clinical signs of light anesthesia until a mild response to surgical stimulation is obtained in order to avoid administration of propofol at rates higher than are clinically necessary. Generally, rates of 50 to 100 mcg/kg/min in adults should be achieved during maintenance in order to optimize recovery times.

Other drugs that cause CNS depression (hypnotics/sedatives, inhalational anesthetics, and opioids) can increase CNS depression induced by propofol. Morphine premedication (0.15 mg/kg) with nitrous oxide-87% in oxygen has been shown to decrease the necessary propofol maintenance infusion rate and therapeutic blood concentrations when compared to non-narcotic (lorazepam) premedication.

Induction of General Anesthesia:
Adult Patients: Most adult patients under 55 years of age and classified ASA I/II require 2 to 2.5 mg/kg of propofol for induction when unpremedicated or when premedicated with oral benzodiazepines or intramuscular opioids. For induction, propofol should be titrated (approximately 40 mg every 10 seconds) against the response of the patient until the clinical signs show the onset of anesthesia. As with other sedative-hypnotic agents, the amount of intravenous opioid and/or benzodiazepine premedication will influence the response of the patient to an induction dose of propofol.

Elderly, Debilitated, or ASA III/IV Patients: It is important to be familiar and experienced with the intravenous use of propofol before treating elderly, debilitated, or ASA III/IV patients. Due to the reduced clearance and higher blood concentrations, most of these patients require approximately 1 to 1.5 mg/kg (approximately 20 mg every 10 seconds) of propofol for induction of anesthesia according to their condition and responses. A rapid bolus should not be used as this will increase the likelihood of undesirable cardiorespiratory depression, including hypotension, apnea, de-

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When administering propofol by infusion, syringe pumps or volumetric pumps are recommended to provide controlled infusion rates. When infusing propofol to patients undergoing magnetic resonance imaging, metered control devices may be utilized if mechanical pumps are impractical.

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For minor surgical procedures (e.g., body surface), nitrous oxide (60%–70%) can be combined with a variable rate propofol infusion to provide satisfactory anesthesia. With more stimulating surgical procedures (e.g., intra-abdominal), or if supplementation with nitrous oxide is not provided, administration rates of propofol and/or opioids should be increased in order to provide adequate anesthesia.

Infusion rates should always be titrated downward in the absence of clinical signs of light anesthesia until a vivid response to surgical stimulation is obtained in order to avoid administration of propofol at rates higher than are clinically necessary. Generally, rates of 50 to 100 mcg/kg/min in adults should be achieved during maintenance in order to optimize recovery times.

Other drugs that cause CNS depression (hypnotics, sedatives, inhalational anesthetics, and opioids) can increase CNS depression induced by propofol. Morphine premedication (0.15 mg/kg) with nitrous oxide 67% in oxygen has been shown to decrease the necessary propofol maintenance infusion rate and therapeutic blood concentrations when compared to non-narcotic (lorazepam) premedication.

Induction of General Anesthesia:

Adult Patients: Most adult patients under 55 years of age and classified ASA I–II require 2 to 2.5 mg/kg of propofol for induction. When unpremedicated or when premedicated with oral benzodiazepines or intramuscular opioids. For induction, propofol should be titrated (approximately 40 mg every 10 seconds) against the response of the patient until the clinical signs show the onset of anesthesia. As with other sedative-hypnotic agents, the amount of intravenous opioid and/or benzodiazepine premedication will influence the response of the patient to an induction dose of propofol.

Elderly, Debilitated, or ASA III/IV Patients: It is important to be familiar and experienced with the intravenous use of propofol before treating elderly, debilitated, or ASA III/IV patients. Due to the reduced clearance and higher blood concentrations, most of these patients require appropriately 1 to 1.5 mg/kg (approximately 20 mg every 10 seconds) of propofol for induction of anesthesia according to their condition and responses. A rapid bolus should not be used as this will increase the likelihood of undesirable cardiorespiratory depression including hypotension, apnea, airway obstruction, and/or oxygen desaturation. (See DOSAGE AND ADMINISTRATION.)

Neurosurgical Patients: Slower induction is recommended using boluses of 20 mg every 10 seconds. Slower boluses or infusions of propofol for induction of anesthesia, titrated to clinical responses, will generally result in reduced induction dosage requirements (1 to 2 mg/kg). (See PRECAUTIONS and DOSAGE AND ADMINISTRATION.)

Cardiac Anesthesia: Propofol has been well studied in patients with coronary artery disease, but experience in patients with hemodynamically significant valvular or congenital heart disease is limited. As with other anesthetic and sedative-hypnotic agents, propofol in healthy patients causes a decrease in blood pressure that is secondary to decreases in preload (ventricular filling volume at the end of the diastole) and afterload (arterial resistance at the beginning of the systole). The magnitude of these changes is proportional to the blood and effect site concentrations achieved. These concentrations depend upon the dose and speed of the induction and maintenance infusion rates.

In addition, lower heart rates are observed during maintenance with propofol, possibly due to reduction of the sympathetic activity and/or resetting of the baroreceptor reflexes. Therefore, anticholinergic agents should be administered when increases in vagal tone are anticipated.

As with other anesthetic agents, propofol reduces myocardial oxygen consumption. Further studies are needed to confirm and delineate the extent of these effects on the myocardium and the coronary vascular system.

Morphine premedication (0.15 mg/kg) with nitrous oxide 67% in oxygen has been shown to decrease the necessary propofol maintenance infusion rates and therapeutic blood concentrations when compared to non-narcotic (lorazepam) premedication. The rate of propofol administration should be determined based on the patient's premedication and adjusted according to clinical responses.

A rapid bolus induction should be avoided. A slow rate of approximately 20 mg every 10 seconds until induction onset (0.5 to 1.5 mg/kg) should be used. In order to assure adequate anesthesia, when propofol is used as the primary agent, maintenance infusion rates should not be less than 100 mcg/kg/min and should be supplemented with analgesic levels of concurrent opioid administration. When an opioid is used as the primary agent, propofol maintenance rates should not be less than 50 mcg/kg/min, and care should be taken to ensure amnesia with concomitant benzodiazepines. Higher doses of propofol will reduce the opioid requirements. (See Table 4.) When propofol is used as the primary anesthetic, it should not be administered with the high dose opioid technique, as this may increase the likelihood of hypotension. (See PRECAUTIONS - Cardiac Anesthesia.)

TABLE 4. CARDIAC ANESTHESIA TECHNIQUES

Primary Agent	Rate	Secondary Agent/Rate (Following Induction with Primary Agent)
Propofol		OPIOID*/0.05–0.075 mcg/kg/min (no bolus)
Preinduction anxiolysis	25 mcg/kg/min	
Induction	0.5–1.5 mg/kg over 60 sec	
Maintenance (Titrated to Clinical Response)	100–150 mcg/kg/min	
OPIOID*		Propofol 50–100 mcg/kg/min (no bolus)
Induction	25–50 mcg/kg	
Maintenance	0.2–0.3 mcg/kg/min	

*OPIOID is defined in terms of fentanyl equivalents, i.e.,
1 mcg of fentanyl = 5 mcg of alfentanil (for bolus)
= 10 mcg of alfentanil (for maintenance) or
= 0.1 mcg of sufentanil

†Care should be taken to ensure amnesia with concomitant benzodiazepine therapy.

Maintenance of General Anesthesia

In adults, anesthesia can be maintained by administering propofol by infusion or intermittent I.V. bolus injection. The patient's clinical response will determine the infusion rate of the amount and frequency of incremental injections.

Continuous Infusion: Propofol 100 to 200 mcg/kg/min administered in a variable rate infusion with 60%-70% nitrous oxide and oxygen provides anesthesia for patients undergoing general surgery. Maintenance by infusion of propofol should immediately follow the induction dose in order to provide satisfactory or continuous anesthesia during the induction phase. During this initial period following the induction dose, higher rates of infusion are generally required (150 to 200 mcg/kg/min) for the first 10 to 15 minutes. Infusion rates should subsequently be decreased 30%-50% during the first hour of maintenance.

Other drugs that cause CNS depression (hypnotics, sedatives, inhalational anesthetics, and opioids) can increase the CNS depression induced by propofol.

Intermittent Bolus: Increments of propofol 25 mg (2.5 mL) to 50 mg (5 mL) may be administered with nitrous oxide in adult patients undergoing general surgery. The incremental boluses should be administered when changes in vital signs indicate a response to surgical stimulation or light anesthesia.

Propofol has been used with a variety of agents commonly used in anesthesia such as atropine, scopolamine, glycopyrrolate, diazepam, depolarizing and nondepolarizing muscle relaxants, and opioid analgesics, as well as with inhalational and regional anesthetic agents.

In the elderly, debilitated, or ASA III/IV patients, rapid bolus doses should not be used as this will increase cardiorespiratory effects, including hypotension, apnea, airway obstruction, and/or oxygen desaturation.

Pediatric Anesthesia:

Induction of General Anesthesia: Most pediatric patients 3 years of age or older and classified ASA I or II require 2.5 to 3.5 mg/kg of propofol for induction when unpremedicated or when lightly premedicated with oral benzodiazepines or intramuscular opioids. Within this dosage range, younger children may require larger induction doses than older children. As with other sedative-hypnotic agents, the amount of intravenous opioid and/or benzodiazepine premedication will influence the response of the patient to an induction dose of propofol. In addition, a lower dosage is recommended for children ASA II or IV. Attention should be paid to minimize pain on injection when administering propofol to pediatric patients. Rapid boluses of propofol may be administered if small veins are preferred with lidocaine or when antecubital or larger veins are utilized. (See PRECAUTIONS - General.)

Propofol administered in a variable rate infusion with nitrous oxide 60%-70% provides satisfactory anesthesia for most pediatric patients 3 years of age or older, ASA I or II, undergoing general anesthesia.

Maintenance of General Anesthesia: Maintenance by infusion of propofol at a rate of 200-300 mcg/kg/min should immediately follow the induction dose. Following the first half hour of maintenance, if clinical signs of light anesthesia are not present, the infusion rate should be decreased; during this period, infusion rates of 125-150 mcg/kg/min are typically needed. However, younger children (5 years of age or less) may require larger maintenance infusion rates than older children.

Monitored Anesthesia Care (MAC) Sedation in Adults

When propofol is administered for MAC sedation, rates of administration should be individualized and titrated to clinical response. In most patients, the rates of propofol administration will be in the range of 25-75 mcg/kg/min.

During initiation of MAC sedation, slow infusion or slow injection techniques are preferable over rapid bolus administration. During maintenance of MAC sedation, a variable rate infusion is preferable over intermittent bolus dose administration. In the elderly, debilitated, or ASA III/IV patients, rapid (single or repeated) bolus dose administration should not be used for MAC sedation. (See WARNINGS.) **A rapid bolus injection can result in undesirable cardiorespiratory supression including hypotension, apnea, airway obstruction, and/or oxygen desaturation.**

Initiation of MAC Sedation: For initiation of MAC sedation, either an infusion or a slow injection method may be utilized while closely monitoring cardiorespiratory function. With the infusion method, sedation may be initiated by infusing propofol at 100 to 150 mcg/kg/min (6 to 9 mg/kg/hr) for a period of 3 to 5 minutes and titrating to the desired level of sedation while closely monitoring respiratory function. With the slow injection method for initiation, patients will require approximately 0.5 mg/kg administered over 3 to 5 minutes and titrated to clinical responses. When propofol is administered slowly over 3 to 5 minutes, most patients will be adequately sedated, and the peak drug effect can be achieved while minimizing undesirable cardiorespiratory effects occurring at high plasma levels.

In the elderly, debilitated, or ASA III/IV patients, rapid (single or repeated) bolus dose administration should not be used for MAC sedation. (See WARNINGS.) The rate of administration should be over 3-5 minutes, and the dosage of propofol should be reduced to approximately 80% of the usual adult dosage in these patients according to their condition, responses, and changes in vital signs. (See DOSAGE AND ADMINISTRATION.)

Maintenance of MAC Sedation: For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the variable rate infusion method, patients will generally require maintenance rates of 25 to 75 mcg/kg/min (1.5 to 4.5 mg/kg/hr) during the first 10 to 15 minutes of sedation maintenance. Infusion rates should subsequently be decreased over time to 25 to 50 mcg/kg/min and adjusted to clinical responses. In titrating to clinical effect, allow approximately 2 minutes for onset of peak drug effect.

Infusion rates should always be titrated downward in the absence of clinical signs of light sedation until mild responses to stimulation are obtained in order to avoid sedative administration of propofol at rates higher than are clinically necessary.

If the intermittent bolus dose method is used, increments of propofol 10 mg (1 mL) or 20 mg (2 mL) can be administered and titrated to desired level of sedation. With the intermittent bolus method of sedation maintenance, there is the potential for respiratory depression, transient increases in sedation depth, and/or prolongation of recovery.

In the elderly, debilitated, or ASA III/IV patients, rapid (single or repeated) bolus dose administration should not be used for MAC sedation. (See WARNINGS.) The rate of administration and the dosage of propofol should be reduced to approximately 80% of the usual adult dosage in these patients according to their condition, responses, and changes in vital signs. (See DOSAGE AND ADMINISTRATION.)

Propofol can be administered as the sole agent for maintenance of MAC sedation during surgical/diagnostic procedures. When propofol sedation is supplemented with opioid and/or benzodiazepine medications, these agents increase the sedative and respiratory effects of propofol and may also result in a slower recovery profile. (See PRECAUTIONS, Drug Interactions.)

ICU Sedation: (See WARNINGS and DOSAGE AND ADMINISTRATION, Handling Precautions.)

For intubated, mechanically ventilated adult patients, Intensive Care Unit (ICU) sedation should be initiated slowly with a continuous infusion in order to titrate to desired clinical effect and minimize hypotension. (See DOSAGE AND ADMINISTRATION.)

Across all 6 US/Canadian clinical studies, the mean infusion maintenance rate for all propofol patients was 27 ± 21 mcg/kg/min. The maintenance infusion rates required to maintain adequate sedation ranged from 2.8 mcg/kg/min to 130 mcg/kg/min. The infusion rate was lower in patients over 55 years of age (approximately 20 mcg/kg/min) compared to patients under 55 years of age (approximately 38 mcg/kg/min). In these studies, morphine or fentanyl was used as needed for analgesia.

Most adult ICU patients recovering from the effects of general anesthesia or deep sedation will require maintenance rates of 5 to 50 mcg/kg/min (0.3 to 3 mg/kg/hr) reconstituted and titrated to clinical response. (See DOSAGE AND ADMINISTRATION.) With medical ICU patients or patients who have recovered from the effects of general anesthesia or deep sedation, the rate of administration of 50 mcg/kg/min or higher may be required to achieve adequate sedation. These higher rates of administration may increase the likelihood of patients developing hypotension.

Although there are reports of reduced analgesic requirements, most patients received opioid for analgesia during maintenance of ICU sedation. Some patients also received benzodiazepines and/or neuromuscular blocking agents. During long-term maintenance of sedation, some ICU patients were awakened once or twice every 24 hours for assessment of neurologic or respiratory function. (See Clinical Trials, Table 3.)

In post-CABG (coronary artery bypass graft) patients, the maintenance rate of propofol administration was usually low (median 11 mcg/kg/min) due to the intraoperative administration of high opioid doses. Patients receiving propofol required 35% less nitroprusside than midazolam patients; this difference was statistically significant ($P<0.05$). During initiation of sedation in post-CABG patients, a 15% to 20% decrease in blood pressure was seen in the first 60 minutes. It was not possible to determine cardiovascular effects in patients with severely compromised ventricular function. (See Clinical Trials, Table 3.)

In Medical or Postsurgical ICU studies comparing propofol to benzodiazepine infusion or bolus, there were no apparent differences in maintenance of adequate sedation, mean arterial pressure, or laboratory findings. Like the comparators, propofol reduced blood cortisol during sedation while maintaining responsivity to challenges with adrenocorticotropic hormone (ACTH). Case reports from the published literature generally reflect that propofol has been used safely in patients with a history of porphyria or malignant hyperthermia.

In hemodynamically stable head trauma patients ranging in age from 19-43 years, adequate sedation was maintained with propofol or midazolam (N=7 in each group). There were no apparent differences in adequacy of sedation, intracranial pressure, cerebral perfusion pressure, or neurologic recovery between the treatment groups. In literature reports from Neurosurgical ICU and severely head-injured patients, propofol infusion, with or without diuresis and hyperventilation, controlled intracranial pressure while maintaining cerebral perfusion pressure. In some patients, bolus doses resulted in decreased blood pressure and compromised cerebral perfusion pressure. (See Clinical Trials, Table 3.)

Propofol was found to be effective in status epilepticus which was refractory to the standard anticonvulsant therapies. For these patients as well as for ARDS/respiratory failure and tetanus patients, sedation maintenance dosages were generally higher than those for other critically ill patient populations. (See Clinical Trials, Table 3.)

Abrupt discontinuation of propofol prior to weaning or for daily evaluation of sedation levels should be avoided. This may result in rapid awakening with associated anxiety, agitation, and resistance to mechanical ventilation. Infusions of propofol should be adjusted to maintain a light level of sedation through the weaning process or evaluation of sedation level. (See PRECAUTIONS.)

INDICATIONS AND USAGE

Propofol injectable emulsion is an I.V. sedative-hypnotic agent that can be used for both induction and/or maintenance of anesthesia as part of a balanced anesthetic technique for inpatient and outpatient surgery in adults and in children 3 years of age or older.

Propofol, when administered intravenously as directed, can be used to initiate and maintain monitored anesthesia care (MAC) sedation during diagnostic procedures in adults. Propofol may also be used for MAC sedation in conjunction with local/regional anesthesia in patients undergoing surgical procedures. (See PRECAUTIONS.)

Propofol should only be administered to intubated, mechanically ventilated adult patients in the Intensive Care Unit (ICU) to provide continuous sedation and control of stress responses. In this setting, propofol should be administered only by persons skilled in the medical management of critically ill patients and trained in cardiovascular resuscitation and airway management.

Propofol is not recommended for obstetrics, including cesarean section deliveries. Propofol crosses the placenta, and as with other general anesthetic agents, the administration of propofol may be associated with neonatal depression. (See PRECAUTIONS.)

Propofol is not recommended for use in nursing mothers because propofol has been reported to be excreted in human milk, and the effects of oral absorption of small amounts of propofol are not known. (See PRECAUTIONS.)

Propofol is not recommended for anesthesia in children below the age of 3 years because safety and effectiveness have not been established. Propofol is not recommended for MAC sedation in children because safety and effectiveness have not been established. Propofol is not recommended for pediatric ICU sedation because safety and effectiveness have not been established.

CONTRAINDICATIONS

Propofol injectable emulsion is contraindicated in patients with a known hypersensitivity to propofol injectable emulsion or its components, or when general anesthesia or sedation are contraindicated.

WARNINGS

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Propofol injectable emulsion is contraindicated in patients with a known hypersensitivity to propofol injectable emulsion or its components, or when general anesthesia or sedation are contraindicated.

WARNINGS

For general anesthesia or monitored anesthesia care (MAC) sedation, propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available.

For sedation of intubated, mechanically ventilated adult patients in the Intensive Care Unit (ICU), propofol should be administered only by persons skilled in the management of critically ill patients and trained in cardiovascular resuscitation and airway management.

In the elderly, debilitated, or ASA III/IV patients, rapid (single or repeated) bolus administration should not be used during general anesthesia or MAC sedation in order to minimize undesirable cardiorespiratory depression including hypotension, apnea, airway obstruction, and/or oxygen desaturation.

MAC sedation patients should be continuously monitored by persons not involved in the conduct of the surgical or diagnostic procedure; oxygen supplementation should be immediately available and provided where clinically indicated; and oxygen saturation should be monitored in all patients. Patients should be continuously monitored for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation. These cardiorespiratory effects are more likely to occur following rapid infusion (loading) bolus(es) or during supplemental maintenance boluses, especially in the elderly, debilitated, or ASA III/IV patients.

Propofol injectable emulsion should not be coadministered through the same IV catheter with blood or plasma because compatibility has not been established. *In vitro* tests have shown that aggregates of the globular component of the emulsion vehicle have occurred with blood/plasma/serum from humans and animals. The clinical significance is not known.

STRICT ASEPTIC TECHNIQUE MUST ALWAYS BE MAINTAINED DURING HANDLING. PROPOFOL INJECTABLE EMULSION IS A SINGLE-USE PARENTERAL PRODUCT WHICH CONTAINS SODIUM METABISULFITE (0.25 mg/mL) TO RETARD THE RATE OF GROWTH OF MICROORGANISMS IN THE EVENT OF ACCIDENTAL EXTRINSIC CONTAMINATION. HOWEVER, PROPOFOL INJECTABLE EMULSION CAN STILL SUPPORT THE GROWTH OF MICROORGANISMS AS IT IS NOT AN ANTIMICROBIALLY PRESERVED PRODUCT UNDER USP STANDARDS. ACCORDINGLY, STRICT ASEPTIC TECHNIQUE MUST STILL BE ADHERED TO. DO NOT USE IF CONTAMINATION IS SUSPECTED. DISCARD UNUSED PORTIONS AS DIRECTED WITHIN THE REQUIRED TIME LIMITS (SEE DOSAGE AND ADMINISTRATION, HANDLING PROCEDURES). THERE HAVE BEEN REPORTS IN WHICH FAILURE TO USE ASEPTIC TECHNIQUE WHEN HANDLING PROPOFOL INJECTABLE EMULSION WAS ASSOCIATED WITH MICROBIAL CONTAMINATION OF THE PRODUCT AND WITH FEVER, INFECTION/SEPSIS, OTHER LIFE-THREATENING ILLNESS, AND/OR DEATH.

PRECAUTIONS

General: A lower induction dose and a slower maintenance rate of administration should be used in elderly, debilitated, or ASA III/IV patients (See CLINICAL PHARMACOLOGY - Individualization of Dosage.) Patients should be continuously monitored for early signs of significant hypotension, and/or bradycardia. Treatment may include increasing the rate of intravenous fluid, elevation of lower extremities, use of pressor agents, or administration of atropine. Apnea often occurs during induction and may persist for more than 60 seconds. Ventilatory support may be required. Because propofol injectable emulsion is an emulsion, caution should be exercised in patients with disorders of lipid metabolism such as primary hyperlipoproteinemia, diabetic hyperlipemia, and pancreatitis.

The clinical criteria for discharge from the recovery/day surgery area established for each institution should be satisfied before discharge of the patient from the care of the anesthesiologist.

When propofol is administered to an epileptic patient, there may be a risk of seizure during the recovery phase.

In adults and children, attention should be paid to minimize pain on administration of propofol. Transient local pain can be minimized if the larger veins of the forearm or antecubital fossa are used. Pain during intravenous injection may also be reduced by prior injection of I.V. lidocaine (1 mL of a 1% solution). Pain on injection occurred frequently in pediatric patients (45%) when a small vein of the hand was utilized without lidocaine pretreatment. With lidocaine pretreatment or when antecubital veins were utilized, pain was minimal (incidence less than 10%) and well tolerated.

Various sequelae (phlebitis or thrombosis) have been reported rarely (<1%). In two well-controlled clinical studies using dedicated intravenous catheters, no instances of various sequelae were observed up to 14 days following induction. Accidental cannula extravasation and intentional injection into subcutaneous or perivascular tissues of animals caused minimal tissue reaction.

Intra-arterial injection in animals did not induce local tissue effects. Accidental intra-arterial injection has been reported in patients, and other than pain, there were no major sequelae.

Intentional injection into subcutaneous or perivascular tissues of animals caused minimal tissue reaction. During the postmarketing period there have been rare reports of local pain, swelling, blisters, and/or tissue necrosis following accidental extravasation of propofol injectable emulsion.

Perioperative myoclonus, rarely including convulsions and opisthotonos, has occurred in temporal relationship in cases in which propofol has been administered.

Clinical features of anaphylaxis, which may include angioedema, bronchospasm, erythema, and hypotension, occur rarely following propofol administration although use of other drugs in most instances makes the relationship to propofol unclear.

There have been rare reports of pulmonary edema in temporal relationship to the administration of propofol although a causal relationship is unknown.

Propofol has no vagolytic activity. Reports of bradycardia, asystole, and rarely cardiac arrest have been associated with propofol. The intravenous administration of anticholinergic agents (e.g., atropine or glycopyrrolate) should be considered to modify potential increases in vagal tone due to concomitant agents (e.g., succinylcholine) or surgical stimuli.

Intensive Care Unit Sedation (See WARNINGS and DOSAGE AND ADMINISTRATION, Handling Procedures.) The administration of propofol should be initiated as a continuous infusion and changes in the rate of administration made slowly (≥5 min) in order to minimize hypotension and avoid acute overdosage. (See CLINICAL PHARMACOLOGY - Individualization of Dosage.)

Patients should be monitored for early signs of significant hypotension and/or cardiovascular depression, which may be profound. These effects are responsive to discontinuation of propofol, I.V. fluid administration, and/or vasopressor therapy.

As with other sedative medications, there is wide interpatient variability in propofol dosage requirements, and these requirements may change with time.

Failure to reduce the infusion rate in patients receiving propofol for extended periods may result in excessively high dose considerations of the drug. Prompt titration to clinical response and daily evaluation of sedation levels are important during use of propofol infusion for ICU sedation, especially of long duration.

Opioids and paralytic agents should be discontinued and respiratory function optimized prior to weaning patients from mechanical ventilation. Infusions of propofol should be adjusted to maintain a light level of sedation prior to weaning patients from mechanical ventilatory support. Throughout the weaning process, this level of sedation may be maintained in the absence of respiratory depression. Because of the rapid clearance of propofol, abrupt discontinuation of a patient's infusion may result in rapid awakening of the patient with associated anxiety, agitation, and resistance to mechanical ventilation, making weaning from mechanical ventilation difficult. It is, therefore, recommended that administration of propofol be continued in order to maintain a light level of sedation throughout the weaning process until 10-15 minutes prior to extubation at which time the infusion can be discontinued.

Since propofol injectable emulsion is formulated in an oil-in-water emulsion, elevations in serum triglycerides may occur when propofol injectable emulsion is administered for extended periods of time. Patients at risk of hyperlipidemia should be monitored for increases in serum triglycerides or serum turbidity. Administration of propofol injectable emulsion should be adjusted if fat is being inadequately cleared from the body. A reduction in the quantity of concurrently administered lipids is indicated to compensate for the amount of lipid infused as part of the propofol injectable emulsion formulation: 1 mL of propofol injectable emulsion contains approximately 0.1 g of fat (1.1 kcal).

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

The long-term administration of Propofol to patients with renal failure and/or hepatic insufficiency has not been evaluated.

Neurological Anesthesia: When propofol is used in patients with increased intracranial pressure or impaired cerebral circulation, significant decreases in mean arterial pressure should be avoided because of the resultant decreases in cerebral perfusion pressure. To avoid significant hypotension and decreases in cerebral perfusion pressure, an infusion or slow bolus of approximately 20 mg every 10 seconds should be utilized instead of rapid, more frequent, and/or larger boluses of propofol. Slower induction titrated to clinical responses will generally result in reduced induction dosage requirements (1 to 2 mg/kg). When increased ICP is suspected, hyperventilation and hypocarbia should accompany the administration of propofol. (See DOSAGE AND ADMINISTRATION.)

Cardiac Anesthesia: Slower rates of administration should be utilized in premedicated patients, geriatric patients, patients with recent fluid shifts or patients who are hemodynamically unstable. Any fluid deficits should be corrected prior to administration of propofol. In those patients where additional fluid therapy may be contraindicated, other measures, e.g., elevation of lower extremities or use of pressor agents, may be useful to offset the hypotension which is associated with the induction of anesthesia with propofol.

Information for Patients: Patients should be advised that performance of activities requiring mental alertness, such as operating a motor vehicle, or hazardous machinery, or signing legal documents, may be impaired for some time after general anesthesia or sedation.

Drug Interactions: The induction dose requirements of propofol may be reduced in patients with intramuscular or intravenous premedication, particularly with narcotics (e.g., morphine, meperidine, and fentanyl, etc.) and combinations of opioids and sedatives (e.g., benzodiazepines, barbiturates, chloral hydrate, droperidol, etc.). These agents may increase the anesthetic or sedative effects of propofol and may also result in more pronounced decreases in systolic, diastolic, and mean arterial pressures and cardiac output.

During maintenance of anesthesia or sedation, the rate of propofol administration should be adjusted according to the desired level of anesthesia or sedation and may be reduced in the presence of supplemental analgesic agents (e.g., nitrous oxide or opioids). The concurrent administration of potent inhalational agents (e.g., isoflurane, enflurane, and halothane) during maintenance with propofol has not been extensively evaluated. These inhalational agents can also be expected to increase the anesthetic or sedative and cardiorespiratory effects of propofol.

Propofol does not cause a clinically significant change in onset, intensity, or duration of action of the commonly used neuromuscular blocking agents (e.g., succinylcholine and nondepolarizing muscle relaxants).

No significant adverse interactions with commonly used premedications or drugs used during anesthesia or sedation (including a range of muscle relaxants, inhalational agents, analgesic agents, and local anesthetic agents) have been observed.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Animal carcinogenicity studies have not been performed with propofol.

In vitro and *in vivo* animal tests failed to show any potential for mutagenicity by propofol. Tests for mutagenicity included the Ames (using *Salmonella* sp) mutation test, gene mutation/gene conversion using *Saccharomyces cerevisiae*, *in vitro* cytogenetic studies in Chinese hamsters, and a mouse micronucleus test.

Studies in female rats at intravenous doses up to 15 mg/kg/day (6 times the maximum recommended human induction dose) for 2 weeks before pregnancy to day 7 of gestation did not show impaired fertility. Male fertility in rats was not affected in a dominant lethal study at intravenous doses up to 15 mg/kg/day for 5 days.

Pregnancy: Teratogenic Effects, Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at intravenous doses of 15 mg/kg/day (6 times the recommended human induction dose) and have revealed no evidence of impaired fertility or harm to the fetus due to propofol. Propofol, however, has been shown to cause maternal deaths in rats and rabbits and decreased pup survival during the lactating period in dams treated with 15 mg/kg/day (or 6 times the recommended human induction dose). The pharmacological activity (anesthesia) of the drug on the mother is probably responsible for the adverse effects seen in the offspring. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: Propofol is not recommended for obstetrics, including cesarean section deliveries. Propofol crosses the placenta, and as with other general anesthetic agents, the administration of propofol may be associated with neonatal depression.

Nursing Mothers: Propofol is not recommended for use in nursing mothers because propofol has been reported to be excreted in human milk and the effects of oral absorption of small amounts of propofol are not known.

Pediatric Use: Propofol is not recommended for use in pediatric patients for ICU or MAC sedation. In addition, propofol is not recommended for general anesthesia for children below the age of 3 years because safety and effectiveness have not been established.

Although no causal relationship has been established, serious adverse events (including fatalities) have been reported in children given propofol for ICU sedation. These events were seen most often in children with respiratory tract infections given doses in excess of those recommended for adults.

ADVERSE REACTIONS

General

Adverse event information is derived from controlled clinical trials and worldwide marketing experience. In the description below, rates of the more common events represent US/Canadian clinical study results. Less frequent events are also derived from publications and marketing experience in over 8 million patients; there are insufficient data to support an accurate estimate of their incidence rates. These studies were conducted using a variety of premedicants, varying lengths of surgical/diagnostic procedures and various other anesthetic/sedative agents. Most adverse events were mild and transient.

Anesthesia and MAC Sedation in Adults

The following estimates of adverse events for propofol include data from clinical trials in general anesthesia/MAC sedation (N=2589 adult patients). The adverse events listed below as probably causally related are those events in which the actual incidence rate in patients treated with propofol was greater than the comparator incidence rate in these trials. Therefore, incidence rates for anesthesia and MAC sedation in adults generally represent estimates of the percentage of clinical trial patients which appeared to have probable causal relationship.

The adverse experience profile from reports of 150 patients in the MAC sedation clinical trials is similar to the profile established with propofol during anesthesia (see below). During MAC sedation clinical trials, significant respiratory events included cough, upper airway obstruction, apnea, hypoventilation, and dyspnea.

Anesthesia in Children

Generally the adverse experience profile from reports of 349 propofol pediatric patients between the ages of 3 and 12 years in the US/Canadian anesthesia clinical trials is similar to the profile established with propofol during anesthesia in adults. [See Pediatric percentages (Peds %) below]. Although not reported as an adverse event in clinical trials, apnea is frequently observed in pediatric patients.

ICU Sedation in Adults

The following estimates of adverse events include data from clinical trials in ICU sedation (N=1591 patients). Probable related incidence rates for ICU sedation were determined by individual case report form review. Probable causality was based upon an apparent dose response relationship

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studies in female rats at intravenous doses up to 1.5 mg/kg/day (6 times the maximum recommended human induction dose) for 2 weeks before pregnancy to day 7 of gestation did not show impaired fertility. Male fertility in rats was not affected in a dominant lethal study at intravenous doses up to 15 mg/kg/day for 5 days.

Pregnancy: Teratogenic Effects. Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at intravenous doses of 15 mg/kg/day (6 times the recommended human induction dose) and have revealed no evidence of impaired fertility or harm to the fetus due to propofol. Propofol, however, has been shown to cause maternal deaths in rats and rabbits and decreased pup survival during the lactating period in dams treated with 15 mg/kg/day (or 6 times the recommended human induction dose). The pharmacological activity (anesthesia) of the drug on the mother is probably responsible for the adverse effects seen in the offspring. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: Propofol is not recommended for obstetrics, including cesarean section deliveries. Propofol crosses the placenta; and as with other general anesthetic agents, the administration of propofol may be associated with neonatal depression.

Nursing Mothers: Propofol is not recommended for use in nursing mothers because propofol has been reported to be excreted in human milk, and the effects of oral absorption of small amounts of propofol are not known.

Pediatric Use: Propofol is not recommended for use in pediatric patients for ICU or MAC sedation. In addition, propofol is not recommended for general anesthesia for children below the age of 3 years because safety and effectiveness have not been established.

Although no causal relationship has been established, serious adverse events (including fatalities) have been reported in children given propofol for ICU sedation. These events were seen most often in children with respiratory tract infections, given doses in excess of those recommended for adults.

ADVERSE REACTIONS

General

Adverse event information is derived from controlled clinical trials and worldwide marketing experience. In the description below, rates of the more common events represent US/Canadian clinical study results. Less frequent events are also derived from publications and marketing experience in over 8 million patients; there are insufficient data to support an accurate estimate of their incidence rates. These studies were conducted using a variety of premedicants, varying lengths of surgical/diagnostic procedures and various other anesthetic/sedative agents. Most adverse events were mild and transient.

Anesthesia and MAC Sedation in Adults

The following estimates of adverse events for propofol include data from clinical trials in general anesthesia/MAC sedation (N=2889 adult patients). The adverse events listed below as probably causally related are those events in which the actual incidence rate in patients treated with propofol was greater than the comparator incidence rate in these trials. Therefore, incidence rates for anesthesia and MAC sedation in adults generally represent estimates of the percentage of clinical trial patients which appeared to have probable causal relationship.

The adverse experience profile from reports of 150 patients in the MAC sedation clinical trials is similar to the profile established with propofol during anesthesia (see below). During MAC sedation clinical trials, significant respiratory events included cough, upper airway obstruction, apnea, hypoventilation, and dyspnea.

Anesthesia in Children

Generally the adverse experience profile from reports of 349 propofol pediatric patients between the ages of 3 and 12 years in the US/Canadian anesthesia clinical trials is similar to the profile established with propofol during anesthesia in adults (See Pediatric percentages (Peds %) below). Although not reported as an adverse event in clinical trials, apnea is frequently observed in pediatric patients.

ICU Sedation in Adults

The following estimates of adverse events include data from clinical trials in ICU sedation (N=159) patients. Probably related incidence rates for ICU sedation were determined by individual case report form review. Probable causality was based upon an apparent dose response relationship and/or positive responses to rechallenge. In many instances the presence of concomitant disease and concomitant therapy make the causal relationship unknown. Therefore, incidence rates for ICU sedation generally represent estimates of the percentage of clinical trial patients which appeared to have a probable causal relationship.

Incidence greater than 1% - Probably Causally Related

	Anesthesia/MAC Sedation	ICU Sedation
Cardiovascular:	Bradycardia Hypotension* (Peds: 17%) (Hypertension Peds: 8%) (see also CLINICAL PHARMACOLOGY)	Bradycardia, Decreased Cardiac Output, Hypotension 26%
Central Nervous System:	Movement* (Peds: 17%)	
Injection Site:	Burning/Stinging or Pain, 17.6% (Peds: 10%)	
Metabolic/Nutritional:		Hyperlipemia*
Respiratory:	Apnea (see also CLINICAL PHARMACOLOGY)	Respiratory Acidosis During Weaning*
Skin and Appendages:	Rash (Peds: 5%)	

Events without an * or % had an incidence of 1%-3%
*Incidence of events 3% to 10%

Incidence less than 1% - Probably Causally Related

	Anesthesia/ MAC Sedation	ICU Sedation
Body as a Whole:	Anaphylaxis/Anaphylactoid Reaction Perinatal Disorder	
Cardiovascular:	Premature Atrial Contractions Syncope	
Central Nervous System:	Hypertonia/Dystonia, Paresthesia	Agitation
Digestive:	Hypersalivation	
Musculoskeletal:	Myalgia	
Respiratory:	Wheezing	Decreased Lung Function
Skin and Appendages:	Flushing, Pruritus	
Special Senses:	Amblyopia	
Urogenital:	Cloudy Urine	Green Urine

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Incidence less than 1% - Causal Relationship Unknown

	Anesthesia/MAC Sedation	ICU Sedation
Body as a Whole	Asthenia, Awareness, Chest Pain Extremities Pain, Fever, Increased Drug Effect, Neck Rigidity/Stiffness, Trunk Pain	Fever, Sepsis, Trunk Pain Whole Body Weakness
Cardiovascular	Arrhythmia, Atrial Fibrillation Atrioventricular Heart Block, Bigeminy Bleeding, Bundle Branch Block Cardiac Arrest, ECG Abnormal, Edema Extrasystole, Heart Block, Hypertension Myocardial Infarction, Myocardial Ischemia, Premature Ventricular Contractions, ST Segment Depression, Supraventricular Tachycardia, Tachycardia, Ventricular Fibrillation	Arrhythmia, Atrial Fibrillation, Bigeminy, Cardiac Arrest, Extrasystole, Right Heart Failure, Ventricular Tachycardia
Central Nervous System	Abnormal Dreams, Agitation, Amnesia Balance, Anxiety, Burning/Jerking/Twitching, Chills/Shivering, Clonic, Myoclonic Movement Confusedness, Confusion, Delirium, Depression Dizziness, Emotional Lability, Euphoria, Fatigue, Hallucinations, Headache, Hypotonia, Hypoxia, Insomnia, Meaning, Neuropathy, Objectifications, Rigidity, Seizures, Somnolence, Tremor, Twitching	Chills/Shivering, Intracranial Hypertension Seizures, Somnolence Thinking Abnormal
Digestive:	Cramping, Diarrhea, Dry Mouth, Enlarged Parotid, Nausea, Swallowing, Vomiting	New Liver Function Abnormal
Hematologic/Lymphatic	Coagulation Disorder, Leukocytosis	
Injection Site:	Hives/Itching, Phlebitis, Redness/Discoloration	
Metabolic/Nutritional:	Hyperkalemia, Hypervolemia	BUN Increased, Creatinine Increased, Dehydration, Hyperglycemia, Metabolic Acidosis, Osmolality Increased
Respiratory:	Bronchospasm, Burning in Throat, Cough, Dyspnea, Hiccough, Hyperventilation, Hypoventilation, Hypoxia, Laryngospasm, Pharyngitis, Sneezing, Tachypnea, Upper Airway Obstruction	Hypoxia
Skin and Appendages:	Conjunctival Hyperemia, Diaphoresis, Urticaria	Rash
Special Senses:	Diplopia, Ear Pain, Eye Pain, Nystagmus, Taste Perversion, Tinnitus	
Urogenital:	Oliguria, Urine Retention	Kidney Failure

DRUG ABUSE AND DEPENDENCE

Rare cases of self administration of propofol by health care professionals have been reported, including some fatalities. Propofol should be managed to prevent the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting.

OVERDOSAGE

If overdosage occurs, propofol administration should be discontinued immediately. Overdosage is likely to cause cardiorespiratory depression. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression may require repositioning of the patient by raising the patient's legs, increasing the flow rate of intravenous fluids and administering pressor agents and/or anticholinergic agents.

DOSAGE AND ADMINISTRATION

Dosage and rate of administration should be individualized and titrated to the desired effect, according to clinically relevant factors, including premedication and concomitant medications, age, ASA physical classification, and level of debilitation of the patient.

The following is abbreviated dosage and administration information which is only intended as a general guide in the use of propofol. Prior to administering propofol, it is imperative that the physician review and be completely familiar with the specific dosage and administration information detailed in the CLINICAL PHARMACOLOGY - Individualization of Dosage section.

In the elderly, debilitated, or ASA III/IV patients, rapid bolus doses should not be the method of administration. (See WARNINGS.)

Intensive Care Unit Sedation:

STRICT ASEPTIC TECHNIQUE MUST ALWAYS BE MAINTAINED DURING HANDLING. PROPOFOL INJECTABLE EMULSION IS A SINGLE-USE PARENTERAL PRODUCT WHICH CONTAINS SODIUM METABISULFITE (0.25 MG/ML) TO RETARD THE RATE OF GROWTH OF MICROORGANISMS IN THE EVENT OF ACCIDENTAL EXTRINSIC CONTAMINATION. HOWEVER, PROPOFOL INJECTABLE EMULSION CAN STILL SUPPORT THE GROWTH OF MICROORGANISMS AS IT IS NOT AN ANTIMICROBIALLY PRESERVED PRODUCT UNDER USP STANDARDS. ACCORDINGLY, STRICT ASEPTIC TECHNIQUE MUST STILL BE ADHERED TO. DO NOT USE IF CONTAMINATION IS SUSPECTED. (SEE DOSAGE AND ADMINISTRATION, HANDLING PROCEDURES.)

Propofol should be individualized according to the patient's condition and response, blood lipid profile, and vital signs. (See PRECAUTIONS - ICU Sedation.) For intubated, mechanically ventilated adult patients, Intensive Care Unit (ICU) sedation should be initiated slowly with a continuous infusion in order to titrate to desired clinical effect and minimize hypotension. When indicated, initiation of sedation should begin at 5 mcg/kg/min (0.3 mg/kg/h). The infusion rate should be increased by increments of 5 to 10 mcg/kg/min (0.3 to 0.6 mg/kg/h) until the desired level of sedation is achieved. A minimum period of 5 minutes between adjustments should be allowed for onset of peak drug effect. Most adult patients require maintenance rates of 5 to 50 mcg/kg/min (0.3 to 3 mg/kg/h) or higher. Dosages of propofol should be reduced in patients who have received large dosages of narcotics. Conversely, the propofol dosage requirement may be reduced by adequate management of pain with analgesic agents. As with other sedative medications, there is interpatient variability in dosage requirements, and these requirements may change with time. (See DOSAGE GUIDE.) **EVALUATION OF LEVEL OF SEDATION AND ASSESSMENT OF CNS FUNCTION SHOULD BE CARRIED OUT DAILY THROUGHOUT MAINTENANCE TO DETERMINE THE MINIMUM DOSE OF PROPOFOL REQUIRED FOR SEDATION. (SEE Clinical Trials, ICU Sedation.)** Bolus administration of 10 or 20 mg should only be used to rapidly increase depth of sedation in patients where hypotension is not likely to occur. Patients with compromised myocardial function, intravascular volume depletion, or abnormally low vascular tone (e.g., sepsis) may be more susceptible to hypotension. (See PRECAUTIONS.)

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

SUMMARY OF DOSAGE GUIDELINES - Dosages and rates of administration in the following table should be individualized and titrated to clinical response. Safety and dosage requirements in pediatric patients have only been established for induction and maintenance of anesthesia. For complete dosage information, see CLINICAL PHARMACOLOGY - Individualization of Dosage.

INDICATION	DOSAGE AND ADMINISTRATION
Induction of General Anesthesia	
	Healthy Adults Less Than 55 Years of Age: 40 mg every 10 seconds until induction onset (2 to 2.5 mg/kg).
	Elderly, Debilitated, or ASA III/IV Patients: 20 mg every 10 seconds until induction onset (1 to 1.5 mg/kg).
	Cardiac Anesthesia: 20 mg every 10 seconds until induction onset (0.5 to 1.5 mg/kg).
	Neurosurgical Patients: 20 mg every 10 seconds until induction onset (1 to 2 mg/kg).
	Pediatric - Healthy, 3 years of age or older: 2.5 to 3.5 mg/kg administered over 20-30 seconds
Maintenance of General Anesthesia: Infusion	
	Healthy Adults Less Than 55 Years of Age: 100 to 200 mcg/kg/min (6 to 12 mg/kg/h).
	Elderly, Debilitated, or ASA III/IV Patients: 50 to 100 mcg/kg/min (3 to 6 mg/kg/h).
	Cardiac Anesthesia: Most patients require:
	Primary Propofol with Secondary Opioid - 100-150 mcg/kg/min
	Low Dose Propofol with Primary Opioid - 50-100 mcg/kg/min (See CLINICAL PHARMACOLOGY Table 4.)
	Neurosurgical Patients: 100 to 200 mcg/kg/min (6 to 12 mg/kg/h).
	Pediatric - Healthy, 3 years of age or older: 125 to 300 mcg/kg/min (7.5 to 18 mg/kg/h).
Maintenance of General Anesthesia: Intermittent Bolus	
	Healthy Adults Less Than 55 Years of Age: Increments of 20 to 50 mg as needed
Initiation of MAC Sedation	
	Healthy Adults Less Than 55 Years of Age: Slow infusion or slow injection techniques are recommended to avoid apnea or hypotension. Most patients require an infusion of 100 to 150 mcg/kg/min (6 to 9 mg/kg/h) for 3 to 5 minutes or a slow injection of 0.5 mg/kg over 3 to 5 minutes followed immediately by a maintenance infusion.