

CL-10193212-7792

THE DOLAN BUILDING  
78 FIRST STREET  
SAN FRANCISCO, CA 94105

**CBD**

2007 JUN 8 11 24 AM '07  
**THE DOLAN LAW FIRM**

CHRISTOPHER B. DOLAN, ESQ.  
(415) 421-2800 TEL  
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May 25, 2007

**VIA US MAIL**

U.S. Department of Transportation  
National Highway Traffic Safety Administration  
Office of Defects Investigation (NVS-211)  
400 7<sup>th</sup> Street, SW  
Washington, D.C. 20590

Re: **Complaint**

Office of Defects Investigation:

We are representing [REDACTED]. [REDACTED] was seriously injured while using a Harley Davidson half Helmet model number 97067-01V/022L. This helmet was defectively designed with a metal D-ring in the chin strap, which puts pressure on the carotid artery during normal use. [REDACTED] carotid artery was damaged by this D-ring causing a stroke.

On or about April 15, 2005, [REDACTED] was injured when he used a Harley-Davidson brand helmet, which we were informed and believe was manufactured by Harley-Davidson Motor Company, Inc., and/or HJC Enterprises, Inc., and/or other unnamed parties. The helmet was sold and/or distributed by Harley-Davidson Motor Company, Inc., and/or HJC Enterprises, Inc. [REDACTED] purchased the helmet in 2002 from McGuire Harley Davidson.

On or about April 15, 2005, [REDACTED] wore the helmet for approximately ten hours while riding his motorcycle, and subsequently suffered a stroke, brain damage, and other injuries when his carotid artery was pressed upon by a D-ring attached to the strap used to affix the helmet to his head. After the ten hour ride, [REDACTED] immediately began to experience symptoms including but not limited to dizziness, blurred vision, severe headaches and blindness in his right eye. [REDACTED] also experienced symptoms including but not limited to weakness on his left side, drooping in his face, as well as permanent loss of motor skills and brain damage. The incident was not reported to the police, and there was no crash or fire.

The medical documentation clearly links his injury to the helmet strap. (Exhibit A.) An x-ray of [REDACTED] was taken with the helmet on, demonstrating how the D-ring presses on the carotid artery. (Exhibit B.) A photo of the helmet box with the model number is also enclosed. (Exhibit C.)

NM  
6/8/07  
CC

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██████████ requests that the National Highway Traffic Safety Administration ("NHTSA") conduct a full defect investigation and recall this product. It is feared that this injury is occurring to other motorcyclists and going unreported, as these incidents are most likely reported as single motorist collisions, with the carotid artery damage being associated with the collision damage.

██████████ respectfully requests NHTSA conduct investigation, compel recall and, in the future, refuse to certify as Department of Transportation or NHTSA compliant, any helmet with this dangerous defect. ██████████ retains the helmet, which he will make available for inspection.

Please do not hesitate to contact us should you have any additional questions.

Sincerely,



Christopher B. Dolan, Esq.  
The Dolan Law Firm



NEUROVASCULAR SERVICE  
NEUROCRITICAL CARE AND STROKE  
505 PARNASSUS AVENUE, Box 0114  
SAN FRANCISCO, CALIFORNIA 94143  
TEL: 415.353.1489  
FAX: 415.353.8705

Wade S. Smith, M.D., Ph.D., Director, Neurovascular Service  
S. Claiborne Johnston, M.D., Ph.D., Director, Stroke Service  
Nerissa Ko, M.D.  
Vincent Singh, M.D.  
David C. Bonovich, M.D.  
Claude Hemphill III, M.D.  
Caroline Morris, R.N.

May 19, 2005

Louis Messina, MD  
Chief of Vascular Surgery  
UCSF Box 0957

RE: [REDACTED]  
DOB: [REDACTED]  
UC#: [REDACTED]  
DATE OF SERVICE: May 19, 2005

Dear Dr. Messina:

I had the pleasure of seeing your patient [REDACTED] for consultation today at the UCSF Neurovascular Clinic. As you know, he is a 53-year-old right-handed gentleman who was admitted to UCSF in April after suffering an acute dissection of the right internal carotid artery. He notes at that time a symptom onset of severe headache and neck pain after a long motorcycle ride with a tight chin strap on his motorcycle helmet.

That evening, he awoke with complete blackout of vision of the right eye which he describes as a shade rising up after approximately 4 hours. He had some cloudy residual vision that resolved to complete normal baseline. Two days later, he developed acute onset of left hemiparesis with associated fall at home and was admitted to a hospital in Reno. He was subsequently transferred to UCSF to your service for further management of a presumed right carotid occlusion. During his hospital stay, he was evaluated by our neurology consult service. He had MRI of the brain that was consistent with a right carotid dissection with extensive T2 signal and diffusion-weighted abnormalities consistent with embolic stroke to the right MCA territory. By this time, the patient had near resolution of all of his symptoms. He was started on Coumadin anticoagulation and was discharged home. Since hospital discharge he returned to work but noted progressive fatigue. He was readmitted to the local hospital at John Muir on 4/28 for overnight observation after a follow-up CT scan showed high grade stenosis of his right ICA. He denies any focal neurologic symptoms except mild slowness of his left hand. Of note, he reports intermittent pulsatile tinnitus especially in the evenings.

His past medical history is notable for a skiing injury to his knee. He currently takes Coumadin and Glucosamine. No other vascular risk factors were noted. His review of systems is otherwise unremarkable.

He has no history of any collagen vascular disease or rheumatologic illness. He currently lives with his wife, who is a physician at John Muir Hospital. He denies any tobacco or drug use. He only drinks alcohol occasionally. His family history is notable for a father with coronary artery disease and prior MI.

On examination today, his blood pressure is slightly elevated at 142/80 in the right arm sitting. Pulse is

5.19.2005

Page 2 of 2

regular. General exam is unremarkable. No carotid bruits were auscultated, although he has a slightly decreased upstroke on the right. No carotid bruits were noted. No cardiac murmurs were noted.

Neurologic testing shows that he is alert and oriented with fluent speech and language. He is able to follow complex commands without difficulty. Cranial nerve exam shows visual fields that are full to confrontation. Funduscopic exam shows clear disc margins bilaterally. Pupils are otherwise reactive to light and face is symmetric with normal sensation. Motor testing showed no evidence of pronator drift. He has symmetric fine motor and coordination skills. He has very subtle weakness of his interossei on the left. His lower extremity strength is full. Deep tendon reflexes were otherwise hyporeflexive but symmetric, and sensory exam was intact to light touch with no evidence of any extinction.

In summary, this is a 52-year-old gentleman who suffered an acute right carotid dissection in the setting of focal neck trauma from his motorcycle helmet strap. He has made a remarkable neurologic recovery despite evidence of embolic strokes in his right MCA territory. There are no other abnormalities on his neurologic exam today. We discussed at length the prognosis for a carotid dissection and the importance of a gradual return to work. He is scheduled to return to work part-time at the end of the month. I have advised 4 hours a day in the short-term, gradually increasing as tolerated. He will also continue his cardiovascular activity and will begin light weight-lifting and karate exercises to improve his left hand coordination skills. He should remain on Coumadin anticoagulation with a goal INR of 2.5.

I will have the patient follow-up with me in six weeks' time. He is scheduled to have an out-patient CT angiogram. I did discuss the possibility that we will not see a significant improvement until 3-6 months' time. In the interim he is advised of signs and symptoms of stroke that would prompt any earlier evaluation.

Thank you once again for allowing me to participate in his care. Please do not hesitate to contact me with further questions.

Sincerely,

Nerissa Ko, M.D.  
UCSF Neurovascular Service

CC:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Martinez, CA [REDACTED]

**This document was digitally reviewed and approved by: Nerissa Ko, M.D.**

# EXHIBIT B

1/1

5/8/2007 1:42:24 PM  
20070508-0113RAD

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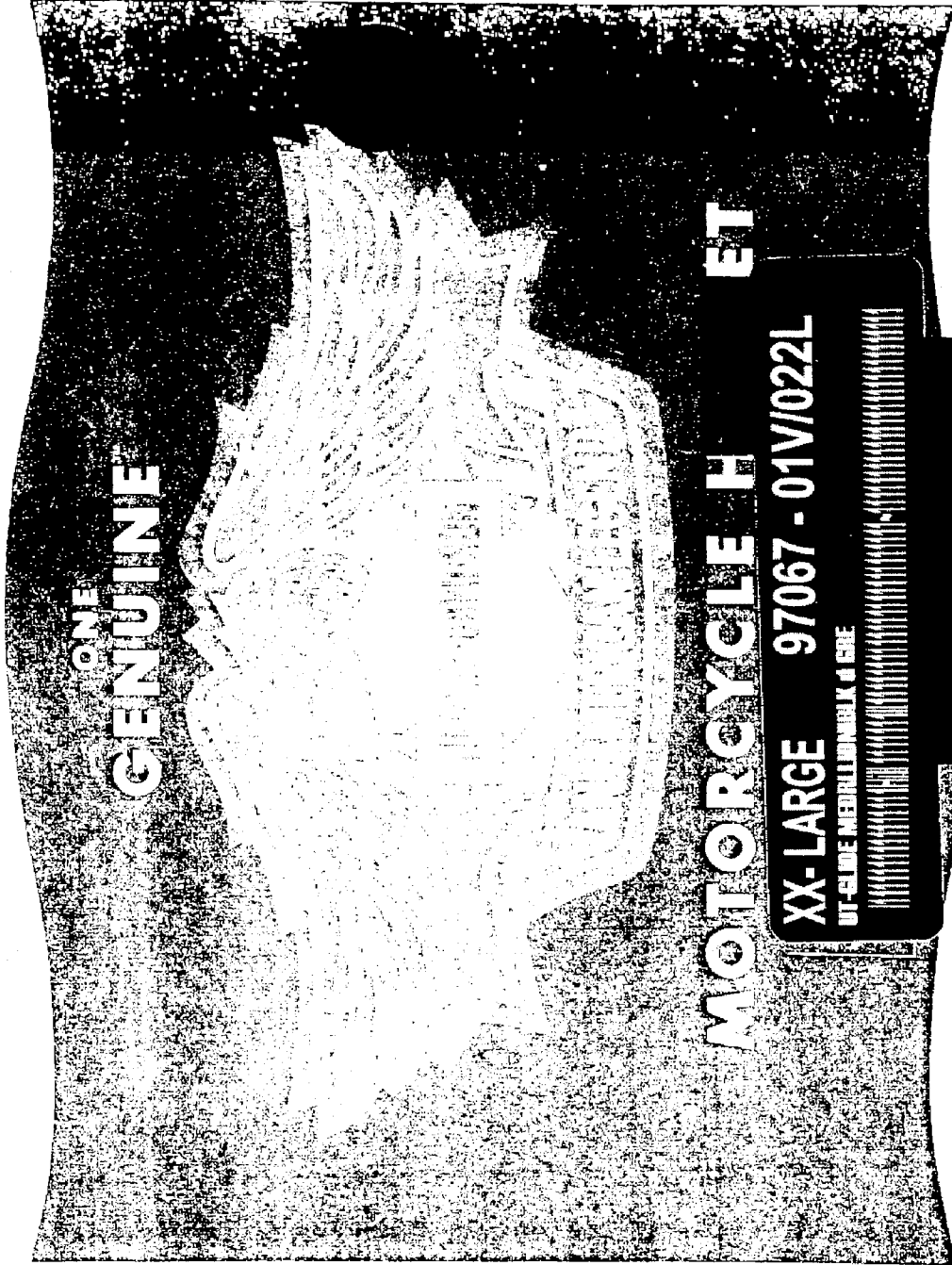
05/02/1952  
055Y  
M

Stent shown with  
coils filling  
aneurysm.

CCRMC  
W 2364 : L 2704  
SA

Metal D-Ring  
hidden inside of  
leather strap

EXHIBIT C



ONE  
GENUINE™

MOTORCYCLE H ET

XX-LARGE 97067 - 01V/022L

UIT-GEWIDE INBESCHRIJVING VAN HET GEBIED



Genuine Harley-Davidson® MotorClothes® helmets carry the spirit, tradition and quality that have made Harley-Davidson an American legend. This helmet is designed and manufactured for your riding comfort. Harley-Davidson recommends that you always wear a helmet when you ride. Harley-Davidson MotorClothes live the legend.

#### HOW TO FIT YOUR HELMET

1. The best way to put on your helmet is to use the chin straps while pulling it over your head. Properly fasten the straps making sure the retention system creates a light but comfortable fit well back against your throat.
2. Rotate the helmet from side to side, observing the movement of your skin in relation to the helmet. Helmet fit is correct when your skin movement and helmet movement are nearly the same.
3. With the chin strap fastened, move the helmet in an up and down motion, observing the movement of your skin in relation to the helmet. Again, the helmet fit is correct when skin movement and helmet movement are nearly the same.
4. With the chin strap fastened, lift up firmly on the rear of the helmet in an effort to roll it off your head in a forward direction. A correctly fit helmet should not be able to be removed this way.

*Genuine Harley-Davidson Quality Since 1903*

**WARNING:** No helmet can protect the user from all foreseeable impacts. To maximize the protection offered by this helmet design, it must fit securely. The chin strap must be securely fastened.