
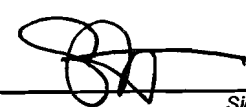
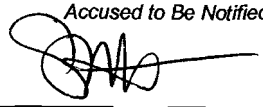


# Exhibit AA

CHARGE SHEET		
I. PERSONAL DATA		
1. NAME OF ACCUSED: IBRAHIM AHMED MAHMOUD AL QOSI		
2. ALIASES OF ACCUSED: Mohammed Saleh Ahmed, Mohammed Salih Ahmed, Mohammed Ali Ahmed, Mohammed Ahmed, Abu Khobaib al Sudani, Abu Khobab al Sudani, Abu Khobaib, Abu Khobab, Abu Khobeib, Khobaib, Khubaib, Khobeib, Khubayb, Khubeib, Khabeeb, Khabib al Sudani, Khubayb al Sudani, Ibrahim Ahmed Mahmoud, Ibrahim al Kossi		
3. ISN NUMBER OF ACCUSED (LAST FOUR): 0054		
II. CHARGES AND SPECIFICATIONS		
4. CHARGE: VIOLATION OF SECTION AND TITLE OF CRIME IN PART IV OF M.M.C.		
SPECIFICATION:  See Attached Charges and Specifications.		
III. SWEARING OF CHARGES		
5a. NAME OF ACCUSER (LAST, FIRST, MI) TREANOR, J.	5b. GRADE 0-6	5c. ORGANIZATION OF ACCUSER OMC-PROSECUTION
5d. SIGNATURE OF ACCUSER 		5e. DATE (YYYYMMDD) 2008/02/08
AFFIDAVIT: Before me, the undersigned, authorized by law to administer oath in cases of this character, personally appeared the above named accuser the <u>8</u> day of <u>February</u> , <u>2008</u> , and signed the foregoing charges and specifications under oath that he/she is a person subject to the Uniform Code of Military Justice and that he/she has personal knowledge of or has investigated the matters set forth therein and that the same are true to the best of his/her knowledge and belief.		
S. MAHER _____ <i>Typed Name of Officer</i>	OMC-PROSECUTION _____ <i>Organization of Officer</i>	
0-5 _____ <i>Grade</i>	10 U.S.C. 1044(b) _____ <i>Official Capacity to Administer Oath</i> (See R.M.C. 307(b) must be commissioned officer)	
 _____ <i>Signature</i>		

**IV. NOTICE TO THE ACCUSED**

6. On 8 February, 2008 the accused was notified of the charges against him/her (See R.M.C. 308).

LT COL S. MAHER  
 Typed Name and Grade of Person Who Caused  
 Accused to Be Notified of Charges  
  
 Signature

OMC-PROSECUTION  
 Organization of the Person Who Caused  
 Accused to Be Notified of Charges

**V. RECEIPT OF CHARGES BY CONVENING AUTHORITY**

7. The sworn charges were received at \_\_\_\_\_ hours, on \_\_\_\_\_, at \_\_\_\_\_

Location

For the Convening Authority: \_\_\_\_\_  
 Typed Name of Officer

Grade

Signature

**VI. REFERRAL**

8a. DESIGNATION OF CONVENING AUTHORITY	8b. PLACE	8c. DATE (YYYYMMDD)
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Referred for trial to the (non)capital military commission convened by military commission convening order \_\_\_\_\_

\_\_\_\_\_ subject to the following instructions<sup>1</sup>: \_\_\_\_\_

By \_\_\_\_\_ of \_\_\_\_\_  
 Command, Order, or Direction

Typed Name and Grade of Officer

Official Capacity of Officer Signing

Signature

**VII. SERVICE OF CHARGES**

9. On \_\_\_\_\_, 2008 I (caused to be) served a copy these charges on the above named accused.

S. MAHER  
 Typed Name of Trial Counsel

0-5  
 Grade of Trial Counsel

Signature of Trial Counsel

**FOOTNOTES**

<sup>1</sup>See R.M.C. 601 concerning instructions. If none, so state.

UNITED STATES OF AMERICA )

v. )

IBRAHIM AHMED MAHMOUD AL QOSI )

a/k/a Mohammed Saleh Ahmed )

a/k/a Mohammed Salih Ahmed )

a/k/a Mohammed Ali Ahmed )

a/k/a Mohammed Ahmed )

a/k/a Abu Khobaib al Sudani )

a/k/a Abu Khobab al Sudani )

a/k/a Abu Khobaib )

a/k/a Abu Khobab )

a/k/a Abu Khobeib )

a/k/a Khobaib )

a/k/a Khubaib )

a/k/a Khobeib )

a/k/a Khubayb )

a/k/a Khubeib )

a/k/a Khabeeb )

a/k/a Khabib al Sudani )

a/k/a Khubayb al Sudani )

a/k/a Ibrahim Ahmed Mahmoud )

a/k/a Ibrahim al Kossi )

**CHARGES:**

**I. CONSPIRACY**

**II. PROVIDING MATERIAL SUPPORT FOR TERRORISM**

CHARGE I: VIOLATION OF 10 U.S.C. § 950v(b)(28), CONSPIRACY

**SPECIFICATION:** In that Ibrahim Ahmed Mahmoud al Qosi, a person subject to trial by military commission as an alien unlawful enemy combatant, did, in the context of and associated with an armed conflict, at various locations in Afghanistan and elsewhere, from on or about 23 August 1996, through on or about 15 December 2001, willfully and knowingly conspire and agree with Usama bin Laden, Abu Hafs al Masri, and other members and associates, known and unknown, of the international terrorist organization known as al Qaeda, and willfully and knowingly join an enterprise of persons known as al Qaeda, the agreement and enterprise sharing a common criminal purpose to commit one or more of the following offenses triable by military commission: targeting civilians, attacking civilians, murdering civilians, attacking civilian objects, murder in violation of the law of war, destruction of property in violation of the law of war, terrorism, and providing material support for terrorism; and with knowledge of the unlawful purpose of the agreement and common criminal purpose of the enterprise, willfully entered into the agreement and enterprise with the intent to further the unlawful purpose, and knowingly committed one or more of the following overt acts in order to accomplish some purpose of the agreement and enterprise:

- a. From in or about 1996, through in or about 2001, in Afghanistan, al Qosi, armed with an AK-47, served as an bodyguard for Usama bin Laden, and other al Qaeda members.
- b. From in or about 1996, through in or about 2001, in Afghanistan, al Qosi, armed with an AK-47, served as a driver for Usama bin Laden, and other al Qaeda members.
- c. From in or about 1996, through in or about 1998, in Afghanistan, al Qosi lived at an al Qaeda compound near Jalalabad known as the "Star of Jihad," with other al Qaeda members, including Usama bin Laden, where he provided security, transportation, and supply services.
- d. From in or about 1998, through in or about 2001, in Afghanistan, al Qosi lived at an al Qaeda compound near Kandahar, ("Kandahar compound"), with other al Qaeda members, including Usama bin Laden, where he provided security, transportation, and supply services.
- e. From in or about 1998, through in or about 2001, in Afghanistan, at various times, al Qosi traveled from the Kandahar compound to the front near Kabul, where he fought in support of al Qaeda near Kabul as part of a mortar crew.
- f. From in or about August 2001, through in or about September 2001, in Afghanistan, approximately two weeks prior to al Qaeda's 11 September 2001 attacks on the United States, Usama bin Laden ordered an alert, and al Qosi and other members of bin Laden's bodyguard detachment, armed with AK-47s and other weapons, evacuated the Kandahar compound with bin Laden and other al Qaeda members.
- g. From in or about August 2001, through in or about October 2001, in Afghanistan, al Qosi and other members of Usama bin Laden's bodyguard detachment, armed with AK-47s and other weapons, traveled in a convoy with bin Laden and other al Qaeda members, and camped at bin Laden's direction, between Kabul, Khowst, and Jalalabad, and provided security and transportation for bin Laden and other al Qaeda members.
- h. From in or about October 2001, through in or about December 2001, in Afghanistan, al Qosi and other members of Usama bin Laden's bodyguard detachment, armed with AK-47s and other weapons, traveled to Tora Bora with bin Laden and other al Qaeda members, and provided security and transportation for bin Laden and other al Qaeda members.
- i. From in or about December 2001, through on or about 15 December 2001, in Afghanistan, at or near Tora Bora, al Qosi, armed with an AK-47, along with other members of Usama bin Laden's bodyguard detachment and other al Qaeda members armed AK-47s and other weapons, separated from bin Laden, and traveled away from Tora Bora where they came under fire from U.S. forces.

**CHARGE II: VIOLATION OF 10 U.S.C. § 950v(b)(25).**  
**PROVIDING MATERIAL SUPPORT FOR TERRORISM**

**SPECIFICATION:** In that Ibrahim Ahmed Mahmoud al Qosi, a person subject to trial by military commission as an alien unlawful enemy combatant, did, in Afghanistan and elsewhere, from on or about 23 August 1996, through on or about 15 December 2001, intentionally provide material support or resources to al Qaeda, an international terrorist organization engaged in hostilities against the United States, by, among other things, serving as a bodyguard, driver, fighter and supplier, for al Qaeda, knowing that such organization has engaged or engages in terrorism, including targeting civilians, attacking civilians, and murdering civilians, said conduct taking place in the context of and associated with an armed conflict.



**DEPARTMENT OF DEFENSE  
OFFICE OF THE CHIEF PROSECUTOR  
OFFICE OF MILITARY COMMISSIONS  
1610 DEFENSE PENTAGON  
WASHINGTON, DC 20301-1610**

\_\_\_\_\_  
(day) (month) (year)

MEMORANDUM FOR Detainee Ibrahim Ahmed Mahmoud al Qosi 0054, Guantanamo Bay, Cuba

SUBJECT: Notification of the Swearing of Charges

1. You are hereby notified that criminal charges were sworn against you on the \_\_\_\_ day of \_\_\_\_\_, 2008, pursuant to the Military Commissions Act of 2006 (MCA) and the Manual for Military Commissions (MMC). A copy of this notice is being provided to you and to your detailed defense counsel.

2. Specifically, you are charged with the following offenses:

CONSPIRACY

PROVIDING MATERIAL SUPPORT FOR TERRORISM

*(Read the charges and specifications to the accused. If necessary, an interpreter may read the charges in a language, other than English, that the accused understands.)*

**AFFIDAVIT OF SERVICE**

I hereby certify that a copy of this document was provided to the named detainee this \_\_\_\_ day of \_\_\_\_\_, 2008.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Organization

\_\_\_\_\_  
Typed or Printed Name and Grade

\_\_\_\_\_  
Address of Organization

عريضة الاتهامات		
أولاً: بيانات شخصية		
1. إسم المتهم: إبراهيم احمد محمود القصي		
2. ألقاب المتهم: محمد صالح احمد، محمد علي احمد، محمد احمد، أبو خبيب السوداني، أبو خباب السوداني، أبو خبيب، أبو خباب، خبيب، خبايب، خبيب السوداني، إبراهيم احمد محمود، إبراهيم القصي		
3. رقم تسلسل المعتقل (الأرقام الأربعة الأخيرة) 0054		
ثانياً: الاتهامات والمواصفات		
4. التهمة: إنتهاك بند وعنوان الجرم في القسم (رابعاً) من دليل اللجان العسكرية		
المواصفة: راجع التهم والمواصفات الملحقه.		
ثالثاً: توجيه الاتهامات		
5أ. إسم المدعي (الأخير، الأول، الحرف الأول للاسم الواسطي) ترينور، ج.	5ب. الرتبة ضابط رتبة 6	5ج. منظمة المدعي مكتب اللجان العسكرية - الادعاء
5د. توقيع المدعي	5هـ. تاريخ (السنة الشهر اليوم)	
شهادة مشفوعة بالقسم: حضر أمامي، أنا الموقع أدناه المفوض قانوناً للتحليف في القضايا ذات الصفة هذه، وبصفة شخصية المدعي سابق الذكر في يوم _____ من 2008 وقام بالتوقيع على الاتهامات والمواصفات السابقة بعد أن حلف اليمين بأنه شخص خاضع لقانون العدالة العسكرية الموحد وبأنه يتمتع بمعرفة شخصية أو قام بنفسه بالتحقيق في المسائل المنصوص عليها هنا، وأن هذه المسائل صحيحة وفقاً لأفضل ما لديه من معلومات واعتقاد.		
س. ماهر اسم الضابط بالحروف المطبوعة	مكتب اللجان العسكرية - الادعاء منظمة الضابط	
ضابط رتبة 5 رتبة	عنوان 10 من مدونة الولايات المتحدة، بند 1044(ب) الصفة الرسمية لتحائف اليمين (راجع لائحة اللجان العسكرية 307(ب) يجب أن يكون ضابط)	
التوقيع		

استمارة رقم 458 الخاصة باللجان العسكرية يناير كانون الثاني 2007



<b>رابعاً: الإشعار المقدم إلى المتهم</b>		
6. بتاريخ _____ 2008 تم إشعار المتهم بالتهمة الموجهة ضده (راجع لائحة اللجان العسكرية رقم (308).		
<b>المقدم س. ماهر</b> الاسم ورتبة الشخص الذي تسبب بإشعار المتهم بالتهمة (بالحروف المطبوعة)	<b>مكتب اللجان العسكرية – الادعاء</b> المؤسسة الخاصة بالشخص الذي تسبب بإشعار المتهم بالتهمة	
التوقيع _____		
<b>خامساً: إستلام سلطة عقد اللجان للاتهامات</b>		
7. تم استلام الاتهامات الموجهة في الساعة _____ بتاريخ _____ في _____		
المقر _____		
بالتبابة عن سلطة عقد اللجان:		
اسم الضابط بالحروف المطبوعة _____		
الرتبة _____		
التوقيع _____		
<b>سادساً: الإحالة</b>		
8أ. تعيين سلطة عقد اللجان	8ب. المكان	8ج. تاريخ (سنة، شهر، يوم)
تمت الإحالة للمحاكمة أمام اللجنة العسكرية المفوضة (غير المفوضة) لإصدار حكم بالإعدام المجتمعة بموجب أمر دعوة اللجنة العسكرية للانعقاد _____		
وفق التعليمات التالية <sup>1</sup> : _____		
من قبل _____ من _____		
القيادة أو الأمر أو التوجيه _____		
الاسم ورتبة الضابط بالحروف المطبوعة _____		
الصفة الرسمية للضابط الموقع _____		
التوقيع _____		
<b>سابعاً: تسليم الاتهامات</b>		
9. في تاريخ _____ 2008 قمت (تسببت) بتسليم نسخة من هذه التهمة للمتهم سابق الذكر.		
<b>س. ماهر</b> اسم مستشار المحاكمة بالحروف المطبوعة	<b>ضابط رتبة 5</b> رتبة مستشار المحاكمة	
توقيع مستشار المحاكمة _____		
<b>الحاشيات</b>		
<sup>1</sup> راجع لائحة اللجان العسكرية 601 بخصوص التعليمات. في حالة عدمها يرجى الإدلاء بذلك.		

استمارة رقم 458 الخاصة باللجان العسكرية يباير كانون الثاني 2007

	(	الولايات المتحدة الأمريكية
التهم:	(	
	(	
أولا: تأمر	(	ضد
	(	
	(	إبراهيم احمد محمود القصي
	(	المدعو أيضا محمد صالح احمد
ثانيا: توفير الدعم	(	المدعو أيضا محمد على احمد
المادي	(	المدعو أيضا محمد احمد
للإرهاب	(	المدعو أيضا أبو خبيب السوداني
	(	المدعو أيضا أبو خباب السوداني
	(	المدعو أيضا أبو خبيب
	(	المدعو أيضا أبو خباب
	(	المدعو أيضا خبيب
	(	المدعو أيضا خبيب السوداني
	(	المدعو أيضا إبراهيم احمد محمود
	(	المدعو أيضا إبراهيم القصي

### التهمة الأولى: انتهاك عنوان 10 من مدونة الولايات المتحدة، بند (28)(b)950v، تأمر

الموصفة 1: على أن إبراهيم احمد محمود القصي، وهو شخص يخضع لمحاكمة اللجان العسكرية كعدو غير مشروع أجنبي مقاتل، قد قام في سياق ومشاركة نزاع مسلح في مناطق مختلفة من أفغانستان وأماكن أخرى من أو من حوالي 23 أغسطس آب 1996 إلى أو إلى حوالي 15 ديسمبر كانون الأول 2001 عمدا وعن معرفة في التآمر والاتفاق مع أسامة بن لادن وأبو حفص المصري وغيرهم من أعضاء ومناصري التنظيم الإرهابي الدولي المعروف بالقاعدة، المعروفين والمجهولين منهم، وقام علما واقتعالا بالالتحاق بمشروع أشخاص عرفوا بالقاعدة، علما أن الاتفاق والمشروع كانا يتشاركان في غرض إجرامي مشترك لارتكاب إحدى أو جملة من الجرائم التالية التي تخضع لمحاكمة اللجان العسكرية: تصويب مدنيين، الهجوم على مدنيين، قتل مدنيين عمدا، الهجوم على أهداف مدنية، القتل العمدي انتهاكا لقانون الحرب، تدمير أملاك انتهاكا لقانون الحرب، الإرهاب، وتوفير الدعم المادي للإرهاب؛ ومع العلم بالهدف الغير قانوني للاتفاق والغرض الإجرامي المشترك للمشروع قام القصي عن عمد بإبرام الاتفاق وانخرط في المشروع مع نية تعزيز الغاية الغير قانونية وشرع بارتكاب عن معرفة إحدى أو جملة من الأعمال السافرة التالية لكي ينجز بعض من الهدف أو الغاية من الاتفاق والمشروع:

أ. من أو من حوالي سنة 1996 إلى أو إلى حوالي سنة 2001 في أفغانستان عمل القصي، وهو يحمل سلاح ال أ.ك. 47، كحرس خاص لأسامة بن لادن وأعضاء آخرين في القاعدة.

ب. من أو من حوالي سنة 1996 إلى أو إلى حوالي سنة 2001 في أفغانستان عمل القصي، وهو يحمل سلاح ال أ.ك. 47، كسائق لأسامة بن لادن وأعضاء آخرين في القاعدة.

ج. من أو من حوالي سنة 1996 إلى أو إلى حوالي سنة 1998 في أفغانستان قطن القصي في مجمع خاص للقاعدة بالقرب من جلالباد كان يعرف باسم "نجمة الجهاد" مع أعضاء آخرين في القاعدة، بما في ذلك أسامة بن لادن، حيث قام بتوفير الخدمات الخاصة بالأمن والنقل واللوازم.

د. من أو من حوالي سنة 1998 إلى أو إلى حوالي سنة 2001 في أفغانستان قطن القصي في مجمع تابع للقاعدة في قندهار ("مجمع قندهار") مع أعضاء آخرين في القاعدة، بما في ذلك أسامة بن لادن، حيث قام بتوفير الخدمات الخاصة بالأمن والنقل واللوازم.

هـ. من أو من حوالي سنة 1998 إلى أو إلى حوالي 2001 وفي فترات متفرقة تنقل القصي من مجمع قندهار إلى الجبهة بالقرب من كابول حيث كافح دعماً للقاعدة بالقرب من كابول كعضو في طاقم مدفع الهاون.

و. من أو من حوالي أغسطس آب 2001 إلى أو إلى حوالي سبتمبر أيلول 2001 في أفغانستان، قبل أسبوعين من هجمات القاعدة في 11 سبتمبر أيلول 2001، أعطى إسامة بن لادن إنذاراً وقام القصي وأعضاء آخرين من فصيلة الحرس الخاص لأسامة بن لادن، حاملين ال أ.ك. 47 وأسلحة أخرى، بإخلاء مجمع قندهار مع بن لادن وأعضاء آخرين في القاعدة.

ز. من أو من حوالي أغسطس آب 2001 إلى أو إلى حوالي أكتوبر تشرين الأول 2001 في أفغانستان تحرك القصي وأعضاء آخرين من فصيلة الحرس الخاص لأسامة بن لادن، حاملين ال أ.ك. 47 وأسلحة أخرى، في قافلة مع بن لادن وأعضاء آخرين في القاعدة، وبأمر من بن لادن نصب معسكراً بين كابول وخوست وجلالباد، وقام بتوفير الحماية والنقل لبن لادن وأعضاء آخرين في القاعدة.

ح. من أو من حوالي أكتوبر تشرين الأول 2001 إلى أو إلى حوالي ديسمبر كانون الأول 2001 في أفغانستان تحرك القصي مع أعضاء آخرين من فصيلة الحرس الخاص لأسامة بن لادن، حاملين ال أ.ك. 47 وأسلحة أخرى، إلى تورا بورا مع بن لادن وأعضاء آخرين في القاعدة، وقام بتوفير الحماية والنقل لبن لادن وأعضاء آخرين في القاعدة.

ط. من أو من حوالي ديسمبر كانون الأول 2001 إلى أو إلى حوالي 15 ديسمبر كانون الأول 2001 في أفغانستان، في أو بالقرب من تورا بورا، انفصل القصي، وهو يحمل سلاح ال أ.ك. 47، مع أعضاء آخرين من فصيلة الحرس الخاص لأسامة بن لادن وأعضاء آخرين في القاعدة يحملون ال أ.ك. 47 وأسلحة أخرى، عن بن لادن ورحل مع الآخرين من تورا بورا حيث وقعوا تحت نيران القوات المسلحة الأمريكية.

التهمة الثانية: انتهاك عنوان 10 من مدونة الولايات المتحدة، بند (25)(b)950v،  
توفير الدعم المادي للإرهاب

المواصفة: على أن إبراهيم احمد محمود القصي، وهو شخص يخضع لمحاكمة اللجان العسكرية كعدو غير مشروع أجنبي مقاتل، قد شرع في أفغانستان ومناطق أخرى من أو من حوالي 23 أغسطس آب 1996 إلى أو إلى حوالي 15 ديسمبر كانون الأول 2001 بتوفير عمدا الدعم المادي أو اللوازم إلى القاعدة وهي منظمة إرهابية دولية ضالعة في معاداة الولايات المتحدة، وبذلك عمل، من بين أشياء أخرى، كحارس خاص وسائق ومكافح ومجهز للقاعدة، وهو يدرك بأن تلك المنظمة كانت متورطة أو هي متورطة في الإرهاب، بما في ذلك تصويب مدنيين، مهاجمة مدنيين، وقتل مدنيين عمدا، وكان ذلك السلوك يحصل في سياق ومشاركة نزاع مسلح.

وزارة الدفاع  
مكتب رئيس هيئة الادعاء  
مكتب اللجان العسكرية  
1610 الدفاع البنتاغون  
واشنطن في مقاطعة كولومبيا 20301-1610

(اليوم) (الشهر) (السنة)

مذكرة موجهة للمعتقل إبراهيم احمد محمود القصي 0054، خليج غوانتانامو، كوبا.

الموضوع: إشعار بإقرار الاتهامات

1. يتم بهذا إبلاغك بأن اتهامات جنائية قد أقرت تجاهك في يوم \_\_\_\_ من \_\_\_\_ 2008، استنادا إلى قانون اللجان العسكرية (MCA) لسنة 2006 وعملا بدليل اللجان العسكرية (MMC). وسوف يتم توفيرك وتوفير المستشار القانوني المعين لك بنسخة من هذا الإخطار.

2. إنك على وجه التحديد متهم بالجرائم التالية:

تأمر

توفير الدعم المادي للإرهاب

(قم بقراءة الاتهامات والمواصفات الخاصة بالمتهم. إذا ما لزم الأمر، يجوز أن يقوم مترجما شفويا بقراءة التهم في لغة غير الإنكليزية التي يفهمها المتهم).

### إقرار بالتبليغ

بهذا أشهد بأن نسخة من هذه الوثيقة قد وفرت للمعتقل المدعو في يوم \_\_\_\_ من \_\_\_\_ 2008.

المؤسسة

التوقيع

عنوان المؤسسة

الاسم والرتبة بالحروف المطبعية أو المطبوعة

# Exhibit AB

UNCLASSIFIED//FOUO



REPLY TO  
ATTENTION OF:

DEPARTMENT OF DEFENSE  
DEPUTY COMMANDER - DETAINEE OPERATIONS  
JOINT TASK FORCE 435  
APO AE 09354



JTF-435-LO

JUN 1 2010

MEMORANDUM FOR Commander, Task Force Protector, Bagram Airfield, Afghanistan, APO AE 09354

SUBJECT: 2 June 2010 Detainee Review Board (DRB) Recommendation Vote for Release for ISN 4191

1. I reviewed the findings and recommendation of the DRB conducted on 2 June 2010 concerning the internment of Detainee ISN 4191. By a vote of 3 to 0, the board members found that ISN 4191 did not meet the criteria for internment. Pursuant to Deputy Secretary of Defense Policy Guidance on Review Procedures and Transfer and Release Authority at Bagram Theater Internment Facility dated 2 July 2009, I approve the DRB's finding and direct that ISN 4191 be released from the Detention Facility in Parwan.

2. The point of contact for this memorandum is CAPT [redacted (b)(3), (b)(6)], Director of Legal Operations, JTF 435, at DSN [redacted (b)(2)].

MARK S. MARTINS  
Brigadier General, U.S. Army  
Deputy Commander

UNCLASSIFIED//FOUO

SECRET//NOFORN



REPLY TO  
ATTENTION OF:

DEPARTMENT OF DEFENSE  
LEGAL DIRECTORATE – DETAINEE OPERATIONS  
US FORCES AFGHANISTAN  
JOINT TASK FORCE 435  
APO AE 09356



JTF-435-LO

6 June 2010

MEMORANDUM FOR Deputy Commander, Joint Task Force 435, Kabul, Afghanistan, APO  
AE 09356

SUBJECT: 2 June 2010 Detainee Review Board (DRB) Legal Review, Abdullah Bari, (b)(6), (b)(1)1.4a, (b)(1)1.4c  
(b)(6), (b)(1)1.4a, (b)(1)1.4c ISN 4191

1. Abdullah Bari (b)(6), (b)(1)1.4a, (b)(1)1.4c ISN 4191, was captured (b)(1)1.4a, (b)(1)1.4c at Sherwin Village, Bala Boluk District, Herat Province on (b)(1)1.4a, (b)(1)1.4c. The premise for capture was his assessment as a high level target. (Subsequently, (b)(1)1.4a, (b)(1)1.4c continued searching for the target, inferring that additional information caused a change in the assessment of ISN 4191.)
2. I reviewed Enclosure 1, the findings and recommendations of Abdullah Bari, ISN 4191's DRB, and find them to be legally sufficient.
3. The DRB found that Abdullah Bari, ISN 4191, does not meet the criteria for internment for reasons stated in Enclosures 1 and 2.
4. The DRB recommended that Abdullah Bari, ISN 4191, be released without conditions and in accordance with a finding that he does not meet internment criteria. The DRB further determined that internment is not necessary to mitigate the threat posed by Abdullah Bari, ISN 4191.
5. The DRB also recommended that Abdullah Bari, ISN 4191, not be classified as an Enduring Security Threat.
6. The point of contact for this review is MAJ (b)(3), (b)(6), JTF-435 DRB, at DSN (b)(2) (b)(2) or (b)(2), (b)(3), (b)(6)

(b)(3), (b)(6)

- 4 Encls.
1. DRB President's Memo
  2. DRB Voting Packet
  3. Summarized Testimony with Exhibits
  4. DC JTF 435 Release Approval/Disapproval Memo  
(Does Not Meet Internment Criteria)

MAJ, JA  
Detainee Review Board Legal Advisor

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BAGRAM / CENTCOM /001543



SECRET//NOFORN



REPLY TO  
ATTENTION OF:

DEPARTMENT OF DEFENSE  
LEGAL DIRECTORATE – DETAINEE OPERATIONS  
US FORCES AFGHANISTAN  
JOINT TASK FORCE 435  
APO AE 09356



JTF-435-LO

6 June 2010

MEMORANDUM FOR Deputy Commander, Joint Task Force 435, Kabul Afghanistan, APO AE 09356

SUBJECT: 2 June 2010 Detainee Review Board (DRB) Recommendation, Release Without Conditions of Abdullah Bari (s)(6), (b)(1)1.4a, (b)(1); ISN 4191, (Does Not Meet Internment Criteria)

1. DRB FINDINGS AND RECOMMENDATIONS. The DRB met on 2 June 2010 and made the following findings and recommendations concerning the internment of Abdullah Bari s/o (b)(6), (b)(1)1.4a, (b)(1); ISN 4191:

a. That Abdullah Bari, ISN 4191, did not meet criteria for initial internment because he was not assessed to be a part of or a substantial supporter of insurgent forces opposing Coalition Forces.

b. That internment is not necessary to mitigate the threat posed by Abdullah Bari, ISN 4191. That Abdullah Bari, ISN 4191, should not continue to be interned at the Detention Facility in Parwan.

c. The DRB recommends approval for release without conditions of Abdullah Bari, ISN 4191, in accordance with a finding that he does not meet internment criteria.

d. That Abdullah Bari, ISN 4191, should be considered for reintegration programs within the DFIP.

e. That Abdullah Bari, ISN 4191, is not an Enduring Security Threat.

2. DRB ASSESSMENT. Abdullah Bari, ISN 4191's story was plausible and assessed likely to be true by the DRB. He travelled to the village to collect money from a chicken sale. Co-captures identified Abdullah Bari as a Taliban. The DRB did not find those allegations to be credible, especially given the total lack of corroboration. Abdullah Bari took a polygraph, showing no deception when denying Taliban membership and activity. There is next to no evidence on this person. He professes to be pro-Coalition Forces. The Board President emphasized that Abdullah Bari should be released immediately, while he is still favorably pre-disposed to the US Government.

Abdul Bari's capture involved an element of "mistaken identity." The capturing unit thought Abdullah Bari, ISN 4191, was a JPEL target of the same name. However, that target is still generating reporting, and the targeting packet on that individual continues to be developed.

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BAGRAM / CENTCOM /001544

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JTF-435-LO

SUBJECT: 2 June 2010 Detainee Review Board (DRB) Recommendation, Release Without Conditions of Abdullah Bari ~~(b)(1)1.4a, (b)(1)1.4c, (b)(1)1.4d~~ ISN 4191, (Does Not Meet Internment Criteria)

3. CIRCUMSTANCES OF CAPTURE. Abdullah Bari ~~(b)(1)1.4a, (b)(1)1.4c, (b)(1)1.4d~~ ISN 4191, was captured ~~(b)(1)1.4a, (b)(1)1.4c, (b)(1)1.4d~~ at Sherwin Village, Bala Boluk District, Herat Province on ~~(b)(1)1.4a, (b)(1)1.4c, (b)(1)1.4d~~. The premise for capture was his assessment as a high level target. (Subsequently, ~~(b)(1)1.4a, (b)(1)1.4c, (b)(1)1.4d~~ continued searching for the target, inferring that additional information caused a change in the assessment of ISN 4191.)

4. BASIS FOR TARGETING AND INTERNMENT. In making its findings and recommendations, the DRB considered the following evidence:

- a. Physical Evidence: Nothing of significance.
- b. CELLEX/DOCEX/TAREX/MEDEX: Nothing.
- c. Explosive Residue Testing: None.
- d. Sensitive Reporting: None.
- e. Classified Reporting: Co-captures at time of capture identified Abdullah Bari, ISN 4191, as being Taliban.

5. DETAINEE ADMISSIONS AND CLAIMS (PRE-DRB). In making its findings and recommendations, the DRB considered information from interrogations and interviews, including but not limited to the following:

- a. Interrogations and Interviews: Abdullah Bari, ISN 4191, said he is not from Shewan Village. He said he was visiting to collect money for a sale of chickens. Abdullah Bari denied being Taliban.
- b. Polygraph: No deception indicated when denying Taliban membership and when denying attacking Coalition Forces.

6. EXHIBITS SUBMITTED & DETAINEE TESTIMONY AT DRB. In making its findings and recommendations, the DRB considered the following exhibits and detainee testimony:

- a. Recorder's Unclassified and Classified Exhibits.
- b. Personal Representative's Exhibits. Exhibit A, indicating that Abdullah Bari, ISN 4191, was advised of the basis for internment and the facts supporting internment. Exhibit B, indicating that Abdullah Bari, ISN 4191, met with a personal representative and was advised of his rights at the DRB.

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JTF-435-LO

SUBJECT: 2 June 2010 Detainee Review Board (DRB) Recommendation, Release Without Conditions of Abdullah Bari (b)(6), (b)(1)1.4a, (b)(1)1.4c ISN 4191, (Does Not Meet Internment Criteria)

c. Detainee Criminal Investigative Detachment (DCID) Report of Investigation (ROI) dated 29 April 2010.

d. Disciplinary and Observation Reports (Theater Internment Facility Progress Report) dated 2 June 2010: No DRs.

e. Behavioral Science Consultation Team (BSCT) Assessment. Risk Level (b)(1)1.4a, (b)(1)1.4c COIN: (b)(1)1.4a, (b)(1)1.4c Confidence: (b)(1)1.4a, (b)(1)1.4c Date: (b)(1)1.4a, (b)(1)1.4c

f. Detainee's DRB Statement and Responses to Questions: Abdullah Bari, ISN 4191, is anti-Taliban. He stated that most of his relatives "work for the government." For this reason, his alliance lies with the government and against the Taliban.

Abdullah Bari lives in Para City, Laman District, Herat Province. He was in Shewan Village, Bala Boluk District for business purposes. It takes two or three hours to walk between the villages. He had sold eight chickens and specified the price. He intended to collect money from (b)(6), (b)(1)1.4a, (b)(1)1.4c. When he arrived, (b)(1)1.4a, (b)(1)1.4c was not present, but the brother was present. Abdullah Bari stayed with the brother, waiting for (b)(1)1.4a, (b)(1)1.4c to return. He ate dinner with the brother and was captured later that evening.

Abdullah Bari said he heard the warning from (b)(1)1.4a, (b)(1)1.4c. He chose to stay in the village. He was detained with little information.<sup>1</sup>

Abdullah Bari, ISN 4191, was proud of his good behavior with the guards.

7. WITNESS INFORMATION. In making its findings and recommendations, the DRB considered the following witness information: The Personal Representative submitted three letters of support, one each from the district chief, provincial governor, and tribal elders. The letters say Abdullah Bari is peace loving and on the side of the government.

8. SUMMATION OF DRB FINDINGS AND RECOMMENDATIONS, THREAT ASSESSMENT. In determining whether continued internment is necessary to mitigate the threat posed by Abdullah Bari, ISN 4191, the DRB assessed DoD criteria for internment, the detainee's level of threat and weighed, among other things, his potential for rehabilitation, reconciliation, and eventual reintegration into society. In considering this recommendation, the DRB noted the risk posed by Abdullah Bari, ISN 4191, in relation to the COIN impact of release versus continued internment. There may have been mistaken identity associated with the detention of

<sup>1</sup> There was a JPEL target with the name "Abdul Bari," hailing from Shewan Village. ISN 4191 does not match the description of the JPEL target named Abdul Bari. There is some evidence in TIRs that the capturing unit at one point thought they had captured a JPEL target. The Recorder explained that the targeting package for Abdul Bari is still active, indicating that ISN 4191 is not the JPEL target. There was no deception indicated during his polygraph testing.

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JTF-435-LO

SUBJECT: 2 June 2010 Detainee Review Board (DRB) Recommendation, Release Without Conditions of Abdullah Bari ~~(b)(6)~~, (b)(1)1.4a, (b)(1)1.6N 4191, (Does Not Meet Internment Criteria)

Abdullah Bari, ISN 4191, because the capturing unit thought he was a JPEL target of the same name. As a result of all of these considerations, the DRB believes that release without conditions is the best alternative, pursuant to a finding that Abdullah Bari, ISN 4191, does not meet internment criteria.

9. The point of contact for this review is MAJ ~~(b)(3), (b)(6)~~, JTF-435 DRB, at DSN ~~(b)(2)~~ ~~(b)(2)~~ or ~~(b)(2), (b)(3), (b)(6)~~.

~~(b)(3), (b)(6)~~

- 2 Encls.
- 1. DRB Voting Packet
- 2. Summarized Testimony

COL, QM, USA  
President, Detainee Review Board

~~SECRET//NOFORN~~

SECRET//NOFORN

(U//FOUO) [redacted] -004191 [redacted]

Abdullah ((BARI)) s/o [redacted]

POC: Sherwan Village, Bala Boluk, Herat DOC: [redacted]

(C//REL USA, CCTF, ISAF, NATO) Capturing Unit: [redacted]

(b)(1)1.4a, (b)(1)1.4c

(U//FOUO) POB/POR: Leman, Gulistan, Farah Tribe/Sub-Tribe: Sher Khan Primary Language: Dari Interrogations/TIR: [redacted]

**Circumstances of Capture:** (S//REL USA, ISAF, NATO) Abdullah Bari, ISN 4191 [redacted] was captured by CF on [redacted] during [redacted] Prior to the start of [redacted] local citizens were warned of the impending mission. The city cleared of women, children, and other Afghani citizens. Abdullah Bari was caught trying to hide ID cards on the roof of the mosque as he was trying to evade capture and running towards [redacted]. (Sworn Statements.) Abdullah Bari was identified by other detainees as being associated with Taliban forces that are engaged in hostilities against U.S. Forces. (Sworn Statements). The detainees told the interpreter accompanying the [redacted] that Bari was a Taliban Fighter. (Sworn Statement).

**Internment Criteria:** (U//FOUO) Was a part of, or substantially supported, Taliban forces or associated forces that are engaged in hostilities against the United States or its coalition partners, including any person who has committed a belligerent act, or has directly supported hostilities in aid of such enemy armed forces.

**SSE:** (U//FOUO) Pakistani ID card.

**Exploitation:** (S//NF) Polygraph: No Deception Indicated was the result of a 18 October 2009 polygraph [redacted]

**Reporting:** None

**Detainee Statement:**

- (S//NF) [redacted] Claimed that he is not from Shewan Village. He was there to collect money from [redacted] for chickens that he sold.
- (S//NF) [redacted] Denied being a Taliban member.

**BSCT Assessment:** Risk Level: [redacted] COIN: [redacted] (Confidence: [redacted]) (Dated: [redacted])

**DR/OR Summary:** See DFIP Progress Report

(C//REL USA, CCTF, ISAF, NATO)

**Organization & Role:**

Taliban Fighter

DRB Hearing: 2 June 2010

(S//REL USA, ISAF, NATO)

**Associated Personalities**

(U//FOUO)

**Other Names/Alias**

None

SECRET//NOFORN

BAGRAM / CENTCOM / 001548

Detainee Review Board Report of Findings and Recommendations – Final Board Result

v.22 Feb 2010

<u>Date of Board</u> 2 JUN 10	<u>Detainee Name</u> Abdullah Bari S/O	(b)(6), (b)(1)1.4a, (b)(1)1.4c	<u>Detainee ISN</u> 4191
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STEP 1 (FINDINGS): By a preponderance of the information presented, as a member of the Detainee Review Board (DRB), I find that:

The detainee DOES NOT MEET THE CRITERIA for internment and will be released. *Stop here and sign at the bottom.*

OR

The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who planned, authorized, committed, or aided the terrorist attacks that occurred on September 11, 2001, and persons who harbored those responsible for those attacks; *(Continue to Step 2)* OR

The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who was part of, or substantially supported, Taliban or al-Qaida forces or associated forces that are engaged in hostilities against the United States or its coalition partners, including any person who has committed a belligerent act, or has directly supported hostilities, in aid of such enemy armed forces. *(Continue to Step 2)*

STEP 2 (THREAT ASSESSMENT RECOMMENDATION): After taking into account the detainee's potential for rehabilitation, reconciliation, and eventual reintegration into society, by a preponderance of the information, I find that continued internment:

IS NOT NECESSARY to mitigate the threat the detainee poses; *(Go to Step 3A)*

OR

IS NECESSARY to mitigate the threat the detainee poses (\* the detainee will remain at the Detention Facility in Parwan (DFIP) to ensure detention required to mitigate his threat) *(Go to Step 3B)*

Explain the facts presented at the DRB which led to your recommendation/  
(Mandatory regardless of which threat assessment is made):

No reporting. Strong evidence that this is a mis taken identical case (similar name to a From (b)(1)1.4a, (b)(1)1.4c D. Passed polygraph  
Release immediately.

Please indicate appropriate threat level regardless of which recommendation is made in STEP 2

- 1 - Minimal threat to our current interests and systems
- 2 - Minimal threat to our current interests
- 3 - Minimal threat to our current interests
- 4 - Minimal threat to our current interests
- 5 - Minimal threat to our current interests
- 6 - Minimal threat to our current interests
- 7 - Minimal threat to our current interests
- 8 - Minimal threat to our current interests

STEP 3A: If your Recommendation in STEP 2 is that continued internment is not necessary to mitigate the threat the Detainee poses, then make one of the following recommendations: *In light of the findings listed above, I recommend that the detainee be (PICK ONLY 1):*

- Released without conditions; or
- Transferred to Afghan authorities for their consideration of criminal prosecution.
- Transferred to Afghan authorities for participation in a reconciliation or reintegration program.
- (For non-Afghan and non-U.S. third-country national): Transferred to a third country for: criminal prosecution // participation in a reconciliation program // or release. (circle one)

STEP 3B: If your Recommendation in STEP 2 is that continued internment is necessary to mitigate the threat the Detainee poses, make the following further recommendation, and then Go to Step 4.

While the Detainee remains interned at the DFIP, he (SHOULD) / SHOULD NOT *(circle one)* be considered for Reintegration programs within the DFIP.

STEP 4:  The Detainee IS or IS NOT an Enduring Security Threat *(circle one)*.

DRB President (Printed)

(b)(3), (b)(6)

DRB President (Signature)

**Detainee Review Board Report of Findings and Recommendations**

v. 5 Feb 2010

<u>Date of Board</u> 2 JUN 10	<u>Detainee Name</u> ABDULLAH BARI	<u>Detainee ISN</u> 4191
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**STEP 1 (FINDINGS):** By a preponderance of the information presented, as a member of the Detainee Review Board (DRB), I find that:

The detainee DOES NOT MEET THE CRITERIA for internment and will be released. *Stop here and sign at the bottom.*

OR

The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who planned, authorized, committed, or aided the terrorist attacks that occurred on September 11, 2001, and persons who harbored those responsible for those attacks; *(Continue to Step 2)*

OR  
The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who was part of, or substantially supported, Taliban or al-Qaida forces or associated forces that are engaged in hostilities against the United States or its coalition partners, including any person who has committed a belligerent act, or has directly supported hostilities, in aid of such enemy armed forces. *(Continue to Step 2)*

**STEP 2 (THREAT ASSESSMENT RECOMMENDATION):** After taking into account the detainee's potential for rehabilitation, reconciliation, and eventual reintegration into society, by a preponderance of the information, I find that continued internment:

IS NOT NECESSARY to mitigate the threat the detainee poses; *(Go to Step 3A)*

OR

IS NECESSARY to mitigate the threat the detainee poses (\* the detainee will remain at the Detention Facility in Parwan (DFIP) to ensure detention required to mitigate his threat) *(Go to Step 3B)*

Please circle the appropriate threat level regardless of which recommendation is made in STEP 2.

- 5- Strategic threat to American and Coalition Forces and Civilians
- 4- National threat to American and Coalition Forces
- 3- Regional threat to CIA's forces or authority
- 2- Provincial threat to CIA's forces or authority
- 1- Threat to local village authorities
- 0- Not a threat to the village or beyond

Explain the facts presented at the DRB which led to your recommendation/  
(Mandatory regardless of which threat assessment is made):

- NO EVIDENCE  
- RELEASE IMMEDIATELY

**STEP 3A:** If your Recommendation in STEP 2 is that continued internment is not necessary to mitigate the threat the Detainee poses, then make one of the following recommendations: In light of the findings listed above, I recommend that the detainee be:

- Released without conditions; or
- Transferred to Afghan authorities for their consideration of criminal prosecution.
- Transferred to Afghan authorities for participation in a reconciliation or reintegration program.
- (For non-Afghan and non-U.S. third-country national):* Transferred to a third country for: criminal prosecution // participation in a reconciliation program // or release. *(circle one)*

**STEP 3B:** If your Recommendation in STEP 2 is that continued internment is necessary to mitigate the threat the Detainee poses, make the following further recommendation, and then Go to Step 4.

While the Detainee remains interned at the DFIP, he SHOULD / SHOULD NOT *(circle one)* be considered for Reintegration programs within the DFIP.

**STEP 4: "Enduring Security Threat" Assessment** — \* Prior to completing your Enduring Security Threat Assessment, go to page 2 of this form and complete the EST Worksheet, paying particular attention to the *criteria and definitions*.

The Detainee IS or IS NOT an Enduring Security Threat *(circle one)*.

(b)(3), (b)(6)

Page 10 redacted for the following reason:

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(b)(1)1.4a, (b)(1)1.4c



**Detainee Review Board Report of Findings and Recommendations**

v. 5 Feb 2010

Date of Board <i>2 June 10</i>	Detainee Name <i>Abdullah, Basil</i>	Detainee ISN (b)(1)1.4a, (b)(1)1.4c <i>4604 (b)(1)1.4a, (b)(1)1.4c</i>
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**STEP 1 (FINDINGS):** By a preponderance of the information presented, as a member of the Detainee Review Board (DRB), I find that:

The detainee DOES NOT MEET THE CRITERIA for internment and will be released. *Stop here and sign at the bottom.*

OR

The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who planned, authorized, committed, or aided the terrorist attacks that occurred on September 11, 2001, and persons who harbored those responsible for those attacks; *(Continue to Step 2)*

The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who was part of, or substantially supported, Taliban or al-Qaida forces or associated forces that are engaged in hostilities against the United States or its coalition partners, including any person who has committed a belligerent act, or has directly supported hostilities, in aid of such enemy armed forces. *(Continue to Step 2)*

**STEP 2 (THREAT ASSESSMENT RECOMMENDATION):** After taking into account the detainee's potential for rehabilitation, reconciliation, and eventual reintegration into society, by a preponderance of the information, I find that continued internment:

IS NOT NECESSARY to mitigate the threat the detainee poses; *(Go to Step 3A)*

OR

IS NECESSARY to mitigate the threat the detainee poses (\* the detainee will remain in the Detention Facility in Parwan (DFIP) to ensure detention required to mitigate his threat). *(Go to Step 3B)*

Please circle the appropriate threat level regardless of which recommendation is made in STEP 2

- 5- Strategic threat to American and Coalition Forces and Civilians
- 4- National threat to American and Coalition Forces
- 3- Regional threat to GIRoA forces or authority
- 2- Provincial threat to GIRoA forces or authority
- 1- Threat to local village authorities
- 0- Is not a threat to his village or beyond

**Explain the facts presented at the DRB which led to your recommendation/ (Mandatory regardless of which threat assessment is made):**

*No reporting in this case*  
*No evidence; release immediately*

**STEP 3A:** If your Recommendation in STEP 2 is that continued internment is not necessary to mitigate the threat the Detainee poses, then make one of the following recommendations: In light of the findings listed above, I recommend that the detainee be:

- Released without conditions; or
- Transferred to Afghan authorities for their consideration of criminal prosecution.
- Transferred to Afghan authorities for participation in a reconciliation or reintegration program.
- (For non-Afghan and non-U.S. third-country national): Transferred to a third country for: criminal prosecution // participation in a reconciliation program // or release. *(circle one)*

**STEP 3B:** If your Recommendation in STEP 2 is that continued internment is necessary to mitigate the threat the Detainee poses, make the following further recommendation, and then Go to Step 4.

While the Detainee remains interned at the DFIP, he SHOULD / SHOULD NOT *(circle one)* be considered for Reintegration programs within the DFIP.

**STEP 4: "Enduring Security Threat" Assessment** — \* Prior to completing your Enduring Security Threat Assessment, go to page 7 of this form and complete the EST Worksheet, paying particular attention to the *criteria and definitions*.

The Detainee IS or IS NOT an Enduring Security Threat *(circle one)*.

DRB Member (Printed) \_\_\_\_\_  
DRB Member Signature \_\_\_\_\_  

(b)(3), (b)(6)

Page 12 redacted for the following reason:

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(b)(1)1.4a, (b)(1)1.4c

**Detainee Review Board Report of Findings and Recommendations**

v. 5 Feb 2010

Date of Board 6-02-10	Detainee Name Abdullah Bari	Detainee ISN (b)(1)1.4a, (b)(1)40024 (b)(1)4a, (b)(1)1.4c
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**STEP 1 (FINDINGS):** By a preponderance of the information presented, as a member of the Detainee Review Board (DRB), I find that:

The detainee DOES NOT MEET THE CRITERIA for internment and will be released. *Stop here and sign at the bottom.*

OR

The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who planned, authorized, committed, or aided the terrorist attacks that occurred on September 11, 2001, and persons who harbored those responsible for those attacks; *(Continue to Step 2)*

The detainee listed above MEETS CRITERIA FOR INTERNMENT because he is a person who was part of, or substantially supported, Taliban or al-Qaida forces or associated forces that are engaged in hostilities against the United States or its coalition partners, including any person who has committed a belligerent act, or has directly supported hostilities, in aid of such enemy armed forces. *(Continue to Step 2)*

**STEP 2 (THREAT ASSESSMENT RECOMMENDATION):** After taking into account the detainee's potential for rehabilitation, reconciliation, and eventual reintegration into society, by a preponderance of the information, I find that continued internment:

IS NOT NECESSARY to mitigate the threat the detainee poses; *(Go to Step 3A)*

OR

IS NECESSARY to mitigate the threat the detainee poses (\* the detainee will remain at the Detention Facility in Parwan (DFIP) to ensure detention required to mitigate his threat) *(Go to Step 3B)*

Explain the facts presented at the DRB which led to your recommendation/

*(Mandatory regardless of which threat assessment is made):*

no substantial evidence of any type  
As Cellery  
passed polygraph

Please circle the appropriate threat level regardless of which recommendation is made in STEP 2

5- Strategic threat to American and Coalition Forces and Civilians

4- National threat to American and Coalition Forces

3- Regional threat to GI/CoA forces or authority

2- Provincial threat to GI/CoA forces or authority

1- Threat to local village authorities

0- is not a threat to his village or beyond

**STEP 3A:** If your Recommendation in STEP 2 is that continued internment is not necessary to mitigate the threat the Detainee poses, then make one of the following recommendations: In light of the findings listed above, I recommend that the detainee be:

Released without conditions; or

Transferred to Afghan authorities for their consideration of criminal prosecution.

Transferred to Afghan authorities for participation in a reconciliation or reintegration program.

*(For non-Afghan and non-U.S. third-country national):* Transferred to a third country for: criminal prosecution // participation in a reconciliation program // or release. *(circle one)*

**STEP 3B:** If your Recommendation in STEP 2 is that continued internment is necessary to mitigate the threat the Detainee poses, make the following further recommendation, and then Go to Step 4.

While the Detainee remains interned at the DFIP, he SHOULD / SHOULD NOT *(circle one)* be considered for Reintegration programs within the DFIP.

**STEP 4: "Enduring Security Threat" Assessment** --- \* Prior to completing your Enduring Security Threat Assessment, go to page 2 of this form and complete the EST Worksheet, paying particular attention to the *criteria and definitions*.

The Detainee IS or IS NOT an Enduring Security Threat *(circle one)*.

DRB Member (Printed)

(b)(3), (b)(6)

DRB Member Signature

Page 14 redacted for the following reason:

-----

(b)(1)1.4a, (b)(1)1.4c

~~SECRET // REL TO USA, ISAF, NATO~~

1 (U//FOUO) [ISN (b)(1) 4191] Abdullah Bari, entered the  
 2 boardroom, took his seat in front of the board members, and the  
 3 unclassified hearing was called to order at 1347, 2 June 2010.]  
 4

5 (U) Persons Present:

6 (U) COLONEL [REDACTED] (b)(3), (b)(6), PRESIDENT OF THE BOARD;

7 (U) MAJOR [REDACTED] (b)(3), (b)(6), MEMBER ONE;

8 (U) MAJOR [REDACTED] (b)(3), (b)(6), MEMBER TWO;

9 (U) CAPTAIN [REDACTED] (b)(3), (b)(6), DETAINEE REVIEW BOARD  
 10 RECORDER TWO;

11 (U) MAJOR [REDACTED] (b)(3), (b)(6), PERSONAL REPRESENTATIVE  
 12 FOUR;

13 (U) MAJOR [REDACTED] (b)(3), (b)(6), LEGAL REPRESENTATIVE; and

14 (U) SERGEANT AMBER ARAZI, PARALEGAL.

15 (U) [The recorder was previously sworn.]

16 (U) The detainee was advised by the president of how this board  
 17 was not a criminal trial and how this board was to determine  
 18 whether or not he met the criteria for further internment.

19 (U) The president also notified the detainee that he may be  
 20 present at all open sessions of the board permitting that he  
 21 acted appropriately. ISN 4191 was also advised that he could  
 22 testify under oath or unsworn if he wished to do so, that he had  
 23 a personal representative who was present at the hearing, that  
 24 he may present information at the hearing including the  
 25 testimony of witnesses, and that he can examine documents  
 26 presented to the board all of which the detainee understood.

27 (U) Further, ISN 4191 was instructed that, at the conclusion of  
 28 the board after the legal review, the board would determine  
 29 whether he met the criteria for further internment at the  
 30 Detention Facility in Parwan. The detainee understood the fact

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1 that if he does not meet the criteria, he would be released as  
2 soon as possible. However, if he did meet the criteria, then he  
3 would be recommended for further internment, transferred to  
4 Afghan authorities, or released without conditions.

5  
6 (U) Captain (b)(3), (b)(6) presented the following unclassified  
7 information to the board:

8  
9 (U//~~FOUO~~) ISN 4191, Abdullah Bari was captured during an  
10 operation designed to rid the Sherwan Village, Bala Boluk  
11 District of Taliban fighters. Prior to the operation,  
12 women, children and innocent men were told to clear the  
13 area. Abdullah Bari remained. He claimed to be visiting  
14 the area.

15  
16 (U//~~FOUO~~) At the time of capture he was seen hiding his  
17 Identification card and discarded his weapon.

18  
19 (U//~~FOUO~~) Detainee took a polygraph and no deception was  
20 indicated when asked about involvement with the Taliban or  
21 attacks on Coalition Forces.

22  
23 (U//~~FOUO~~) The detainee is assessed to be a Taliban fighter  
24 operating in the Bala Boluk District.

25  
26 (U//~~FOUO~~) He meets Internment criteria if he was part of, or  
27 substantially supported Taliban forces or associated forces  
28 that were engaged in hostiles against the United States or  
29 is coalition partners, including any person who has  
30 committed a belligerent act, or has directly supported  
31 hostilities, in aid of such enemy armed forces.

32  
33 (U) The detainee, ISN 4191, made the following statements to the  
34 board:

35  
36 (U//~~FOUO~~) I appreciate this opportunity. I always welcome  
37 Coalition Forces, and am always glad to see them. I came  
38 to the village to visit (b)(6) who owed me money, but  
39 he was not there. I met with his brother instead. I am  
40 not with the Taliban, because most of my relatives are

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1 working with the government. There is no reason for me to  
2 be with the Taliban.

3  
4 (U//~~FOUO~~) I recognize and know that the Coalition Forces  
5 help and do a lot for the country and for the people. I  
6 expect that they will continue to help. I promise help the  
7 Coalition Forces. I will not take even one step against  
8 the Americans or Coalition Forces. I know what the  
9 Americans are doing for this country.

10  
11 (U//~~FOUO~~) I am worried about my children; therefore, I  
12 would like to ask to be released. I want to leave here and  
13 take care of my children and my family. If there is any  
14 proof that I deserve punishment, I will take any  
15 punishment. I would like to help the American people.  
16 While I was detained here, the treatment has been good.

17  
18 (U//~~FOUO~~) The Coalition Forces showed me a card and asked  
19 if it belonged to me, but it wasn't mine. It was a  
20 Pakistani ID. If you look at the picture you will see  
21 right away that it is not me.

22  
23 (U) DETAINEE TESTIMONY

24  
25 (U//~~FOUO~~) Abdullah Bar (b)(1.4a, (b)(1) 0041914 (b)(1) was called for the  
26 board and testified, in substance, as follows:

27  
28 (U) DIRECT EXAMINATION

29  
30 (U) Captain (b)(3), (b)(6) asked, in substance, the following questions:

31  
32 (U//~~FOUO~~) I live in Laman village, Ghulistan district,  
33 Farah province. It is about two to three hour walking  
34 distance from there to Sherwan. The day I was detained I  
35 walked to Kurah, from there I took a bus to see Abu Khaliq  
36 [Name] so that I could collect my money. So I stayed with  
37 his brother. It was dinner time when the Coalition Forces  
38 came and I was captured. I didn't have a weapon with me.  
39 I did hear the warning that Coalition Forces were coming,  
40 but they had nothing to do with me.

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1 (U//~~FOUO~~) I handed my personal identification card to the  
2 forces. I have gone by Abdul Bari. In the country they  
3 call me Abdullah Bari.

4  
5 (U) CROSS-EXAMINATION

6  
7 (U) Major ~~(b)(3), (b)(6)~~ asked, in substance, the following questions:

8  
9 (U//~~FOUO~~) ~~(b)(6), (b)(1)1.4a, (b)(1)1.4c~~ owned me 800 Afgani, for 8 chickens.  
10 I was captured in the late evening around nine or ten  
11 o'clock. ~~\_\_\_\_\_~~ said not to run from the area.  
12 There was some yelling and shouting, and he couldn't tell  
13 exactly what they were saying. When I was captured I was  
14 walking toward the ~~(b)(1)1.4a, (b)(1)1.4c~~. I had been in the  
15 village for around three hours before I was captured.

16  
17 (U//~~FOUO~~) I don't know anyone else in that village and they  
18 don't know me.

19  
20 (U) Personal Representative provided the board with petitions  
21 for release written on detainees' behalf.

22  
23 (U) EXAMINATION BY THE BOARD

24  
25 (U) Member 1 asked, in substance, the following questions:

26  
27 (U//~~FOUO~~) I do many things. I take care of my land, I grow  
28 corn and sometimes I go to town and buy and sell chickens.  
29 I own about 5 acres of land.

30  
31 (U) Member 2 asked, in substance, the following questions:

32  
33 (U//~~FOUO~~) I was born in my village, and I have never lived  
34 in Pakistan.

35  
36 (U) The recorder did offer unclassified exhibits.

37  
38 (U) The personal representative did offer unclassified exhibits.

39  
40 (U) The recorder had no further unclassified information to  
41 offer the board and, per the recorders request, the president

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1 granted a closed hearing at the culmination of the unclassified  
2 hearing.

3

4 (U) The president announced the conclusion of the unclassified  
5 hearing.

6

7 (U) The president of the board instructed the detainee that he  
8 would be notified of the board's decision within a couple of  
9 weeks and that he would be released if the decision is made that  
10 further internment would not be required. However, if the board  
11 decided that further internment is required, he would be  
12 retained at the Detention Facility in Parwan, transferred to  
13 Afghan authorities for participation in a reconciliation  
14 program, or released transferred to his national country for  
15 participation in a reconciliation program. Furthermore, if  
16 continued internment was recommended, then an additional  
17 Detainee Review Board would be reconvened in 6 months.

18

19 (U) The detainee made the following statement:

20

21 (U//FOUO) I have been here three months, I have done  
22 nothing wrong against the government.

23

24 (U) [The unclassified hearing adjourned at 1417, 2 June 2010.]

25

26 (U) [The detainee withdrew from the boardroom.]

27

28 (U) [The classified hearing was called to order at 1417, 2 June  
29 2010.]

30

31 (U) Captain (b)(3), (b)(6) presented the following information to the  
32 board:

33

34 (~~S//REL TO USA, ISAF, NATO~~) This detainee was detained  
35 during (b)(1)1.4a, (b)(1)1.4c There is no reporting in  
36 this case. So there isn't much information. He was  
37 detained on site. He was assessed as a target Abdul Bari,  
38 who lived in the village. My research shows that he is not  
39 the target Abdul Bari. He doesn't match the description of  
40 the Abdul Bari. They are still receiving reporting on that  
41 target. So, it doesn't appear that this detainee is that

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1 target. He did give some information about Opium during  
2 his polygraph. He passed a polygraph. They said he was  
3 trying to hide an ID. There are some sworn statements from  
4 people identifying him as a Taliban fighter. There were  
5 several people in a group and some gave statement that they  
6 over heard someone saying they caught a Taliban fighter.  
7

8 (U) Major ~~(b)(3), (b)(6)~~ presented the following information to the  
9 board:

10  
11 ~~(S//REL TO USA, ISAF, NATO)~~

~~(b)(1)1.4a, (b)(1)1.4c~~

~~(b)(1)1.4a, (b)(1)1.4c~~

12  
13  
14  
15 (U) The recorder did offer classified exhibits.

16  
17 (U) The personal representative did not offer classified  
18 exhibits.

19  
20 (U) The president and members of the board voted on ISN 4191.  
21 The votes were then collected and handed to the legal  
22 representative.

23  
24 (U) [The classified session adjourned at 1423, 2 June 2010.]

25  
26 (U) [The detainee review board adjourned at 1423, 2 June 2010.]  
27

28 [END OF PAGE]

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## STAFF SUMMARY ROUTING SHEET

### JTF 435/DCDO USFOR-A



**SUBJECT:** Status recommendation for ISN 4191 to be released from the Detention Facility In Parwan (DFIP).

**DATE:** 7 June 2010

**PROBLEM OR REASON FOR ACTION:** To obtain DC JTF 435 approval or disapproval to change or validate the status of ISN 4191 to be released without conditions from the DFIP.

**ACTION OFFICER NAME/SECTION/PHONE NUMBER:**  
 CAPT (b)(3), (b)(6) Director Legal Operations  
 DSN (b)(2)

**Office Primarily Responsible (OPR):** JTF 435 Dir Legal  
**Office Supporting Response (OSR):**

#### COORDINATION

TO	ACTION	SIGNATURE (SURNAME), GRADE AND DATE	TO	ACTION	SIGNATURE (SURNAME), GRADE AND DATE
1 DRB President	Review/ Sign	(b)(3), (b)(6) <i>ISN D</i>	6 DC JTF 435	Sign	
2 DRB Recorder	Review	<i>PT, JA 9 Jun 10</i>	7		
4 DRB Legal Advisor	Review/ Sign	<i>May</i> (b)(3), (b)(6)	9		
5 JTF 435 Director Legal Operations	Review		10		

*Weak evidence - passed polygraph - DMMC. release. (b)(3), (b)(6)*

UNCLASSIFIED WHEN SEPARATED FROM ATTACHMENTS

SCJS TRACKING NUMBER

DATE Logged

BAGRAM / CENTCOM /001562

# Exhibit AC

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Attorneys for Defendant HHS

13 UNITED STATES DISTRICT COURT  
14 NORTHERN DISTRICT OF CALIFORNIA  
15 SAN FRANCISCO DIVISION

16 HERSH & HERSH, )  
17 )  
18 Plaintiff, )  
19 v. )  
20 UNITED STATES DEPARTMENT OF )  
HEALTH AND HUMAN SERVICES, et al., )  
21 Defendant, )  
22 and )  
23 GUIDANT CORPORATION, )  
24 Intervenor. )

CASE NO.: C 06-4234 PJH  
**JOINT MOTION FOR SUMMARY  
JUDGMENT BY DEFENDANTS  
DEPARTMENT OF HEALTH AND  
HUMAN SERVICES AND  
INTERVENOR GUIDANT  
CORPORATION**

Date: December 19, 2007  
Time: 9:00 a.m.  
Judge: Hon. Phyllis J. Hamilton

Courtroom #3, 17<sup>th</sup> Floor

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26

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28



**NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT**

NOTICE IS HEREBY GIVEN that, on December 19, 2007 at 9:00 a.m., or as soon thereafter as the matter may be heard before the Honorable Phyllis J. Hamilton of the United States District Court for the Northern District of California, Courtroom 3, 17<sup>th</sup> Floor, 450 Golden Gate Avenue, San Francisco, CA, Defendants U.S. Department of Health and Human Services (“HHS”) and Guidant Corporation (“Guidant”) will, and hereby do, move the Court for an order granting summary judgment to Defendants.

Defendants move for summary judgment in this action because HHS performed a thorough search for records responsive to Plaintiff’s request under the Freedom of Information Act, 5 U.S.C. § 552 (2007) (“FOIA”), and has produced a thorough Vaughn Index (*see Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973)) in support of the Agency’s proper withholding and redaction of documents exempt from disclosure under FOIA, pursuant to exemptions b(4) and b(6). Defendants’ Motion for Summary Judgment is based on this Notice of Motion and Motion; the Memorandum of Points and Authorities; the accompanying declarations of Robert Eckert, Darolyn Hamada, Sara Winslow, and Michele Chin-Purcell; all pleadings and papers filed herein; and such additional evidence and oral argument that the Court may consider and other matters properly before the Court.

**RELIEF REQUESTED**

Defendants seek summary judgment in their favor. Defendants further request that the Court order Plaintiff to return the entire first production of documents, which the Agency provided on March 31, 2006 and February 27, 2006, respectively, and which mistakenly contained documents exempt from disclosure under FOIA.

**STATEMENT OF ISSUES**

1. Whether Defendants are entitled to summary judgment; specifically, whether HHS performed an adequate search for documents responsive to Plaintiff’s FOIA request, and whether the Vaughn Index is adequate to support HHS’s withholding and redaction of documents pursuant to FOIA exemptions b(4) and b(6).

1           2.     Whether Plaintiff should be ordered to return the first production of documents,  
2 which mistakenly contained documents exempt from disclosure under FOIA.

3                                   **MEMORANDUM OF POINTS AND AUTHORITIES**

4   **INTRODUCTION**

5           When considering a motion for summary judgment in a FOIA matter, federal district  
6 courts give considerable deference to the declarations of the federal officers who processed the  
7 underlying FOIA request. As long as the declarations adequately describe the agency's efforts  
8 to identify responsive records, and the Vaughn Index sufficiently details the proper bases for  
9 withholding or redacting otherwise responsive records, summary judgment in the  
10 Government's favor is warranted. *See generally Oglesby v. United States Dep't of Army*, 920  
11 F.2d 57, 68 (D.C. Cir. 1990); *King v. Dept. of Justice*, 830 F.2d 210, 218-19 (D.C. Cir. 1987).

12           The documents at issue here are those of Guidant Corporation and its subsidiaries  
13 (collectively referred to for ease of reference as "Guidant"). Guidant's subsidiaries  
14 manufacture, research, develop and market advanced medical device technologies to assist  
15 patients with a variety of serious and often life-threatening diseases. Guidant and its  
16 subsidiaries operate in a highly regulated and fiercely competitive business environment;  
17 effective regulatory compliance is a key component to commercial success and competitiveness  
18 in the industry. As such, Guidant and its subsidiaries invest considerable resources to  
19 understand and meet the complex regulatory requirements applicable to these operations.

20           To this end, Guidant and its subsidiaries employ many individuals, including outside  
21 counsel and regulatory consultants, to ensure that the Company complies with applicable legal  
22 and regulatory requirements. Guidant and its subsidiaries expend substantial resources to  
23 develop detailed policies and procedures relating to compliance, compliance training, and  
24 internal monitoring and auditing practices and procedures. Given the competitive market in  
25 which they operate, as well as the significant ramifications for regulatory noncompliance,  
26 Guidant and its subsidiaries consider the materials related to its compliance program and the  
27 efficient operation of the Company to be highly proprietary and confidential commercial  
28 information. Public disclosure of this information would greatly advantage competitors, who

1 could simply appropriate Guidant's materials and avoid the cost and effort of developing their  
2 own compliance materials. This would cause significant competitive harm. Consequently,  
3 Guidant goes to great lengths to preserve the confidentiality of all materials relating to these  
4 policies and procedures.

5 In addition to Guidant's confidential commercial information, a relatively small number  
6 of the documents at issue here contain the personal identification information of certain  
7 Guidant employees and/or consultants. This information is not publicly available, and is not  
8 disclosed outside of the Company. Both categories of documents are exempt from public  
9 disclosure under FOIA.

10 In response to Plaintiff's FOIA request, HHS performed a diligent search for responsive  
11 records, as detailed in the accompanying Declaration of Robert Eckert. HHS properly withheld  
12 or redacted documents containing Guidant's confidential commercial information and personal  
13 private information, pursuant to FOIA exemptions b(4) and b(6), respectively. HHS has also  
14 provided a thorough Vaughn Index, documenting its rationale for every record withheld or  
15 redacted, as described in the accompanying Declaration of Michele Chin-Purcell. For these  
16 reasons, HHS and Guidant are entitled to summary judgment.

### 17 **FACTUAL BACKGROUND**

18 On September 19, 2005, Hersh & Hersh submitted a Freedom of Information Act  
19 ("FOIA") request to the United States Department of Health and Human Services ("HHS").  
20 Hersh & Hersh's request sought certain documents submitted to HHS by Guidant and its  
21 former subsidiary Endovascular Technologies, Inc. ("EVT") attendant to a Corporate Integrity  
22 Agreement ("CIA") between HHS and EVT. The request, attached as Exhibit 1 to the  
23 accompanying Declaration of Robert Eckert ("Eckert Decl."), sought the following documents:

- 24 • Any and all Implementation Reports submitted by Endovascular Technologies,  
25 Inc. ("EVT"), a wholly owned subsidiary of Guidant Corporation ("Guidant"),  
26 and/or Guidant pursuant to the Corporate Integrity Agreement ("CIA") between  
the OIG and EVT entered on June 30, 2003 as part of the plea and settlement  
agreement in the Ancure Endograft System case; and
- 27 • Any and all Annual Reports submitted by EVT and/or Guidant to the OIG  
28 pursuant to the CIA; and

- 1 • Any and all Data Monitoring Committee (“DMC”) Review Reports submitted to  
2 the OIG pursuant to the CIA; and
- 3 • Any and all Independent Review Organization (“IRO”) Reports submitted to the  
4 OIG pursuant to the CIA, including any and all Medical Device Reporting  
5 (“MDR”) Review Reports.

6 (Eckert Decl. Ex. 1; *See also* Compl. for Injunctive Relief (Dkt No. 1) ¶7.)

7 On March 31, 2006, HHS responded to the request by releasing to Hersh & Hersh 859  
8 pages of responsive documents, and withholding other documents or portions of documents as  
9 exempt from disclosure under FOIA exemptions b(4) and b(6). (Eckert Decl., Ex. 3.) The  
10 response expressly notified Hersh & Hersh that “[i]f you have reason to believe that any denied  
11 information should not be exempt from disclosure, you may appeal . . . to the Deputy Assistant  
12 Secretary for Public Affairs (Media), U.S. Department of Health and Human Services.” (*Id.* at  
13 1-2.)

14 Instead of initiating an administrative appeal as FOIA requires, and as unambiguously  
15 directed by HHS, Hersh & Hersh filed this lawsuit on July 7, 2006.

16 On February 27, 2007, HHS provided a second response to Hersh & Hersh’s FOIA  
17 request, enclosing 439 additional pages. (Eckert Decl., Ex. 4.) This second response explained  
18 that, based on FOIA exemptions (b)(4) and (b)(6), HHS withheld documents including  
19 “policies and procedural guidelines, training and procedural codes; audit dates; employees’  
20 names, email messages, home and work addresses and telephone numbers; and home telephone  
21 numbers of an employee’s reference.” (*Id.* at 1.)

22 On March 14, 2007, Guidant moved to intervene as a defendant. Guidant’s motion to  
23 intervene was accompanied by a proposed motion to dismiss the case on the grounds that  
24 Hersh & Hersh failed to exhaust administrative remedies. (Dkt. No. 15.)

25 On March 23, 2007, Hersh & Hersh commenced an administrative appeal of HHS’s  
26 replies to its FOIA request.

27 On March 29, 2007, this Court held a case management conference during which Hersh  
28 & Hersh and HHS agreed to stipulate to Guidant’s intervention. As a result, the Court ordered  
29 Guidant to formally file its motion to dismiss. (Dkt. No. 24.) Guidant’s motion to dismiss was

1 formally filed on April 4, 2007. (Dkt. No. 29.) The Court denied Guidant's motion on May 11,  
2 2007, reasoning that plaintiff had cured any procedural deficiencies by appealing HHS' second  
3 response. (Dkt. No. 42.)

4 On May 17, 2007, Hersh & Hersh propounded discovery requests on HHS and Guidant,  
5 seeking the very documents at issue in this case. The discovery requests also sought production  
6 of a Vaughn Index, though the Court had expressly stated that the Vaughn Index should  
7 accompany defendants' summary judgment motion. (*See Winslow Decl. in Support of HHS'*  
8 *Mot. for Relief from Premature Disc.*, filed June 20, 2007 (Dkt. No. 56).) HHS and Guidant  
9 objected to the discovery requests as premature and inappropriate, and on June 20, 2007, HHS  
10 filed a motion seeking relief from the discovery. (Dkt. No. 55.) Between July 3, 2007 and July  
11 20, 2007, Hersh & Hersh filed three separate motions seeking production of the documents  
12 withheld by HHS as subject to FOIA exemption as well as production of the Vaughn Index:  
13 (1) July 3, 2007 Motion to Compel Discovery Responses (Dkt. No. 65, withdrawn on July 6,  
14 2007); (2) July 18, 2007 Motion for an Order Requiring Complete Response to Plaintiff's  
15 Request and a Vaughn Index (Dkt. No. 80); and (3) July 20, 2007, Motion to Compel  
16 Responses to Discovery requests and for a Vaughn Index (Dkt. No. 84).

17 Plaintiff attached as exhibits to its motions, several Guidant documents that were  
18 exempt from FOIA but had been inadvertently produced by HHS. From the face of these  
19 documents, Hersh & Hersh had reason to know that they had been inadvertently produced.  
20 (*See, e.g., Haggas Decl. in Supp. of Pl's Mot. to Compel*, filed July 20, 2007 (Dkt. No. 86),  
21 Exhibits G-M.)

22 For instance, Exhibits G and H to the July 20, 2007 Haggas Declaration are copies of  
23 the same Guidant document. However, as produced, Exhibit G's pages are bates numbered and  
24 portions of text are redacted, while Exhibit H has no bates numbers and no redactions. In this  
25 circumstance, a reasonable person would have to conclude that, at the very least, Exhibit H was  
26 inadvertently produced. Hersh & Hersh had an ethical duty from the moment it reviewed these  
27 documents, to notify defendants of this inadvertent production. *See, e.g., State Compensation*  
28

1 *Ins. Fund v. WPS, Inc.*, 70 Cal. App. 4th 644, 656-57 (1999). Hersh and Hersh not only failed  
2 to do so, but purposefully submitted the documents into the public record.

3 Because of the Court's prior admonishment against additional motion practice, Guidant  
4 and HHS sought to resolve this issue extra-judicially. HHS and Guidant wrote to Hersh &  
5 Hersh requesting that the inadvertent production be returned and that Hersh & Hersh stipulate  
6 to sealing the exhibits already filed in the record. (See accompanying Declaration of Darolyn  
7 Hamada ("Hamada Decl."), Ex. 1 (July 24, 2007 Letter from Darolyn Hamada to Hersh &  
8 Hersh); Eckert Decl., Ex. 5 (July 30, 2007 Letter from Robert Eckert to Jeanette Haggas); and  
9 Hamada Decl., Ex. 2 (August 8, 2007 Letter from Darolyn Hamada to Hersh & Hersh).) On  
10 August 8, 2007, Hersh & Hersh responded by expressly refusing to return the inadvertently  
11 produced documents, citing a wholly unrelated Supreme Court opinion:

12 You have probably read *New York Times Co. v. U.S.* (also known as the Pentagon  
13 Papers case). There, the Supreme Court permitted the New York Times' publication of  
14 a leaked report on the internal planning and policy decisions within the U.S.  
government regarding the Vietnam War. Not even concerns of national security  
stopped the public dissemination of that report.

15 (Eckert Decl., Ex. 6, at 1.)

16 In its letter, Hersh & Hersh also argued, notwithstanding HHS' representation to the  
17 contrary, that the production was actually intentional:

18 Instead, we believe that HHS' production was intentional. Several documents are  
19 redacted, but are also followed by unredacted copies, which indicates HHS mistakenly  
withheld portions of information and meant to produce the entire document.

20 (*Id.*)

21 On July 26, 2007, the Court granted Guidant's Motion to Remand the matter to HHS for  
22 processing of Plaintiff's administrative appeal. (Dkt. No. 90.) Because of Hersh & Hersh's  
23 refusal to cooperate in the wake of HHS's inadvertent production, HHS did not have an  
24 accurate record of what it had produced to Hersh & Hersh in the first instance, and thus could  
25 not properly process the appeal. Accordingly, HHS requested that Hersh & Hersh return the  
26 entire production. (See Eckert Decl. ¶ 23 and Ex. 5 (July 30, 2007 Letter from Robert Eckert to  
27 Jeanette Haggas); accompanying Decl. of Sara Winslow ("Winslow Declaration"), Ex. 1  
28

1 (August 15, 2007 letter from Sara Winslow to Jeanette Haggas.) Once again, Plaintiff did not  
2 cooperate.

3 As a result, HHS was forced to re-process the entire FOIA request and to provide a  
4 revised release:

5 As noted in our July 30, 2007, letter, we learned after reviewing the attachments to your  
6 July 18, 2007, declaration that Guidant Corporation's documents were inadvertently  
7 released to Hersh and Hersh. In response to your appeal and as a result of this  
8 discovery, we are providing a revised release of the Guidant Corporation's records.

8 (Eckert Decl. Ex. 7 (August 23, 2007 letter from Christina Pearson to Jeanette Haggas).) In the  
9 administrative appeal, HHS re-reviewed approximately 4,563 pages of responsive Guidant  
10 records, released approximately 791 pages to Hersh & Hersh, withheld 3,772 pages in their  
11 entirety, and redacted portions of approximately 412 pages under exemption b(4), as well as  
12 portions of 18 pages under exemption b(6). (*Id.* at 1.) HHS' response clarified that "[t]his new  
13 release of pages replaces the pages previously provided to you on March 31, 2006, and  
14 February 27, 2007." (*Id.* at 2.) Finally, HHS implored Hersh & Hersh to "return all of the  
15 Guidant Corporation's records which were previously sent to you." (*Id.*)

16 Guidant sent a third letter to Hersh & Hersh on October 10, 2007, in advance of filing  
17 the instant motion, to again request that Hersh & Hersh return the inadvertently produced  
18 documents. (Hamada Decl., Ex. 3 (October 10, 2007 letter from Darolyn Hamada to Nancy  
19 Hersh, et al.)) Guidant and HHS have sent six letters informing Hersh & Hersh of the  
20 inadvertent production, and seeking its return. To date, Hersh & Hersh has not returned the  
21 initial production nor any of the identified inadvertently produced documents.

22 Consistent with FOIA's requirements, HHS submits herewith a Vaughn Index, detailing  
23 document-by-document the basis for withholding and redacting certain records otherwise  
24 responsive to Plaintiff's request. The Vaughn Index is attached as Exhibit 8 to the Eckert  
25 Declaration. Accordingly, Guidant and HHS jointly bring the present Motion for Summary  
26 Judgment.

27  
28

## DISCUSSION

**I. Legal Standard for Considering a Motion for Summary Judgment in FOIA Proceedings**

"Summary judgment is the procedural vehicle by which nearly all FOIA cases are resolved." *Nat'l Res. Def. Council v. Dep't of Def.*, 388 F. Supp. 2d 1086, 1094 (C.D. Cal. 2005) (quoting *Mace v. EEOC*, 37 F. Supp. 2d 1144, 1146 (E.D. Miss. 1999)). However, the well-known standard for summary judgment is not employed in FOIA cases as the underlying facts are rarely in dispute. *Minier v. CIA*, 88 F.3d 796, 800 (9th Cir. 1996). Rather, "[t]he real question before the Court...is the adequacy of the Vaughn Ind[ex]...and whether [it] support[s] withholding information under one of the FOIA exemptions." *Heeney v. FDA*, 1999 U.S. Dist. LEXIS 23365, \*13 n.7 (C.D. Cal., Mar. 11, 1999) (copy attached hereto as Exhibit 1). Because the plaintiff in a FOIA action will not have access to the underlying documents, district courts will frequently "rule on summary judgment in FOIA cases solely on the basis of government affidavits describing the documents sought." *Lion Raisins, Inc. v. U.S. Dep't of Agric.*, 354 F.3d 1072, 1082 (9th Cir. 2004).

As demonstrated below, HHS conducted a thorough search for records potentially responsive to Plaintiff's FOIA request. The Agency carefully processed Plaintiff's administrative appeal, and compiled a fulsome Vaughn Index, detailing its proper application of FOIA exemptions b(4) and b(6). Thus, the Court should grant this joint Motion for Summary Judgment, by upholding the Government's proper withholding and redaction of records exempt from disclosure under FOIA. Further, the Court should order Hersh & Hersh to return the documents that were produced inadvertently.

**II. HHS Performed a Thorough and Adequate Search For Responsive Documents**

In support of its Motion for Summary Judgment, the agency must establish that it has conducted a search reasonably calculated to uncover all responsive records. *See Oglesby*, 920 F.2d at 68. The issue is not whether any other potentially responsive records might exist, but rather whether the search for responsive records was reasonable. *Citizens Comm'n on Human Rights v. FDA*, 45 F.3d 1325, 1328 (9th Cir. 1995). The agency can establish the



1 reasonableness of its search via an affidavit detailing the scope and nature of the search.  
2 *Zemansky v. EPA*, 767 F.2d 569, 573 (9th Cir. 1985). Agency affidavits are given a  
3 presumption of good faith that withstands speculative claims about the existence of other  
4 documents. *Chamberlain v. United States Dep't of Justice*, 957 F. Supp. 292, 294 (D.D.C.  
5 1997). In the absence of countervailing evidence, or apparent inconsistency of proof, summary  
6 judgment in the Government's favor on this point is appropriate. *See Perry v. Block*, 684 F.2d  
7 121, 127 (D.C. Cir. 1982).

8 In the instant matter, HHS met its burden to perform an adequate search for responsive  
9 records. Based on the records sought by Hersh & Hersh, Plaintiff's FOIA request was  
10 forwarded from the Office of Inspector General ("OIG") to the Office of Counsel to the  
11 Inspector General (OCIG). The OCIG is the only office likely to contain the records in  
12 question. (Eckert Decl. at ¶ 12.)

13 The OCIG FOIA liaison reviewed the Agency's CIA database and identified one  
14 Implementation Report, two Annual Reports (2004 and 2005) and multiple Independent  
15 Review Organization ("IRO") Reports responsive to Plaintiff's request. (Eckert Decl. at ¶ 13.)  
16 As part of the search for responsive records, the FOIA liaison confirmed with the attorney  
17 monitoring the CIA on behalf of the Agency that no Data Monitoring Committee ("DMC")  
18 Review Reports had been submitted, and were not required, given that neither EVT nor  
19 Guidant manufactured the Ancure device or any "next generation device" since 2003. *Id.*

20 The FOIA liaison then searched the OCIG's "Compliance File Room," the location  
21 where OCIG maintains many of its active compliance case files, and located all three Reports  
22 responsive to the underlying request. *Id.* The liaison also contacted the attorney monitoring  
23 the CIA, and confirmed that she did not possess any responsive records in her office. *Id.* Thus,  
24 all locations reasonably likely to contain responsive records were searched, and all responsive  
25 records were forwarded to the HHS FOIA office for review, redaction and release to Hersh &  
26 Hersh. *Id.*

27 Because the records at issue were submitted by Guidant Corporation and HHS  
28 reasonably believed that Guidant's information could be considered exempt under exemption

1 b(4), the HHS FOIA office consulted with Guidant regarding release of the records. This  
2 consultation, which is known as “predisclosure notification,” was required by both Executive  
3 Order 12,600 and the HHS FOIA regulation at 45 C.F.R. § 5.65(d). (*See* Eckert Decl. ¶ 15.)

4 Prior to releasing the responsive records to Hersh & Hersh, each document was  
5 reviewed by Robert Eckert, the HHS FOIA officer. (Eckert Decl. ¶ 21.) Mr. Eckert verified  
6 that all reasonably segregable non-exempt information was to be provided to the plaintiff, and  
7 that documents withheld in their entirety contained no reasonably segregable non-exempt  
8 portions. (*Id.*)

9 **III. HHS Properly Withheld and Redacted Records Containing Confidential**  
10 **Commercial or Financial Information Pursuant to FOIA Exemption b(4)**

11 FOIA exemption b(4) protects “trade secrets and commercial or financial information  
12 obtained from a person [that is] privileged or confidential.” 5 U.S.C. § 552(b)(4). The  
13 exemption encourages individuals and corporations to voluntarily furnish useful commercial or  
14 financial information to the Government, and it provides assurances to the submitter that the  
15 Government will protect his/her commercial interest in the information submitted. *See Sterling*  
16 *Drug v. FTC*, 450 F.2d 698, 709 (D.C. Cir. 1971) (citing FOIA legislative history). The  
17 exemption covers (1) trade secrets; and (2) information which is commercial or financial,  
18 obtained from a person, and privileged or confidential. *See GC Micro Corp. v. Defense*  
19 *Logistics Agency*, 33 F.3d 1109, 1112 (9th Cir. 1994); 45 C.F.R. § 5.65 (2007) (HHS regulation  
20 explaining exemption b(4)).

21 Records are commercial so long as the submitter has a “commercial interest” in them.  
22 *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983). A  
23 “commercial interest” is generally found when the records in question relate to business or  
24 trade. *See Public Citizen Health Research Group*, 704 F.2d at 1290; *Allnet Communications*  
25 *Servs., Inc. v. FCC*, 800 F. Supp. 984, 988 (D.D.C. 1992). Information is obtained “from a  
26 person” when the source is an individual or non-Governmental entity. *See Starkey v. U.S.*  
27 *DOL*, 238 F. Supp. 2d 1188, 1195 (S.D.C.A. 2002).

28

1           The information must also be confidential in nature. To determine whether  
2 information is confidential, the Ninth Circuit applies the balancing test described in *National*  
3 *Parks & Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974) (subsequent history  
4 omitted). In that case, the D.C. Circuit found that information is confidential if disclosure  
5 would either impair the Government's ability to obtain necessary information in the future, or  
6 cause substantial harm to the competitive position of the person from whom the information  
7 was obtained. *See GC Micro Corp.*, 33 F.3d at 1112-13 (quoting *National Parks*, 498 F.2d at  
8 770). Disclosure will be found to impair the Government's ability to obtain necessary  
9 information in the future in cases "where the Government has obligated itself in good faith not  
10 to disclose documents or information which it receives..." *See National Parks*, 498 F.2d at  
11 768 (quoting legislative history). As to the second *National Parks* factor, evidence of actual  
12 competition and a likelihood of substantial competitive injury constitute "substantial harm" to  
13 the submitter's competitive position. *See GC Micro Corp.*, 33 F.3d at 1113.

14           Although only one of the *National Parks* factors is necessary to establish the existence  
15 of "confidential information," both are implicated here. First, Hersh & Hersh is seeking  
16 documents attendant to an *agreement* negotiated between Guidant, EVT (a Guidant  
17 subsidiary) and HHS. Guidant entered into the agreement with the understanding that the  
18 Government would preserve the confidentiality of its information. (Chin-Purcell Decl. ¶ 16.)  
19 It is axiomatic that if HHS were to produce Guidant's confidential commercial information in  
20 response to a FOIA request, Guidant and other entities would be far less likely to negotiate  
21 similar agreements in the future. Second, public disclosure of the withheld and redacted  
22 records identified in the Vaughn Index would cause substantial and irreparable competitive  
23 harm to Guidant.

#### 24           **A. Reports Submitted to HHS Pursuant to the CIA**

25           Hersh & Hersh's FOIA request seeks documents submitted by Guidant and EVT to  
26 HHS pursuant to the CIA, namely Guidant's Implementation Report, Annual Reports, and  
27 Independent Review Organization ("IRO") Reports. The CIA was part of a settlement  
28 agreement between EVT and the United States relating to EVT's ANCURE Endograft System

1 for the treatment of abdominal aortic aneurysms. A copy of the CIA is attached as Exhibit 1  
2 to the Declaration of Michele Chin-Purcell. The CIA required EVT to implement, update  
3 and/or review its policies and procedures relating to compliance with relevant federal  
4 regulations, and to make regular status reports to HHS's Office of the Inspector General  
5 ("OIG"). (Chin-Purcell Decl. ¶ 4.) Guidant was not a party to the underlying settlement, but,  
6 as EVT's parent, agreed to enter into certain of the CIA's provisions. (*Id.*)

7 The Implementation Report was required by the CIA to summarize Guidant's and  
8 EVT's efforts to implement the requirements imposed by the CIA. (Chin-Purcell Decl. ¶ 14.)  
9 The Implementation Report was to include, among other things, information about the  
10 companies' Compliance Officer and Compliance Committee; copies of all relevant  
11 compliance policies, procedures and training materials; and the identity of the IRO selected to  
12 audit the companies' compliance programs. (*Id.*)

13 The Annual Reports are required by the CIA for the purpose of providing the status of  
14 the companies' compliance activities. These reports must contain information about the  
15 Compliance Officer and Committee; summaries of any changes to company compliance  
16 policies and procedures with copies of all such procedures; copies of all materials used to  
17 conduct the employee training required by the CIA; all IRO reports along with any responses  
18 or corrective action plans relating to issues raised by the IRO; summaries of "reportable  
19 events" and disclosures; and summaries of relevant government investigations or other legal  
20 proceedings. (Chin-Purcell Decl. ¶ 15.)

21 When Guidant submitted these reports to OIG, it expressly stated that the documents  
22 produced were confidential and subject to FOIA exemption:

23 Guidant considers information in this report and the attachments that are not otherwise  
24 public, to be confidential commercial information under applicable FOIA rules.  
25 Please contact Guidant prior to the release of any information submitted by Guidant or  
EVT pursuant to any FOIA or similar request.

26 (Chin-Purcell Decl. ¶ 16.) As detailed below, the Implementation Report and Annual  
27 Reports sought by Hersh & Hersh contain highly confidential commercial information  
28 relating to, among other things, (1) Guidant's policies and procedures; (2) training materials;

1 (3) IRO reports and related information; (4) reportable events; and (5) disclosure logs. (Chin-  
2 Purcell Decl at ¶ 17.)

3 **B. Guidant Policies and Procedures<sup>1</sup>**

4 The Implementation Report and Annual Reports are comprised in large part of  
5 Guidant’s new or updated corporate procedures and policies. Many of these procedures relate  
6 directly to compliance with regulatory requirements or with the CIA itself. Examples of such  
7 procedures include:

- 8 • Medical Device Reporting Criteria;
- 9 • Return Goods Criteria;
- 10 • Complaint Processing Procedures; and
- 11 • Complaint Handling Procedures.

12 (Chin-Purcell Decl. ¶ 18.)

13 Other documents subject to Plaintiff’s FOIA request contain Guidant procedures  
14 relating to product manufacturing. These include:

- 15 • CRM Production Process Validation;
- 16 • Handling of Non-Conforming Material or Product;
- 17 • Process Validation; and
- 18 • Design Controls.

19 (Chin-Purcell Decl. ¶ 19.)

20 Finally, certain procedures withheld from production relate to Guidant’s Corrective  
21 and Preventive Action (CAPA) program, and include procedures for:

- 22 • Supplier Evaluation and Corrective Action;
- 23 • Production and Process Control;

24  
25 <sup>1</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
26 represent Guidant’s Processes and Procedures: 2, 5 - 12, 16 - 17, 23 - 54, 69 - 91, 94 - 95, 103  
27 - 144, 148 - 168, 170 - 181, 186 - 215, 226 - 241.  
28

- 1 • Post Market Surveillance;
- 2 • Product Risk Management;
- 3 • Design Controls; and
- 4 • Design Validation.

5 (Chin-Purcell Decl. ¶ 20.)

6 The procedures listed above relate directly to compliance with the CIA or other  
7 regulatory requirements. For example, a majority of the procedures referenced delineate  
8 Guidant's process for complying with current Good Manufacturing Practice requirements set  
9 forth in FDA's Quality System regulations (21 C.F.R. § 820) and with Medical Device  
10 Reporting ("MDR") requirements (21 C.F.R. § 803). (Chin-Purcell Decl. ¶ 21.) The Quality  
11 System regulations require that domestic or foreign manufacturers have a quality system for  
12 the design, manufacture, packaging, labeling, storage, installation, and servicing of finished  
13 medical devices intended for commercial distribution in the United States in order to assure  
14 that medical devices are safe and effective for their intended use. (*Id.*) The Medical Device  
15 Reporting regulations require medical device manufacturers, importers and user facilities to  
16 timely report certain information about significant medical device adverse events to FDA.  
17 (*Id.*) Therefore, a medical device company's interpretation of the Quality System and Medical  
18 Device Reporting requirements and its methods for adhering to those requirements are critical  
19 to its overall function and success. (Chin-Purcell Decl. ¶ 22.)

20 Each of the policies and procedures listed above contains highly proprietary and  
21 confidential commercial information. As such, disclosure of these documents in response to a  
22 FOIA request would result in competitive harm to Guidant. (Chin-Purcell Decl. ¶ 23.)  
23 Guidant and its competitors in the medical device industry devote substantial resources to the  
24 development and implementation of compliance programs, and effective policies and  
25 procedures are a key component of such programs. Compliance policies are highly  
26 customized and are tailored to a company's specific business activities, organizational  
27 structure, and other needs. (Chin-Purcell Decl. ¶ 7.)

28

1           The relative effectiveness and efficiency of its compliance and training policies give  
2 Guidant an advantage over its competitors. Thus, the Company routinely reviews and updates  
3 its compliance policies to optimize effectiveness, reduce costs, improve quality, and achieve  
4 other important legal and business objectives. (Chin-Purcell Decl. ¶ 8.) Typically, Guidant's  
5 procedures describe the Company's interpretation of the regulation at issue, and provide a  
6 step-by-step guide for complying with the regulatory requirements within the framework of  
7 Guidant's unique business plan. (*See, e.g.*, Eckert Decl., Ex. 8 (Vaughn Index) entry 214.)  
8 The policies and procedures also often establish organizational structures and reporting  
9 relationships as part of the overall compliance program. This information would be of notable  
10 value to Guidant's competitors. (Chin-Purcell Decl. ¶ 9.)

11           Consequently, Guidant treats all of these policies and procedures as confidential and  
12 proprietary corporate information, and actively protects them from disclosure to competitors  
13 or the public. (Chin-Purcell Decl. ¶ 10.) Procedures are normally marked "Confidential," and  
14 are not posted on the Company's website. (This is also true for procedures marked  
15 "released," which means that the procedure received management approval and is ready for  
16 implementation; it does not mean that the procedure is non-confidential.) While the Company  
17 publicly discloses its Code of Business Conduct, it does not post or disclose any information  
18 about the actual procedures created to implement the Code or any other policies. (*Id.*)  
19 Guidant also does not publicly disclose the procedure number, format or substance of any of  
20 its procedures. Policies and procedures can be accessed by employees only through a  
21 password-protected intranet website. (Chin-Purcell Decl. ¶ 11.)

22           In addition to being commercially valuable, some of the procedures listed above also  
23 contain trade secrets, defined by HHS as "a secret, commercially valuable plan, formula,  
24 process or device that is used for the making, preparing, compounding, or processing of trade  
25 commodities and that can be said to be the end product of either innovation or substantial  
26 effort." 45 C.F.R. § 5.65(a); *see also, e.g., Heeney v. Garvey*, 200 F. Supp. 2d 1321, 1326 (D.  
27 Wyo. 2000) (protecting materials "[that] represent plans, formulae, processes and procedures  
28 which were used for the development, quality assurance, and manufacture" of an aircraft.).

1 (Chin-Purcell Decl. ¶ 12.) Due to the innovation and substantial effort involved in developing  
2 the procedures described above, many of Guidant’s processes and procedures also qualify for  
3 protection as trade secrets and should be exempt from disclosure. (*Id.*)

4 **C. Guidant’s Training Materials<sup>2</sup>**

5 The Annual Reports and Implementation Report submitted pursuant to the CIA,  
6 contain training materials used by Guidant to educate employees about the internal  
7 compliance policies and procedures described in the previous section. (Chin-Purcell Decl. ¶  
8 24.) These materials also consist of confidential commercial or financial information that  
9 would competitively harm Guidant if released. (*Id.*)

10 Guidant’s training materials are vital to ensuring company-wide compliance with  
11 important Company procedures. (Chin-Purcell Decl. ¶ 25.) As with the step-by-step  
12 processes detailed in a procedure, the training materials describe Guidant’s perspective on  
13 applicable regulations. These materials also reflect the business judgment of Guidant’s  
14 management, regulatory compliance department and legal counsel, and are often developed or  
15 reviewed by legal counsel or other consultants. (*Id.*) Training materials frequently are based  
16 on and summarize the Company’s compliance policies and procedures. (*Id.*) Effective  
17 compliance training materials allow Guidant to implement the key components of its  
18 compliance program in a cost-effective manner, resulting in competitive advantage to  
19 Guidant. Moreover, the materials reflect Guidant’s proprietary and confidential training  
20 methods and techniques, the disclosure of which would benefit its competitors. (Chin-Purcell  
21 Decl. ¶ 26.)

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22  
23  
24  
25 <sup>2</sup>The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
26 represent Guidant’s Training Materials: 2, 13, 23, 55 - 60, 69, 96 - 99, 145, 147, 169, 182 -  
27 185, 223, 225, 242, 244.  
28



1 Because of the business sensitive nature of these materials, Guidant takes steps to  
2 prevent disclosure of its training materials to the public. Guidant employees are instructed not  
3 to share these materials with anyone outside the Company. (*Id.*)

4 **D. Guidant’s IRO Information<sup>3</sup>, Reportable Events<sup>4</sup>, Certifications<sup>5</sup>,  
5 Disclosure Logs<sup>6</sup>, and Computer System for Product-Based Complaints<sup>7</sup>**

6 Under the CIA, Guidant was required to retain an independent auditor, known as an  
7 Independent Review Organization (“IRO”). The function of the IRO is to assess and evaluate  
8 EVT's program for compliance with Medical Device Reporting requirements in accordance  
9 with 21 C.F.R. 803. (Chin-Purcell Decl. ¶ 27.) Materials related to the IRO’s engagement are  
10 extremely sensitive and highly confidential to the Company. Therefore, all materials  
11 generated by, and relating to, the IRO are confidential commercial information. (Chin-Purcell  
12 Decl. ¶ 29.) The name of Guidant’s IRO itself is confidential. The engagement is not public  
13 information; Guidant does not release the name of its IRO, nor does the IRO disclose that  
14 Guidant is its client. (Chin-Purcell Decl. ¶ 30.)

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17 <sup>3</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
18 represent records relating to the IRO: 14 - 16, 61 - 64, 100.

19 <sup>4</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
20 represent records relating to Reportable Events: 2, 17, 19, 22, 23, 65.

21 <sup>5</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
22 represent records relating to Certifications: 20 - 21, 67 - 68, 101-102.

23 <sup>6</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
24 represent records relating to Disclosure Logs: 18, 66.

25 <sup>7</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
26 represent records relating to Guidant’s computer system for handling product-based  
27 complaints: 139, 148, 170, 186, 209, 216 – 222.

1 The IRO reports also contain highly confidential commercial information. (Chin-  
 2 Purcell Decl. ¶ 31.) Before generating a report, the IRO audits Guidant’s internal processes.  
 3 The IRO then issues a report which provides Guidant with an extensive analysis of the  
 4 strengths and weaknesses of these processes and procedures. (*Id.*) These reports are highly  
 5 valuable to Guidant because they permit the Company to evaluate its processes and  
 6 procedures and make adjustments to improve efficiency and ensure compliance. (Chin-  
 7 Purcell Decl. ¶ 28.) By the same token, disclosure of this information would be competitively  
 8 devastating to Guidant. These reports would serve as a guide to competitors in structuring  
 9 programs and policies to compete with Guidant. (*Id.*)

10 The CIA also requires Guidant to notify OIG of any Reportable Events. A  
 11 “Reportable Event” is defined by the CIA as “anything brought to the attention of senior  
 12 management at Guidant’s corporate headquarters that involves:”

- 13 (1) a matter that a reasonable person would consider a probable  
 14 violation of criminal, civil, or administrative laws for which  
 15 penalties or exclusion from any Federal health care program may  
 be authorized;
- 16 (2) an adverse event or complaint occurred that Guidant and/or  
 17 EVT was required to report as an MDR and Guidant and/or EVT  
 failed to report to the FDA this adverse event or complaint as  
 required pursuant to 21 U.S.C. § 360i, within 30 days.

18 (CIA at 18, attached as Exhibit 1 to Chin-Purcell Decl.) Guidant’s reportable events  
 19 submissions to OIG must include a complete description of the event, any corrective action  
 20 taken, and any plans to prevent the reoccurrence of the event. (Chin-Purcell Decl. ¶ 32.)

21 Materials disclosed to OIG relating to Reportable Events are highly confidential and  
 22 commercially sensitive. (Chin-Purcell Decl. ¶ 33.) Guidant’s internal investigations into  
 23 preliminary reports of adverse product events, and any corrective action taken, reflect  
 24 Guidant’s proprietary compliance policies and procedures. (*Id.*) Moreover, public disclosure  
 25 of such events prior to a government investigation or any determination of wrongdoing would  
 26 plainly be detrimental to Guidant’s commercial interests. (*Id.*)

27 Pursuant to the CIA, Guidant submitted to HHS reportable event summaries,  
 28 correspondence with OIG regarding governmental investigations, and disclosure logs

1 indexing correspondence regarding compliance efforts. (Chin-Purcell Decl. ¶ 34.) The  
2 Reportable Events summaries contain detailed information concerning product-related events.  
3 (See, e.g., Eckert Decl. Ex. 8 (Vaughn Index) entry 17.) Guidant provided this information to  
4 HHS with the understanding that the information would remain confidential. (*Id.*) These  
5 summaries often include the names of individuals, Company organizational structures, sales  
6 and marketing tactics, analysis of compliance with the CIA, and whether disciplinary action  
7 was taken and/or other personnel information. (*Id.*) As such, much of this information is also  
8 exempt from disclosure pursuant to exemption b(6), discussed *infra*.

9 Notices of governmental investigations and certifications by compliance officers are  
10 also highly confidential commercial information. (Chin-Purcell Decl. ¶ 35.) These  
11 communications to HHS contain details about Guidant personnel and Company activities that  
12 are not publicly disclosed. (See, e.g., Eckert Decl. Ex. 8 (Vaughn Index) entry 67.) Like the  
13 IRO Reports and Reportable Events, this information, if disclosed, would provide competitors  
14 with details of Guidant's corporate structure and its strengths and vulnerabilities. (Chin-  
15 Purcell Decl. ¶ 35.) Moreover, information about governmental investigations, if publicly  
16 disclosed, could have a detrimental effect on the Company's good will and, ultimately, its  
17 sales and revenues. (*Id.*)

18 Information available in compliance Disclosure Logs is also highly confidential  
19 commercial information. (Chin-Purcell Decl. ¶ 36.) These logs contain information reported  
20 to the EVT Compliance Officer related to any issues or questions associated with Company  
21 policies, conduct, practices or procedures, believed by the reporting individual to be a  
22 potential violation of law. The Disclosure Logs also include information about Company  
23 personnel, organization and practices. Pursuant to the CIA, the Disclosure Log is required to  
24 include a record and summary of each disclosure received, the status of the internal review of  
25 the issues, and any corrective action taken in response to the internal reviews. (CIA at 16; see  
26 also, e.g., Eckert Decl. Ex. 8 (Vaughn Index) entry 18; Chin-Purcell Decl. ¶ 37.) This  
27 information is actively shielded from disclosure by Guidant, and for good reason: disclosure  
28 would allow competitors to gain insight into Guidant's compliance and preventive action

1 procedures and programs. (Chin-Purcell Decl. ¶ 37.) Disclosure of this information would  
2 also discourage individuals from making thorough reports and would serve as a disincentive  
3 for industry to include detailed information in their disclosure logs. (*Id.*)

4 Finally, Guidant developed a computer system, which it specifically designed to  
5 handle product-based complaints. (Chin-Purcell Decl. at ¶ 38.) The system also warrants  
6 protection under exemption b(4) because it demonstrates how Guidant implements complaint-  
7 handling requirements. (*Id.*) The system is unique to Guidant, is Guidant’s intellectual  
8 property and was developed specifically for the Company. Therefore, it is highly  
9 confidential, and would cause competitive harm to Guidant, if disclosed. (*Id.*)

10 **E. Guidant’s Corporate Organization Information<sup>8</sup>**

11 The documents withheld under FOIA exemption (b)(4) also contain information about  
12 the restructuring of Guidant’s business organization pursuant to the CIA. While most  
13 information concerning Guidant’s organizational structure (including most organizational  
14 charts) is publicly available, information relating to the organizational structure of Guidant’s  
15 Compliance Committee is commercially sensitive and highly confidential. (Chin-Purcell  
16 Decl. ¶ 39.) Guidant and other companies in this industry are constantly striving to structure  
17 their organization to promote their business strategies. Certain elements of Guidant’s  
18 organizational structure reflect its business strategies and impact its operational efficiency.  
19 (Chin-Purcell Decl. ¶ 40.) Accordingly, this information reflecting Guidant’s strategic  
20 decisions would cause commercial harm to Guidant if disclosed. (*Id.*)

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<sup>8</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8) represent records relating to Guidant’s Corporate Organization Information: 2, 23, 69.

1 **IV. HHS Properly Withheld and Redacted Records Containing Information That, if**  
2 **Disclosed, Would Constitute an Invasion of Personal Privacy Pursuant to**  
3 **Exemption b(6)**

4 Exemption (b)6 of FOIA protects “personnel and medical files and similar files the  
5 disclosure of which would constitute a clearly unwarranted invasion of personal privacy.”  
6 5 U.S.C. § 552(b)(6); *see also* 45 C.F.R. § 5.67 (HHS regulation explaining exemption b(6)).

7 District courts construing exemption b(6) will “balanc[e] the harm to the individual  
8 whose privacy is breached against the public interest served by disclosure.” *Federal Labor*  
9 *Relations Auth. v. United States Dep’t of Treasury*, 884 F.2d 1446, 1451 (D.C. Cir. 1989).  
10 The Supreme Court elaborated on the application of this balancing test in *United States Dep’t*  
11 *of Justice v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749 (1989) (“*Reporters*  
12 *Committee*”). In that case, the Court applied a three-step test: “(i) identification and  
13 evaluation of the specific privacy interest implicated, (ii) identification and evaluation of the  
14 specific public interest implicated, and (iii) balancing of these two interests.” *Painting Indus.*  
15 *Mkt. Recovery Fund v. United States Dep’t of Air Force*, 751 F. Supp. 1410, 1416 (D. Haw.  
16 1990) (citing *Reporters Committee*, 489 U.S. at 762-71), *rev’d on other grounds*, 26 F.3d  
17 1479 (9th Cir. 1994).

18 There is a clear privacy interest in “the individual’s control of information concerning  
19 his or her person” (*Reporters Committee*, 489 U.S. at 763) and in keeping such information  
20 “not freely available to the public” (*id.* at 764, quoting *Webster’s Third New Int’l Dictionary*  
21 1804 (1976)). Courts have long recognized that private citizens have a privacy interest in  
22 their identities, home addresses, home telephone numbers, home fax numbers, Social Security  
23 Numbers, other personal identifying numbers, personal medical information, personal  
24 opinions, dates of birth, marital status, number of children, citizenship information, credit card

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25 <sup>9</sup> The following entries on the Vaughn Index (attached to Eckert Declaration as Exhibit 8)  
26 represent records containing personal information: 1 - 4, 13 - 14, 20 - 22, 64, 69, 92 - 94, 100  
27 - 102, 146, 169, 182 - 184, 224, 243.  
28

1 numbers, and individuals' sources of private, non-Government research income. *See, e.g.,*  
2 *Bibles v. Oregon Natural Desert Ass'n*, 519 U.S. 355, 355-56 (1997) (protecting names and  
3 home address of private citizens who received agency publication); *Sheet Metal Workers Int'l*  
4 *Ass'n v. United States Dep't of Veterans Affairs*, 135 F.3d 891, 903-05 (3d Cir. 1998)  
5 (protecting Social Security numbers); *Strout v. United States Parole Comm'n*, 40 F.3d 136,  
6 139 (6th Cir. 1994) (protecting identities of people who wrote to the Government);  
7 *McDonnell v. United States*, 4 F.3d 1227, 1259 (3d Cir. 1993) (protecting medical records);  
8 *Minnis v. United States Dep't of Agric.*, 737 F.2d 784, 787-88 (9th Cir. 1984) (protecting  
9 names and addresses of permit applicants); *Rural Hous. Alliance v. United States Dep't of*  
10 *Agric.*, 498 F.2d 73, 77 (D.C. Cir. 1974) (protecting marital status); *Physicians Comm. for*  
11 *Responsible Medicine v. Glickman*, 117 F. Supp. 2d 1, 6 (D.D.C. 2000) (finding privacy  
12 interest in individual's source of income); *Judicial Watch, Inc. v. United States Dep't of*  
13 *Commerce*, 83 F. Supp. 2d 105, 122 (D.D.C. 1999) (protecting date of birth); *Hill v.*  
14 *Department of Agric.*, 77 F. Supp. 2d 6, 8-9 (D.D.C. 1999) (protecting financial status);  
15 *Professional Review Org. of Fl., Inc. v. HHS*, 607 F. Supp. 423, 427 (D.D.C. 1985)  
16 (protecting professional credentials and other personal information contained in resumes of  
17 proposed professional staff of successful Government contract bidder); *Hemenway v. Hughes*,  
18 601 F. Supp. 1002, 1006 (D.D.C. 1985) (protecting citizenship data). The documents  
19 withheld by HHS pursuant to FOIA exemption (b)(6) plainly implicate these protected  
20 privacy interests.

21 On the other hand, there is no identifiable public interest to justify disclosure of this  
22 personal information. FOIA only recognizes a single public interest – the interest of the  
23 public in knowing “what their government is up to.” *See Painting Indus. of Haw. Mkt.*  
24 *Recovery Fund v. U.S. Dept. of Air Force*, 26 F.3d 1479, 1484 (9th Cir. 1994) (quoting  
25 *Reporter's Committee*, 489 U.S. at 772-73). The disclosure of personal information of  
26 Guidant personnel does not serve that public interest, and therefore must be withheld. (*See*  
27 *Chin-Purcell Decl.* ¶ 41.)

28

1 **V. The Court Should Order Hersh & Hersh to Return the Inadvertent Production**  
2 **of Documents**

3 The Court should Order Hersh & Hersh to return all copies of documents originally  
4 released to Plaintiff in two installments, on March 31, 2006 and February 27, 2007. As  
5 detailed in the Factual Background Section, *supra*, the first production contained an  
6 unspecified number of documents considered by Guidant and HHS to contain confidential  
7 commercial information, exempt from disclosure under FOIA.

8 Both Guidant and HHS attempted to work with Plaintiff to determine the full extent of  
9 the inadvertent production, but Hersh & Hersh refused to cooperate. Consequently, Hersh &  
10 Hersh has deprived the Agency and now the Court of the opportunity to even identify all of  
11 the inadvertently produced documents, much less consider whether they are subject to  
12 disclosure under FOIA. Therefore, even if the Court concludes that some of the documents  
13 described on the Vaughn Index do not contain information exempt from disclosure, it should  
14 still order return of the first production.

15  
16 **CONCLUSION**

17 For all the foregoing reasons, HHS and Guidant ask that the Court grant this Motion for  
18 Summary Judgment. HHS and Guidant further request that the Court order Hersh & Hersh to  
19 return the entire first production of documents, which the Agency provided on March 31, 2006  
20 and February 27, 2006, respectively, and which mistakenly contained documents exempt from  
21 disclosure under FOIA.

22 Respectfully submitted,  
23 Dated: October 23, 2007 SHOOK, HARDY & BACON L.L.P.

24  
25 By:           /s/ Darolyn Y. Hamada            
26           Darolyn Y. Hamada          

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# Exhibit AD

HERSHANDHERSH  
A Professional Corporation

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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
(SAN FRANCISCO DIVISION)**

HERSH & HERSH,	)	CASE NUMBER C 06-4234 PJH
	)	
Plaintiff,	)	<b>MEMORANDUM OF POINTS AND</b>
	)	<b>AUTHORITIES IN SUPPORT OF</b>
vs.	)	<b>PLAINTIFF'S OPPOSITION TO</b>
	)	<b>JOINT MOTION FOR SUMMARY</b>
UNITED STATES DEPARTMENT OF	)	<b>JUDGMENT BY DEFENDANTS</b>
HEALTH AND HUMAN SERVICES,	)	<b>DEPARTMENT OF HEALTH AND</b>
	)	<b>HUMAN SERVICES AND</b>
Defendant,	)	<b>INTERVENOR GUIDANT</b>
	)	<b>CORPORATION</b>
and	)	
	)	Date: December 19, 2007
GUIDANT CORPORATION,	)	Time: 9:00 a.m.
	)	Judge: Hon. Phyllis J. Hamilton
Intervenor.	)	

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A Professional Corporation

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## I. INTRODUCTION

Lawsuits arising under the Freedom Of Information Act (“FOIA”) are unique in that the plaintiff and the court are left to rely solely on the government’s representations that certain documents are exempted from disclosure. Indeed, HHS’ response to Plaintiff’s September 19, 2005, Request (“FOIA Request”) under FOIA indicates that its claims of exemption are unfounded: (1) withheld documents were attached to the moving papers here, (2) withheld documents have been publicly available on PACER since July 2007, (3) withheld “personnel information” is easily accessible on the internet, (4) policies (and their associated numbers) for implementing compliance with FDA regulations are not “trade secrets” under FOIA, and (5) the name and report of an independent review organization is not a “trade secret”.

12 Further, HHS failed to provide a sufficiently detailed agency affidavit or *Vaughn* Index to warrant summary judgment. Accordingly, summary judgment should be denied.<sup>1</sup> In addition, Plaintiff should be allowed discovery to investigate the egregious mishandling of its FOIA request, and further, Plaintiff is entitled to sanctions.

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## II. STATEMENT OF FACTS

18 Guidant’s wholly-owned subsidiary, Endovascular Technologies, Inc. (“EVT”) pled guilty to ten felony charges as a result of its misconduct related to the development, marketing, and sale of the ANCURE Endograft System (“Ancure”).<sup>2</sup> Declaration of Jeanette Haggas (“Decl.”) ¶4, Exh. A (Felony Plea Bargain); Exh. B (Guilty Plea Transcript). On June 30, 2003, Guidant entered into a Corporate Integrity Agreement (“CIA”) with the Office of Inspector General (“OIG”), whereby Guidant agreed to a reciprocal monitoring program with EVT. Decl. ¶7, & Exh. D (CIA). Specifically, each

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<sup>1</sup> Whether HHS inadvertently produced documents has nothing to do with whether HHS has shown that summary judgment is appropriate. Plaintiff will address HHS’ bootstrapped motion to compel separately.

<sup>2</sup> The Ancure device is a medical product used for the treatment of abdominal aortic aneurysms (a stretched and bulging section in the wall of the aorta that supplies oxygen-rich blood to the lower body).



1 company assumed responsibility for the other's compliance with the FDA and federal  
2 health care program requirements. Decl. ¶7, Exh. D (CIA) at 1, 18. Further, the CIA  
3 required Guidant to provide certain documents to the OIG: documents demonstrating  
4 Guidant's compliance with the Felony Plea Bargain. Decl. ¶4, & Exh. A (Felony Plea  
5 Bargain). These are the very documents that Plaintiff requested in its September 19, 2005,  
6 FOIA Request.

7 The compliance documents are crucial to examine Guidant's and EVT's adherence  
8 to their obligations under the Felony Plea Bargain and CIA. They include: Implementation  
9 Reports; Annual Reports; Data Monitoring Committee ("DMC") Review Reports; and  
10 Independent Review Organization ("IRO") Reports, including any and all Medical Device  
11 Reporting ("MDR") Review Reports. Decl. ¶8, Exh. E (FOIA Request).

12 Although Plaintiff requested documents from the Department of Health and Human  
13 Services ("HHS") in September 2005, HHS failed to respond within the statutory 20 days.  
14 Decl. ¶9. Instead, HHS provided an "interim" response on March 31, 2006, more than five  
15 months later. Decl. ¶9. HHS provided a "final" response on February 27, 2007 after  
16 Plaintiff filed its Complaint. Decl. ¶11. Plaintiff timely filed an appeal of the final  
17 response on March 23, 2007. Decl. ¶12.

### 18 19 III. STATEMENT OF THE CASE

20 Because Plaintiff did not receive a complete and timely response to its FOIA  
21 Request, Plaintiff filed a Complaint on July 10, 2006. Defendant filed its Answer on  
22 January 9, 2007, admitting that it failed to timely respond to Plaintiff's FOIA request. The  
23 parties stipulated to the intervention of Guidant Corporation on April 2, 2007. The Court  
24 ordered HHS to complete its appeal process, which it did on August 23, 2007. Decl. ¶13.  
25 That same day, HHS produced another set of documents, which it indicated was a  
26 "corrected" production in response to Plaintiff's two year old FOIA Request. Decl. ¶13,  
27 Exh. I.

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IV. ARGUMENT

A. THE MOTION AND SUPPORTING AFFIDAVITS FAIL TO SHOW THAT SUMMARY JUDGMENT IS APPROPRIATE.

The motion and supporting affidavits fail to demonstrate that no genuine issue of material fact exists. Specifically, HHS must show it performed an adequate search for responsive documents and justify its withholdings. FOIA Guide, *Litigation Considerations*, March 2007, available at [http://www.usdoj.gov/oip/foia\\_guide07.htm](http://www.usdoj.gov/oip/foia_guide07.htm).

Affidavits and documents in support of summary judgment must be also admissible as evidence. Fed. R. Civ. Proc. 56(e); *Kamman v. IRS*, 56 F.3d 46, 49 (9th Cir. 1995) (finding that agency failed to satisfy burden of proof and awarding summary judgment to plaintiff when agency affidavits "are nothing more than "conclusory and generalized allegations"). Moreover, the "underlying facts and the inferences to be drawn from them are construed in the light most favorable to the FOIA requester." 28 U.S.C. §1746; see *Summers v. U.S. Dep't of Justice*, 999 F.2d 570, 572-73 (D.C. Cir. 1993); accord, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (evidence of the non-movant is to be believed, and all justifiable inferences are drawn in his favor).

1. Only Agency Affidavits May Justify Nondisclosure: Thus, Summary Judgment Turns On Mr. Eckert's Declaration, Which Lacks Foundation And Contains Purely Hearsay Statements.

Summary judgment may be granted solely on the basis of *agency affidavits* if they provide reasonably detailed descriptions of the withheld information in a factual and nonconclusory manner, and if there is no contradictory evidence on the record or evidence of agency bad faith. 5 U.S.C. §552(a)(4)(B) (emphasis added); see, e.g., *L.A. Times Communications v. Dep't of the Army*, 442 F. Supp. 2d 880, 899-900 (C.D. Cal. 2006); *Hemenway v. Hughes*, 601 F. Supp. 1002, 1004 (D.D.C. 1985) (recognizing that in FOIA cases, summary judgment does not hinge on existence of genuine issue of material fact, but rather on whether *agency affidavits* are reasonably *specific, demonstrate logical use of*

1 exemptions, and are not controverted by evidence in record or by bad faith) (emphasis  
 2 added); *Wishart v. Comm'r*, No. 98-17248, 1998 WL 667638 (N.D. Cal. Aug. 6, 1998),  
 3 *aff'd*, 1999 WL 985142 (9th Cir. June 25, 1999); *Judicial Watch, Inc. v. Dep't of the Army*,  
 4 402 F. Supp. 2d 241, 245 (D.D.C. 2005) (stating, "the defendant agency has the burden of  
 5 justifying nondisclosure") (emphasis added).

6 To do this, the government must submit detailed affidavits, identifying the  
 7 documents withheld and explaining why they fall under the claimed exemptions. *See*  
 8 *Summers v. Dep't of Justice*, 140 F.3d 1077, 1080 (D.C. Cir. 1998); *King v. U.S. Dep't of*  
 9 *Justice*, 830 F.2d 210, 217 (D.C. Cir. 1987); *Vaughn v. Rosen*, 484 F.2d 820, 826-28 (D.C.  
 10 Cir. 1973); *Niagara Mohawk Power Corp. v. U.S. Dep't of Energy*, 169 F.3d 16, 18 (D.C.  
 11 Cir. 1999) (finding agency affidavits conclusory and denying summary judgment).  
 12 Moreover, agency affiants must have personal knowledge of the withheld records, the way  
 13 in which information is processed, and the documents at issue. *Spannaus v. DOJ*, 813 F.2d  
 14 1285, 1289 (4th Cir. 1987); *see Kamman*, 56 F.3d at 49 (rejecting affidavit that revealed  
 15 that signer "did not even review the actual documents at issue").

16 Here, the government's sole affidavit is silent as to the adequacy of HHS'  
 17 withholdings, and replete with unfounded, conclusory statements. First, Mr. Eckert does  
 18 not have personal knowledge of the initial decision as to what to withhold. Rather, he  
 19 merely states he has reviewed the documents and agrees with the decision to withhold  
 20 certain information. In fact, he never identifies who at HHS was responsible for initially  
 21 determining what information to withhold. *See e.g.*, Eckert Decl. ¶14 ("The agency  
 22 withheld..."); ¶15 ("my office"); ¶16 ("we discovered"). Second, his Declaration contains  
 23 inadmissible hearsay statements and does not adequately explain why the withheld  
 24 information is exempted.

25 Instead, HHS shirked its responsibility under FOIA and rubberstamped Guidant's  
 26 reasons as to why the documents should be withheld. Eckert Decl. ¶1 ("I understand that  
 27 Guidant Corporation is filing a separate declaration to explain the nature of the withheld  
 28

1 Guidant documents.”), ¶19 (“A separate declaration filed by Guidant Corporation explains  
 2 the confidential nature of the information, as well as the competitive nature of the  
 3 submitter’s industry and the likelihood of substantial competitive harm.”). HHS cannot  
 4 incorporate another’s statements and not set forth reasons for nondisclosure that stand on  
 5 their own. As filed, HHS’ affidavit offered zero evidence as to *why* disclosure would harm  
 6 Guidant, but attempted to incorporate Guidant’s reasons by reference, which is classic  
 7 hearsay. *See* Eckert Decl. ¶¶1, 19; *see also* Fed. R. Evid. 801(c). HHS must supply  
 8 standalone, admissible reasons for withholding information from Plaintiffs’ FOIA Request.  
 9 5 U.S.C. §552(a)(4)(B); *see Niagara Mohawk Power Corp.*, 169 F.3d at 18; *Kamman*, 56  
 10 F.3d at 49; FOIA Guide, *available at* [http://www.usdoj.gov/oip/foia\\_guide07.htm](http://www.usdoj.gov/oip/foia_guide07.htm) HHS  
 11 failed to do so, thus summary judgment should be denied.

12  
 13 **2. HHS’ And Guidant’s Affidavits Are Made In Bad Faith As Evidenced**  
 14 **By Their Wholly Conclusory Statements And Failure To Explain *Why***  
 15 **Disclosure Of The Withheld Information Would Harm Guidant.**

16 Mr. Eckert’s Declaration is proof of Plaintiff’s persistent allegations of bad faith:  
 17 Guidant improperly controlled HHS’ decisions as to what to withhold from Plaintiff’s  
 18 FOIA Request. Decl. ¶12, Exh. H. Mr. Eckert’s Declaration does nothing to demonstrate  
 19 that HHS indeed reviewed the responsive documents in the first place. In other words,  
 20 nowhere in Eckert’s Declaration does he state that HHS, not Guidant, performed the initial  
 21 review of responsive matter. Although the moving papers allege otherwise (Motion at  
 22 10:4-5), a careful review of Eckert’s Declaration shows that he never stated that he himself  
 23 reviewed the documents *prior* to the initial March 31, 2006, “interim response” or the  
 24 February 27, 2007, “final response.” To the contrary, it appears he only reviewed the  
 25 documents upon appeal. *See* Eckert Decl. ¶22.

26 In fact, because he points to Guidant’s declaration to “explain the nature of the  
 27 withheld Guidant documents,” it is more likely than not that Guidant, not HHS, determined  
 28 what to withhold and HHS merely rubberstamped Guidant’s determination. *See* Eckert

1 Decl. ¶¶1, 19. The statements contained in both Eckert’s and Chin-Purcell’s Declarations  
 2 are conclusory and do not explain specific, detailed reasons why Guidant would suffer  
 3 competitive harm when it (1) no longer exists, and (2) maintains a “highly tailored” and  
 4 “custom” compliance program.

5 Further, the *Vaughn Index* (attached as Exhibit 8 to Eckert’s Declaration) fails to  
 6 provide sufficiently detailed information other than a statement asserting the claimed  
 7 exemption. Thus, facially, HHS has not met its burden to present evidence demonstrating  
 8 that no material issue of fact remains.

9 Guidant claims that disclosure of any of the withheld information would be  
 10 “devastating.” Chin-Purcell Decl. ¶28. However, this case is uniquely positioned in that  
 11 some contested documents have been publicly available through PACER since July 3,  
 12 2007. *See* Exhibits G-M to the Declaration Of Jeanette Haggas In Support Of Motion To  
 13 Compel, Dkt. No. 67 (*e.g.* compliance policy numbers, employee names, IRO identity and  
 14 report); Decl. ¶¶17-18. No devastating consequences have occurred.

15 Guidant’s instructions to HHS to hold secret the information it provided HHS  
 16 pursuant to the CIA do not automatically confer a FOIA exemption, nor could they because  
 17 Guidant waived privileges as to these documents. Instead, the agency itself must determine  
 18 independent reasons to withhold the information from the public. 5 U.S.C. §552(a)(4)(B);  
 19 *see*, Part A.1, *supra*. In addition, Guidant was a party to the Felony Plea Bargain. Decl. ¶4,  
 20 Exh. A (Felony Plea Bargain) at 15 (signature block is for EVT “and its Parent  
 21 Corporation,” meaning Guidant); Decl. 7, Exh. D (CIA). Guidant is therefore is bound by  
 22 its terms. Further, during the sentencing hearing, Guidant acknowledged it could not  
 23 protect the information Plaintiff seeks. Decl. ¶5, Exh. B (Guilty Plea Transcript) at 21:15-  
 24 16 (“Guidant will not be able to assert a privilege to anything that [the government] would  
 25 seek in connection with the investigation.”). The information Plaintiff seeks is the very  
 26 information that the government obtained pursuant to the CIA, which was executed to  
 27 ensure Guidant’s compliance with the FDA. Thus, Guidant is barred from asserting the  
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1 documents turned over the HHS pursuant to the CIA are “confidential,” “privileged,” or  
2 “trade secrets.”

3 Guidant’s twist on the program guidance mandated by the government does not  
4 confer protection under FOIA exemption b(4) for “trade secrets.” The HHS and OIG  
5 codified the framework for compliance programs for medical device manufacturers. Decl.  
6 ¶31, Exh. X (Fed. Reg., vol. 68 no. 86, *OIG Compliance Program Guidance for*  
7 *Pharmaceutical Manufacturers* (May 5, 2003), endnote 5 (“this compliance program  
8 guidance may also have application to manufacturers of . . . medical devices”).

9 Moreover, Guidant is trying to assert that the withheld information is a “trade  
10 secret,” but Guidant itself no longer exists. Guidant was acquired by Boston Scientific  
11 Corporation on or about January 2006. Even if Guidant’s acquirer used Guidant’s  
12 compliance program and it was construed as a “trade secret,” the FOIA exemption would  
13 not apply because no party demonstrates (nor can it) that *Guidant* would be competitively  
14 disadvantaged if the compliance program was disclosed. *See*, Part D.1(b), *infra* (a “trade  
15 secret” in the FOIA context is limited to ideas that will benefit competitors at the expense  
16 of the creating party). Indeed, no party suggests that Guidant’s compliance program is still  
17 in use today.

18 Finally, chief competitors such as Pfizer Inc. invite public inquiry of their FDA  
19 compliance programs, and announce their organizational structure and processes for  
20 reporting. *See e.g.*, Decl. ¶25, Exh. R. Guidant also shared its compliance strategies with  
21 Johnson & Johnson. Decl. ¶21, Exh. N (joint powerpoint presentation). Because Guidant  
22 concedes that competitors have “highly tailored” compliance programs, and because  
23 competitors like Pfizer publish theirs online, it makes no sense that Guidant (a company  
24 that no longer exists) would assert that its compliance program either is a “trade secret” or  
25 could benefit competitors.

1           **B.     THE DOCUMENTS ARE NOT EXEMPTED UNDER FOIA BECAUSE EVT**  
 2           **AND GUIDANT WAIVED ALL POTENTIALLY APPLICABLE**  
 3           **PRIVILEGES UPON EXECUTING THE FELONY PLEA BARGAIN.**

4           The Felony Plea Bargain waived any privilege that might have attached to the  
 5 documents Plaintiff sought in its FOIA Request. Decl. ¶4, Exh. A (Felony Plea Bargain) at  
 6 10 (“[EVT] agrees to give up all rights that it would have if it chose to proceed to trial,  
 7 including . . . to raise any other Fourth or Fifth Amendment claims”) & 12 (“[EVT] will not  
 8 object, including asserting any privilege against the government”). This waiver applied to  
 9 Guidant as well. “Guidant will not be able to assert a privilege to anything that [the  
 10 government] would seek in connection with the investigation.” Decl. ¶5, Exh. B (Guilty  
 11 Plea Transcript) at 21:15-16; Decl. ¶4, Exh. A (Felony Plea Bargain) at 15 (signature block  
 12 for EVT “and its Parent Corporation,” meaning Guidant); Decl. 7, Exh. D (CIA).

13           Importantly, voluntary disclosure of information waives the privileges that may  
 14 have attached to that information, even if the waiver of certain privileges was unintentional.  
 15 *U.S. v. Grammer*, 513 F.2d 673, 676 (9th Cir. 1975) (holding that disclosure of fingerprint  
 16 report waived attorney-client and Fifth Amendment privileges); *Handgards, Inc. v. Johnson*  
 17 *& Johnson*, 413 F. Supp. 926, 929 (N.D. Cal. 1976) (holding that voluntary disclosure of  
 18 part of a document “is a waiver as to the remainder . . . about the same subject”).

19           Thus, EVT and Guidant waived any privilege as to the documents they turned over  
 20 to the government in connection with the Felony Plea Agreement and CIA. Further, HHS  
 21 cannot resurrect these privileges. As the federal practice guide articulates:

22           First, [the waiver] applies to the entire world; waiver due to an interaction  
 23 with one person ordinarily deprives the privilege-holder of the right to assert  
 24 the privilege against anyone else. Second, it often is held to extend beyond  
 25 materials revealed and to include any other materials or communications on  
 26 the same subject matter. For this reason, the consequences of waiver in much  
 27 civil litigation can be very great.” 8 Fed. Prac. & Proc. Civ. 2d §2016.2  
 28 (2007) (citing *U.S. v. Workman*, 138 F.3d 1261 (8th Cir. 1998) (“The waiver  
 covers any information directly related to that which was actually  
 disclosed.”)).

Once EVT and Guidant waived its privileges and rights, any privileges that may have raised  
 in the future as to the Ancure documents were also waived. Accordingly, HHS’ claimed

1 exemptions lack foundation and the Court should compel HHS to withdraw these claims  
2 and produce the requested documents.

3 HHS also produced unredacted versions of “exempted” information, which waives  
4 any exemption as to similar information. Indeed, attached as exhibits to the Declaration of  
5 Michele Chin-Purcell are documents that HHS produced in redacted form as recently as  
6 August 23, 2007 (which supposedly “corrected” the production). *Compare* Chin-Purcell  
7 Decl. Exhs. 2-3 *with* Haggas Decl. ¶¶14-15, Exhs. J-K. Thus, where the submitter itself  
8 waives a privilege, the government may not assert the privilege instead.

9 No party has moved to seal the allegedly inadvertently produced documents that  
10 were filed under Docket Number 67 (dated July 2007). Those Exhibits were produced by  
11 HHS and disclosed the name of EVT’s independent review organization, the engagement  
12 letter, and report; the number of reportable events as well as the reports; and Guidant’s  
13 compliance policy numbers and related information. Plaintiff’s Motion For Discovery  
14 (Dkt. No. 66) & Exhs. G-M (Dkt. No. 67); Decl. ¶¶17-18. Notably, report summaries of  
15 reportable events can be found online at the FDA’s MAUDE database.

16 Based on these examples, it is clear that additional documents (or portions thereof)  
17 are also withheld without basis. *See Fujisawa Pharmaceutical Co. v. Kapoor*, 162 F.R.D.  
18 539 (D.C. Ill. 1995) (“[v]oluntary disclosure of privileged information about a matter  
19 waives the privilege as to all information on the same subject matter.”); *Handgards, Inc.*,  
20 413 F. Supp. at 929. Accordingly, Guidant and HHS have waived exemptions, if any were  
21 valid, by allowing the documents to remain available to the public through the Court’s  
22 PACER website or a court records request for the last four months.

23 HHS and Guidant cannot arbitrarily choose to disclose or withhold this non-  
24 confidential information. Accordingly, the Court should compel production of the  
25 documents Plaintiff seeks, or in the alternative, allow discovery concerning the remainder  
26 of information HHS wrongfully withheld.



1           **C. THE PUBLIC HAS A STRONG INTEREST IN THE DOCUMENTS**  
2           **SOUGHT BY PLAINTIFF'S FOIA REQUEST.**

3           The public has a strong interest in and is entitled to access to the information  
4           Plaintiff seeks. Thousands of people suffered injuries as a result of EVT's deceit, including  
5           death. Decl. ¶6 & Exh. C (June 13, 2003, NY Times article). Plaintiff's FOIA Request  
6           sought the very information that EVT was required to turn over to the government pursuant  
7           to the Felony Plea Agreement. Despite the company's guilty plea, the government failed to  
8           prosecute a single individual. The public is entitled to scrutinize the government's  
9           enforcement of the guilty plea and its relationship with major medical device manufacturer.  
10          "In enacting FOIA, Congress "emphasize[d] a preference for the fullest possible agency  
11          disclosure of . . . information consistent with a responsible balancing of competing concerns  
12          . . . ." *ACLU v. DOD*, 339 F. Supp. 2d 501, 504 (S.D.N.Y. 2004). Here, the *Vaughn* Index  
13          proves that none of those competing concerns exist. Equally unprotected are Guidant's  
14          "Disclosure Logs" which detail reports from employees concerned the company is  
15          engaging in unlawful conduct. Motion at 19:20-22. The public would be extremely  
16          interested in this information, particularly given Guidant's product liability lawsuits  
17          stemming from its defective defibrillators.

18           **D. EMPLOYEE IDENTITIES AND BUSINESS CONTACT INFORMATION**  
19           **ARE NOT PRIVILEGED UNDER EXEMPTION B(6), ESPECIALLY**  
20           **WHERE IT IS PUBLICLY AVAILABLE ON THE INTERNET.**

21          HHS withheld the business telephone numbers, business addresses, business email  
22          addresses, signatures, and position titles for several employees under Exemption b(6).<sup>3</sup>  
23          Haggas Decl. ¶¶14-15, Exhs. J-K. Generally, HHS and Guidant claim that release of this  
24          information "would constitute an invasion of privacy." Eckert Decl. ¶21.

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27          <sup>3</sup> The sole piece of non-business related information is Jon Nygaard's home contact information.  
28          See entry 3, Eckert Decl., Exh. 8 (*Vaughn* Index). But, HHS disclosed his name, and his home contact  
        information is easily available through an internet search on [www.google.com](http://www.google.com) or [www.whitepages.com](http://www.whitepages.com)

1           A privacy interest must be ascertained that would be threatened by disclosure. If  
2 found, the privacy interest must outweigh the public's interest in order to remain protected.  
3 *See Ripskis v. HUD*, 746 F.2d 1, 3 (D.C. Cir. 1984). The names, work contact information,  
4 and position titles of Guidant's employees are not privileged information. *See, e.g.*, 5  
5 U.S.C. §552(b)(6); *Or. Natural Desert Ass'n v. U.S. Dep't of the Interior*, 24 F. Supp. 2d  
6 1088, 1089 (D. Or. 1998) (concluding that cattle owners who violated federal grazing laws  
7 have "diminished expectation of privacy" in their names when such information relates to  
8 commercial interests). Once disclosed, "the information belongs to the general public."  
9 *NARA v. Favish*, 541 U.S. 157, 174 (2004).

10           Most of the information HHS withheld under Exemption b(6) has been released to  
11 the public already. First, HHS withheld the name and signature block on documents, which  
12 were produced on August 23, 2007, in response to Plaintiff's appeal. Decl. ¶¶13-15, Exh. I-  
13 K. However, these documents are attached without redaction to the Declaration of Michele  
14 Chin-Purcell, Ph.D. as Exhibits 2 and 3. Haggas Decl. ¶¶14-15, Exhs. J-K. HHS and  
15 Guidant cannot withhold responsive and non-exempt information only to produce it at a  
16 more convenient time.

17           Second, review of the documents that have been repeatedly produced by HHS  
18 shows that there is no basis for HHS' claimed exemptions. For instance, Guidant claims  
19 the identities of compliance committee members and their business contact information are  
20 secret. But, Guidant, as a publicly traded company, regularly identifies its employees,  
21 particularly the executive board members who comprise its compliance committee. *See*  
22 *e.g.*, Decl. ¶16, Exh. L (SEC filings); *see, e.g.*, Guidant Corporation, Proxy Statement,  
23 Annual Meeting of Shareholders (May 17, 1999), *available at*  
24 <http://www.secinfo.com/dsvRs.61Nc.htm>. Especially where Guidant provided the  
25 biographical and income information of its compliance committee members (including  
26 stock options that their immediate family owns) through its SEC filings, proxy statements,  
27 and annual reports or meeting minutes, HHS' withholding of their identities is entirely  
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1 inappropriate. *See e.g.*, Decl. ¶16, Exh. L (SEC Filings); Exh. N (powerpoint presentation  
2 identifying compliance committee members with accompanying photographs, *available at*  
3 [www.ehcca.com/presentations/ pharmacolloquium2/mehrotra.ppt.](http://www.ehcca.com/presentations/pharmacolloquium2/mehrotra.ppt.), dated June 6, 2005);  
4 Exh. 20 (internet website printouts from [www.zoominfo.com](http://www.zoominfo.com) and [www.whitepages.com](http://www.whitepages.com)  
5 listing work telephone and address information for Guidant Compliance Committee officers  
6 Kathy Lundberg and Michele Chin-Purcell); *see* <http://www.secinfo.com>, *Guidant*  
7 (available for free).

8 Equally invalid are HHS' redactions of the signature blocks on the compliance  
9 certificates, when the acting compliance officer's names appear throughout the "corrected"  
10 August 2007 production. *Compare* Decl. ¶¶22-23, Exh. O-P *with* Decl. ¶24, Exh. Q  
11 (indicating Morris Waxler was EVT's compliance officer in 2003 and Kathy Lundberg is  
12 Guidant's compliance officer).

13 Guidant and HHS cite to a number of inapplicable cases to justify HHS'  
14 withholdings. Motion at 21-22. Plaintiff does not seek to learn the "social security  
15 numbers, personal medical information, personal opinions, dates of birth, marital status,  
16 number of children, citizenship information, credit card numbers, or sources of private  
17 research income." *Id.* Indeed, neither HHS nor Guidant allege that this is the type of  
18 information withheld under Exemption b(6). Instead, the "corrected" production makes  
19 clear that the redacted information is limited to business contact information and identities  
20 of certain compliance committee members. This information is not confidential.  
21 Moreover, no legal authority holds that an employee's name should not be disclosed except  
22 for national security purposes, which are not present here.

23 These examples clearly demonstrate that HHS and Guidant's Motion For Summary  
24 Judgment is brought in bad faith. Accordingly, it should be denied.

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**E. HHS WRONGFULLY WITHHELD INFORMATION AND DOCUMENTS UNDER EXEMPTION B(4).**

Exemption 4 protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. §552(b)(4). The exemption covers only two categories of information: "(1) trade secrets; and (2) information that is [] commercial or financial . . . and [] privileged or confidential." FOIA Guide, available at [http://www.usdoj.gov/oip/foia\\_guide07.htm](http://www.usdoj.gov/oip/foia_guide07.htm) (emphasis in original).

**1. "Trade Secrets" In The FOIA Context Are Narrowly Defined.**

A "trade secret" is narrowly defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983). This definition also incorporates a requirement that there be a "direct relationship" between the trade secret and the productive process. *Id.*; *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 150-51 (D.C. Cir. 2001) (emphasizing that the definition "narrowly cabins trade secrets to information relating to the 'productive process' itself").

Ultimately, Exemption b(4) protects manufacturing and design information from public disclosure, but not much else. *Appleton v. FDA*, 451 F. Supp. 2d 129, 142 & n.8 (D.D.C. 2006); *Herrick v. Garvey*, 200 F. Supp. 2d 1321, 1326 (D. Wyo. 2000) (protecting technical blueprints); *Heeney v. FDA*, No. 97-5461, 1999 U.S. Dist. LEXIS 23365, at \*25 & n.13 (C.D. Cal. Mar. 18, 1999) (protecting "compliance testing" and "specification of the materials used in constructing" electrode catheter), *aff'd*, 7 F. App'x 770 (9th Cir. 2001); *Citizens Comm'n on Human Rights v. FDA*, No. 92-5313, 1993 WL 1610471, at \*7 (C.D. Cal. May 10, 1993) (protecting "information about how a pioneer drug product is formulated, chemically composed, manufactured, and quality controlled"), *aff'd in part & remanded in part on other grounds*, 45 F.3d 1325 (9th Cir. 1995).

1           “The mere fact that an event occurs in connection with a commercial operation does  
2 not automatically transform documents regarding that event into commercial information.”  
3 *Chi. Tribune Co. v. FAA*, No. 97-2363, 1998 WL 242611, at \*2 (N.D. Ill. May 7, 1998).  
4 “Examples of items usually regarded as commercial or financial information include:  
5 business sales statistics; research data; technical designs; customer and supplier lists; profit  
6 and loss data; overhead and operating costs; and information on financial condition.” *See,*  
7 *e.g., Landfair v. U.S. Dep’t of the Army*, 645 F. Supp. 325, 327 (D.D.C. 1986).

8           HHS withheld Guidant’s policies for FDA compliance and the associated internal  
9 policy numbers, the identity of the independent review organization and report, and  
10 information regarding the company’s organizational structure. But, this information is  
11 categorically excluded from “trade secrets” under the narrow definition applied in FOIA  
12 cases. Moreover, this very information has been available to the public since July. *See*  
13 Dkt. No. 67. Accordingly, HHS’ withholdings are improper.

14  
15           **2. All Documents Withheld Under Exemption b(4) Must Be “Privileged Or  
16 Confidential.”**

17           Guidant uses FOIA Exemption b(4) to shield its annual reports,  
18 implementation reports, and compliance program information from disclosure because  
19 Guidant claims it never shared this information.<sup>4</sup> But, the test for confidentiality is an  
20 objective one: whether information would customarily be secreted from the public by the  
21 person from whom it was obtained is not dispositive. *Nat’l Parks & Conservation Ass’n v.*  
22 *Morton*, 498 F.2d 765, 766 (D.C. Cir. 1974); *see Wash. Post Co. v. HHS*, 690 F.2d 252, 268  
23 (D.C. Cir. 1982) (citing *Nat’l Parks*). Instead, “confidential” information is information  
24 that is likely to either “(1) impair the Government’s ability to obtain necessary information  
25 in the future; or (2) to cause substantial harm to the competitive position of the person from  
26 whom the information was obtained.” *Nat’l Parks*, 498 F.2d at 770.

27           <sup>4</sup> *But see*, Decl. ¶21, Exh. N (Guidant and Johnson & Johnson present joint powerpoint lecture on  
28 compliance programs).

## 1 a) □□ “Impairment prong.”

2 Here, HHS’ disclosure of Guidant’s policies and procedures will not impair  
3 Guidant’s future dealings with the government. Indeed, Guidant and EVT provided the  
4 documents to the government pursuant to a Felony Plea Bargain and CIA agreement due to  
5 EVT’s “knowing and willful” misrepresentations concerning Ancure. Decl. ¶5, Exh. B  
6 (Guilty Plea Transcript) at 8:17-25. Thus any anticipated impairment in the government’s  
7 future dealings with Guidant cannot be blamed on HHS’ disclosure here, but perhaps  
8 Guidant’s continued misconduct.

9 Indeed, the “impairment prong” applies to limited situations in which information is  
10 required to be provided to the government, but disclosure of that information under the  
11 FOIA will result in a diminution of the "reliability" or "quality" of what is submitted.  
12 *Critical Mass Energy Proj. v. Nuclear Reg. Com’n*, 975 F.2d 871, 878 (D.C. Cir. 1992);  
13 *Pub. Citizen Health Research Group v. FDA*, 964 F. Supp. 413, 415 (D.D.C. 1997). Given  
14 Guidant’s history with fraudulent conduct, it would seem that Guidant has a sufficient  
15 interest in procuring information to the government to boast FDA compliance, avoid  
16 additional product liability lawsuits, and rebuild good will. *See, e.g., Teich v. FDA*, 751 F.  
17 Supp. 243, 252 (D.D.C. 1990) (rejecting, as "absurd," a submitter's contention that  
18 companies would be less likely to conduct and report safety tests to the FDA for fear of  
19 public disclosure, because the companies' own interests in engendering good will and in  
20 avoiding product liability suits is sufficient assurance that they will conduct "the most  
21 complete testing program" possible).

22 EVT and Guidant were forced to supply the information Plaintiff seeks pursuant to a  
23 Felony Plea Bargain. Whether public dissemination of the information sought may impair  
24 Guidant’s future disclosures to the government is therefore irrelevant. Moreover, the  
25 information sought centers around the reporting obligations to the government pursuant to  
26 the CIA and adherence to federal regulations, which will not be impaired by disclosure of  
27 the compliance policies. Importantly, EVT and Guidant are required to disclose some of  
28

1 the information Plaintiff seeks, such as the Annual Reports, independent of the CIA or  
 2 Felony Plea Bargain. Adverse event reports are also publicly available via the internet on  
 3 the FDA's "MAUDE" database at <http://www.fda.gov/cdrh/maude.html>. Thus, the  
 4 "impairment prong" is no bar to disclosure here.

5  
 6 **b) □□ "Competitive harm prong."**

7 "Competitive harm" in the FOIA context is "limited to harm flowing from the  
 8 affirmative use of proprietary information by competitors" and "should not be taken to  
 9 mean simply any injury to competitive position, as might flow from customer or employee  
 10 disgruntlement." *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291 n.30  
 11 (D.C. Cir. 1983). Importantly, "the Ninth Circuit emphasized, in *Public Citizen*, the agency  
 12 declarant had supported his conclusions with 'detailed and specific descriptions' of the  
 13 withheld information, including '*the ways in which each category of information could be*  
 14 *turned to [the requester's] competitive advantage.'*" *Lion Raisins Inc. v. USDA*, 354 F.3d  
 15 1072, 1080 (9th Cir. 2004) (emphasis added).

16 Evidence of "actual competition and a likelihood [not mere possibility] of  
 17 substantial competitive injury" is all that need be shown. *CNA Fin. Corp. v. Donovan*, 830  
 18 F.2d 1132, 1152 (D.C. Cir. 1987); *accord Frazee v. U.S. Forest Serv.*, 97 F.3d 367, 371  
 19 (9th Cir. 1996); *GC Micro Corp. v. Def. Logistics Agency*, 33 F.3d 1109, 1113 (9th Cir.  
 20 1994); *see, e.g., Judicial Watch*, 337 F. Supp. 2d at 169 (finding that substantial harm must  
 21 be "likely"). Bare allegations of harm cannot support an agency's decision to withhold  
 22 requested documents. *Pub. Citizen*, 704 F.2d at 1291; *Lee v. FDIC*, 923 F. Supp. 451, 455  
 23 (S.D.N.Y. 1996) (rejecting competitive harm without "adequate documentation of the  
 24 specific, credible, and *likely reasons why* disclosure of the document would actually cause  
 25 substantial competitive injury") (emphasis added); *Martin Marietta Corp. v. Dalton*, 974 F.  
 26 Supp. 37, 41 (D.D.C. 1997) (holding that neither cost and pricing data nor proprietary  
 27 management strategies were protected under Exemption b(4)).

1           Guidant and HHS failed to show with any particularity how a competitor could use  
 2 the information at issue to cause competitive injury. Disclosure of Guidant’s reports,  
 3 policies and procedures for compliance with the FDA regulations, training manuals, IRO  
 4 information, reportable events, certifications, or computer system are not likely to result in  
 5 such egregious injury as to disable it as an effective competitor. By conceding that its  
 6 “interpretation of the [FDA’s] Quality System and Medical Device Reporting requirements  
 7 . . . are critical to its overall function and success” (Motion at 14:17-19), Guidant embraces  
 8 a self-supporting construction of the law. Indeed, its interpretation is exactly what earned it  
 9 the felony plea bargain and the FDA’s heightened surveillance. Further, Guidant is  
 10 required to conform to the FDA regulations.

11           Neither Guidant nor HHS provided, in the motion itself or the supporting affidavits,  
 12 any explanation as to *how* Guidant’s competitors would benefit, let along the likelihood that  
 13 competitors would use Guidant’s information. Instead, whether these competitors would  
 14 benefit from release of the requested information remains purely speculative. Fear of a  
 15 competitor’s advantage cannot justify withholding information under FOIA Exemption  
 16 b(4). In fact, due to the “unique” nature of the information sought, any perceived benefit a  
 17 competitor could gain is negligible at best. Notably absent from any declaration filed in  
 18 support of this summary judgment is an explanation why any competitor would want to use  
 19 Guidant’s information for a compliance program. Given the felony convictions and  
 20 continued problems thereafter, any Guidant program would be the model of what not to do,  
 21 and the least likely program a competitor would want to copy.

22  
 23           **c)   “Confidential or Privileged Information.”**

24           If the information sought is publicly available, no FOIA Exemptions apply. *Inner*  
 25 *City Press/Cnty. on the Move v. Bd. of Governors of the Fed. Reserve Sys.*, 463 F.3d 239,  
 26 244 (2d Cir. 2006). Examples of Guidant’s compliance policy numbers, the IRO name and  
 27 report, and the reportable event summaries, attached as exhibits to Docket Number 67, have  
 28



1 been publicly available without formal objection from Guidant or HHS, *e.g.* via a motion to  
2 seal, since July. Moreover, Guidant attached unredacted versions of withheld information  
3 to its moving papers here. Thus, any Exemption claimed as to these documents and similar  
4 data has been waived. *See*, Part C, *supra*.

5 Further, Exemption b(4) protects only information such as the type and volume of  
6 sales, actual costs, profits margins and the like, unannounced and future products,  
7 proprietary technical information, pricing strategy, distributor information, and raw  
8 research data. *Citizens Comm'n*, 1993 WL 1610471, at \*9-10; *Heeney v. FDA*, 7 F. App'x  
9 770, 771 (9th Cir. 2001). General information regarding publicly held corporation's  
10 management structure, financial and production capabilities, corporate history and  
11 employees, most of which would be found in corporation's annual report and SEC filings, is  
12 readily available to any stockholder interested in obtaining such information. *SMS*, 1989  
13 WL 201031, at \*4. Likewise, Guidant's annual reports are not confidential or privileged  
14 because they are regularly produced to the public. *See, e.g.*, <http://www.secinfo.com>,  
15 *Guidant* (available for free).

16 In addition, medical device manufacturers compete on a variety of factors including  
17 product design and development: corporate structure and strategies in implementing  
18 compliance with FDA regulations are not likely to substantially aid competitors. This is  
19 particularly true given that "compliance policies are highly customized and are tailored to a  
20 company's specific business activities, organizational structure, and other needs." Motion  
21 at 14. Indeed, neither HHS nor Guidant allege that competitors would restructure their  
22 companies, let alone their compliance programs, upon learning of Guidant's internal  
23 compliance policies. Instead, it is apparent that competitors would have nothing to gain  
24 from Guidant's compliance programs. Further, Guidant provides training seminars to  
25 openly encourage competitors to follow its compliance program. Decl. ¶21 Exh. N  
26 (presentation by Guidant's Chief Compliance Officer, Kathy Lundberg, and Johnson &  
27 Johnson's VP Health Care Compliance, Louise Mehrotra, entitled "A Primer on  
28

1 Compliance Programs for Pharmaceutical and Medical Device Companies,” dated June 6,  
2 2005). This evidence demonstrates that it is only Plaintiff that HHS and Guidant seek to  
3 keep information from because they are concerned about public scrutiny.

4  
5 **F. PLAINTIFF HAS NO OBLIGATION TO RETURN ANY DOCUMENTS  
6 PRODUCED BY HHS.**

7 Guidant and HHS “implore” the Court to compel the return of documents by  
8 claiming that they were “inadvertently” produced. A “majority of federal courts . . . have  
9 adopted a five-factor test to determine whether an inadvertent production actually  
10 occurred.” *Flores v. Albertson's, Inc.*, No. 01-0515, 2004 WL 3639290 (C.D. Cal. April 9,  
11 2004) (compelling return of 38 inadvertently produced income documents, which raised  
12 defendant’s concerns about multiple social security number use by plaintiffs); *Bagley v.*  
13 *TRW, Inc.*, 204 F.R.D. 170, 177 (C.D. Cal. 2001); *Hartford Fire Ins. Co. v. Garvey*, 109  
14 F.R.D. 323, 332 (N.D. Cal. 1985). Those five factors are: (1) the reasonableness of the  
15 precautions to prevent inadvertent disclosure; (2) the time taken to rectify the error; (3) the  
16 scope of the discovery; (4) the extent of the disclosure; and (5) the overriding issue of  
17 fairness to the disclosing party. *Flores*, 2004 WL 3639290, at \*1, \*5. Neither Guidant nor  
18 HHS provides an explanation of why these documents are privileged or legal precedent  
19 requiring us to return the documents.

20 Here, the facts overwhelmingly demonstrate that the documents were not  
21 “inadvertently” produced; rather, HHS regrets producing them. First, HHS used a “FOIA  
22 Specialist” to review the documents prior to production. The mere fact that the reviewer’s  
23 title is “specialist” demonstrates the degree of expertise that individual possessed when he  
24 or she reviewed the documents to prevent inadvertent disclosure. Second, no one raised  
25 concerns of inadvertent production until July 2007, well over a year after HHS’ initial  
26 production in March 2006. Third, no one disputes that the documents are directly  
27 responsive to Plaintiff’s FOIA request. Fourth, the contested documents bear non-  
28 confidential information and the only declaration from any Guidant employee stating the

1 documents were private, not meant for public dissemination, or could somehow assist  
2 Guidant's competitors was received in connection with this summary judgment motion.  
3 But, the conclusory statements in Eckert's Declaration fail to explain *why* disclosure would  
4 harm Guidant. Fifth, neither HHS nor Guidant explains *how* disclosure prejudices either  
5 party. Guidant has not set forth any reason why the documents are privileged until this  
6 summary judgment motion. Importantly, Guidant has not alleged that the documents at  
7 issue have not been produced in other lawsuits (such as the MDL and state court  
8 proceedings in Minnesota). In fact, Guidant promised to identify the specific documents  
9 that were supposedly inadvertently produced, but never did. Decl. ¶26, Exh. S.  
10 Accordingly, the documents are not "inadvertently" produced, as defined by the California  
11 federal courts.

12 Instead, the surrounding circumstances indicate the specific intent on the part of  
13 HHS to consent to the disclosure of the information. Notably, Plaintiff was first alerted to  
14 an alleged "inadvertent" production by Guidant, not the source of the production: HHS.  
15 Neither Guidant nor HHS ever moved to seal the exhibits filed with the Court (*see, e.g.*,  
16 Dkt. No. 67), or provided Plaintiff with a stipulation to seal the documents. Because the  
17 documents were filed with the Court, they are instantly available to anyone with access to  
18 PACER and are also available to the general public through a court records request. But,  
19 these documents have been readily available to the public, without formal objection, since  
20 July. *See* Dkt. No. 67; Decl. ¶¶17-18. HHS cannot back-pedal now and claim that certain  
21 previously disclosed documents (or portions thereof) are now exempted and therefore were  
22 inadvertently produced.

23 The case *State Compensation Insurance Fund v. WPS, Inc.* does not apply to the  
24 circumstances here. The controlling rule of law issued by that decision was that an attorney  
25 must return documents that are obviously privileged and unintended for disclosure. That is  
26 not the case here. Decl. ¶28, ¶30, Exhs. U, W; *see also* Complaint at ¶12 ("On March 31,  
27 2006 . . . Plaintiff received an "interim response" containing 859 pages of documents, with  
28

1 non-sequential Bates Number and approximately 250 unnumbered pages. *The documents*  
 2 *were neither indexed nor organized in any recognizable fashion*”) (emphasis added). Based  
 3 on the fact that certain information HHS withheld is publicly available, or could be found  
 4 unredacted elsewhere in the “corrected” production, Plaintiff believed in good faith that  
 5 HHS’ production was sloppy, but not unintentional. Plaintiff therefore has no duty to return  
 6 any documents.

7  
 8 **G. THE COURT SHOULD REVIEW THE RESPONSIVE DOCUMENTS *IN***  
 9 ***CAMERA* TO UNEARTH HHS’ WRONGFUL WITHHOLDINGS.**

10 An *in camera* inspection is necessary and appropriate (1) where affidavits are not  
 11 sufficiently detailed, (2) where the plaintiff alleges waiver of exemptions, or (3) to verify  
 12 the agency’s withholdings. 5 U.S.C. §552(a)(4)(B); *Nowak v. U.S.*, No. 98-56656, 2000  
 13 WL 60067, at \*2 (9th Cir. Jan. 21, 2000) (finding *in camera* review unnecessary where  
 14 affidavits were sufficiently detailed); *Pub. Citizen v. U.S. Dep’t of State*, 787 F. Supp. 12,  
 15 13 (D.D.C. 1992) (finding exemptions properly invoked after reviewing records *in camera*),  
 16 *aff’d*, 11 F.3d 198 (D.C. Cir. 1993); *see, e.g., Lion Raisins Inc.*, 354 F.3d 1072, 1082 (9th  
 17 Cir. 2004) (acknowledging that “[u]nder certain limited circumstances, we have endorsed  
 18 the use of *in camera* review of government affidavits as the basis for FOIA decisions”);  
 19 *Nat’l Wildlife Fed’n v. U.S. Forest Serv.*, 861 F.2d 1114, 1116 (9th Cir. 1988) (“[W]here a  
 20 trial court properly reviewed contested documents *in camera*, an adequate factual basis for  
 21 the decision exists.”); *Judicial Watch, Inc. v. Dep’t of the Army*, 402 F. Supp. 2d 241, 249 &  
 22 n.6 (D.D.C. 2005) (ordering *in camera* inspection to review accuracy of agency’s  
 23 descriptions of withheld information after inadvertent disclosure revealed discrepancies and  
 24 inaccuracies in *Vaughn* Index).

25 Plaintiff showed that HHS’ affidavit lacks the requisite detail and HHS and Guidant  
 26 waived all exemptions. *See*, Parts A.1-2, *supra*. Thus, an *in camera* review is critical to  
 27 verify HHS’ remaining claims of exemption. This is particularly true where the total  
 28 number of documents is relatively small. Here, HHS claims a universe of 4,563 pages (two

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bankers boxes) was reviewed, of which 3,265 pages are either entirely or partially withheld. Decl. ¶13, Exh. I. Accordingly, the Court should review the withheld information, in conjunction with the CIA, Felony Plea Bargain, and the allegedly “inadvertent” information attached as Exhibits to Docket Number 67. Upon review, the Court will likely determine the remaining information HHS withholds is not exempt.

**H. THE COURT SHOULD SANCTION HHS AND GUIDANT FOR BRINGING THIS MOTION AND SUPPORTING AFFIDAVITS IN BAD FAITH.**

Where affidavits are presented in bad faith, the court shall order the party employing them to pay to the other party the amount of the reasonable expenses which the filing of the affidavits caused the other party to incur, including reasonable attorney's fees, and any offending party or attorney may be adjudged guilty of contempt. Fed. R. Civ. Proc. 56(g).

Here, where so much of the information Plaintiff seeks is publicly available, or the potential FOIA protections have been waived, HHS’ and Guidant’s assertions to the contrary are wholly inappropriate. HHS’ sole affidavit fails to meet a single element of HHS’ burden on summary judgment: personal knowledge of the documents themselves and the detailed reasons why certain information was exempted from disclosure. Accordingly, the Court should sanction HHS and Guidant.

**V. CONCLUSION**

For the foregoing reasons, Plaintiff respectfully requests that this Court DENY summary judgment and further rule that Plaintiff has no obligation to return any documents. In addition, the Court should GRANT Plaintiff’s request for sanctions due to the egregiously inaccurate and baseless statements in HHS’ and Guidant’s affidavits filed in support of summary judgment.

DATED: November 21, 2007.

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A Professional Corporation

By   
JEANETTE HAGGAS  
Attorneys for Plaintiffs

# Exhibit AE

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**DEPARTMENT OF DEFENSE**  
DEPUTY COMMANDER – DETAINEE OPERATIONS  
US FORCES AFGHANISTAN  
JOINT TASK FORCE 435  
APO AE 09356



REPLY TO  
ATTENTION OF:

JTF-435-1.0

MAR 27 2010

MEMORANDUM FOR Commander, Task Force Protector, Bagram Airfield, Afghanistan, APO  
AE 09354

SUBJECT: 10 February 2010 Detainee Review Board (DRB) Recommendation for Continued  
Internment Approval/Disapproval for ISN 1464

1. I reviewed the findings and recommendation of the DRB conducted on 10 February 2010 concerning the internment of Detainee ISN 1464. After consideration, the DRB's recommendation that ISN 1464 continue to be detained at the Detention Facility in Parwan is approved.

2. Further, the DRB's recommendation that ISN 1464 be assessed as an Enduring Security Threat is approved.

3. The point of contact for this memorandum is CAPT (b)(3) 40 USC 1306.(b)(6) Director of Legal Operations, JTF 435, at DSN (b)(2)

MARK S. MARTINS  
Brigadier General, U.S. Army  
Deputy Commander

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REPLY TO  
ATTENTION OF:

DEPARTMENT OF DEFENSE  
DEPUTY COMMANDER - DETAINEE OPERATIONS  
US FORCES AFGHANISTAN  
JOINT TASK FORCE 435  
APO AE 09356



JTF-435-LO

FEB 23 2010

MEMORANDUM FOR Commander, Task Force Protector, Bagram Airfield, Afghanistan, APO  
AE 09354

SUBJECT: 7 January Detainee Review Board (DRB) Recommendation for Continued  
Internment Approval/Disapproval for ISN 3863

1. I reviewed the findings and recommendation of the DRB conducted on 7 January 2010 concerning the internment of Detainee ISN 3863. After careful consideration, the DRB's recommendation that ISN 3863 continue to be detained at the Detention Facility in Parwan is approved.
2. Further, the DRB's recommendation that ISN 3863 be assessed as an Enduring Security Threat is disapproved.
3. The point of contact for this memorandum is CAPT (b) (6), (b) (7) (C), USC 1506 Director of Legal Operations, JTF 435, at DSN (b) (6)

MARK S. MARTINS  
Brigadier General, U.S. Army  
Deputy Commander

*I direct that  
this case be reviewed by the  
Abolko Commission.  
MSM*

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**DEPARTMENT OF DEFENSE**  
DEPUTY COMMANDER – DETAINEE OPERATIONS  
US FORCES AFGHANISTAN  
JOINT TASK FORCE 435  
APO AE 09356



REPLY TO  
ATTENTION OF:

JTF-435-LO

FEB 15 2010

MEMORANDUM FOR Commander, Task Force Protector, Bagram Airfield, Afghanistan, APO AE 09354

SUBJECT: 20 January 2010 Detainee Review Board (DRB) Recommendation for Continued Internment Approval for ISN 4037

1. I reviewed the findings and recommendation of the DRB conducted on 20 January 2010 concerning the internment of Detainee ISN 4037. After consideration, the DRB's recommendation that ISN 4037 continue to be detained at the Detention Facility in Parwan is approved.
2. Further, the DRB's recommendation that ISN 4037 not be assessed as an Enduring Security Threat is approved.
3. The point of contact for this memorandum is CAPT (b)(3) 10 USC 1205, (b)(6), Director of Legal Operations, JTF 435, at DSN (b)(2)

MARK S. MARTINS  
Brigadier General, U.S. Army  
Deputy Commander

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