UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KING & SPALDING LLP **Plaintiff,** **v.** **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.** **Defendants.**	)	**Case No. 16-cv-01616 (APM)**

PLAINTIFF'S MOTION FOR ATTORNEYS' FEES AND EXPENSES

Pursuant to Federal Rule of Civil Procedure 54(d)(2) and 5 U.S.C. § 552(a)(4)(E), Plaintiff King & Spalding LLP moves for an Order awarding reasonable attorneys' fees and litigation costs incurred over the three-and-a-half years it spent litigating this action. As the prevailing party, King & Spalding is eligible for and deserving of an award of fees and costs. On February 3, 2020, defendants through counsel stated they will oppose this motion.

BACKGROUND

This motion caps off nearly four years of unnecessary wrangling over the release of public records due to King & Spalding under the Freedom of Information Act (FOIA). On April 14, 2016, the firm submitted narrowly tailored FOIA requests to the U.S. Department of Health and Human Services ("HHS"), the U.S. Food and Drug Administration ("FDA"), and the U.S. Department of Justice ("DOJ") seeking documents related to the federal government's 2012 investigation of Abiomed, Inc., a medical device company. *See* ECF No. 20 ¶¶ 2, 10. King & Spalding's request asked for documents that were from a short time frame, that avoided

deliberative material, and that excluded communications from Abiomed to the government. These carefully tailored requests could have been easily and expeditiously responded to in full with limited expenditure of resources. Instead of responding quickly, the government dragged its feet, costing King & Spalding hundreds of thousands of dollars in attorneys' fees and costs. Aside from a limited production from the FDA, neither HHS nor DOJ released any documents to King & Spalding for almost four full months. *See generally* ECF No. 13 (detailing the pre-litigation history of the FOIA requests). At the same time, the government failed to put forward any colorable basis for withholding the records. *See* ECF No. 13 ¶ 10. So, King & Spalding sued. *See* ECF No. 1; *see also* 5 U.S.C. § 552(a)(4)(B) (granting federal courts the power to compel FOIA productions).

Yet despite being haled into court, the government's foot-dragging continued. It constantly sought to delay production and briefing deadlines, *see* ECF No. 9; ECF No. 12; ECF No. 13 ¶ 8; ECF No. 15, and did not finish releasing the *uncontested* documents for nearly eight months after King & Spalding's initial FOIA requests. *See* ECF No. 29 ¶ 4. On December 5th and 8th 2016, The U.S. Centers for Medicare and Medicaid Services ("CMS"), a component of HHS, released documents in full and did not claim any exemptions to withhold documents or make redactions. Exhibits C & D. On December 23, 2016, the Executive Office for United States Attorneys ("EOUSA"), a component of DOJ, made two productions. In the first, EOUSA released 344 pages in full and withheld fifty-one pages in full. Exhibit E. In the second, EOUSA released twenty-seven pages in full and withheld sixteen pages in full. Exhibit F. The productions were not complete until April 5, 2017, when EOUSA released forty-six pages in full and released thirty-three pages with redactions. Exhibit G.

It then attempted to stall litigation over the withheld documents and redactions by any means necessary. Indeed, the government rarely missed an opportunity to request a protracted briefing schedule or extension. *See* ECF No. 18 ¶¶ 7, 8; ECF No. 29 ¶¶ 12, 19; ECF No. 30. It then took advantage of this Court's patience, requiring multiple rounds of summary judgment papers just to establish the factual predicates for its most hotly contested redactions, *which the government had the burden to prove*. *See* ECF No. 28 at 1; ECF No. 38 at 31–32. And when King & Spalding's persistence finally paid off, the government took nearly *six more months* to produce the remaining records even after this Court ruled they must release the remaining documents with only minor redactions. *See* Exhibit H. On January 22, 2020, EOUSA finally made a production of seventy-nine pages with very minor redactions. *Id*. EOUSA's letter makes clear that *all documents previously withheld in full were now being turned over with only minor redactions* and some documents that were previously released with redactions were being re-released with modified redactions. The government was finally forced to give way and *not one single responsive document that was disputed in this case was withheld in full by EOUSA* (at least not that the government told King & Spalding about in its release letters, *see* Exhibits C–H). King & Spalding's victory is complete.

Although late-coming, the released documents have shed light on matters of public concern. As King & Spalding long suspected, the government attorneys spearheading the Abiomed investigation acted at the urging of a former colleague who had left the Justice Department for private practice. *See* Exhibit H, Items 1, 9, 10, 11, 12, & 16. That attorney's firm, in turn, represented one or more private interests with obvious stake in frustrating Abiomed's business. *Id.*, Item 12 (Letter to FDA dated December 21, 2010). Accordingly, by providing

this window into the government's troubling prosecutorial conduct, this lawsuit has doubtless furthered the public interests Congress enacted FOIA to serve.

In light of the public interest in these documents, King & Spalding's private burdens litigating this case, and the government's obdurate behavior, King & Spalding now moves for an award of reasonable attorneys' fees and costs under FOIA's statutory fee-shifting provision.

ARGUMENT

The Court should award King & Spalding reasonable fees and costs for persisting against a stubborn government defense, despite King & Spalding's narrow and reasonable FOIA request, and bringing valuable public records to light. To receive such an award under FOIA, a party must be both "eligible" for fees and "entitled" to fees. *See, e.g.*, *Brayton v. Office of U.S. Trade Representative*, 641 F.3d 521, 524 (D.C. Cir. 2011). Here, King & Spalding is eligible for fees because of its early success prompting government productions and because of its ultimate victory on highly contested issues. The firm is likewise *entitled* to fees because (1) its FOIA requests concerned matters of public interest, (2) it persisted in this litigation notwithstanding its private incentive to fold, and (3) the government should face some consequence for its obdurate behavior. Finally, King & Spalding's requested award is reasonable in light of the time and effort spent dogging the government through numerous obfuscations and delays over the past three-and-a-half years.

I. King & Spalding Has Won a Complete Victory in this Litigation.

As a threshold matter, King & Spalding is eligible for an award of fees and costs under the FOIA statute. Statutory eligibility extends to any party that "substantially prevail[s]" against the government in a FOIA case. 5 U.S.C. § 552(a)(4)(E)(i). To "substantially prevail[]," a party must obtain "a judicial order," "an enforceable written agreement or consent decree," or "a

voluntary or unilateral change in position by the agency." *Id.* § 552(a)(4)(E)(ii)(I)–(II). King & Spalding has "substantially prevailed" in multiple respects.

First, King & Spalding won this case at the summary judgment stage. Naturally, a party that receives judgment on the merits has "substantially prevailed." *Judicial Watch, Inc. v. FBI*, 522 F.3d 364, 367 (D.C. Cir. 2008). In this case, the firm obtained multiple orders from this Court granting summary judgment in its favor. On September 7, 2018, after two rounds of summary judgment briefing, the Court ordered release of sixty-seven pages of responsive documents that the government had previously withheld in full. *See* ECF No. 38 at 40. Several months later, after another round of briefing, the Court granted King & Spalding's remaining production requests "in full." ECF No. 62 at 1–2. This included requests for information that the Court had previously rejected as exempt, only to reconsider in King & Spalding's favor. *See id.* at 5–11. As a result, the government eventually produced all the disputed documents with only minor redactions. Exhibits C–H.

Second, King & Spalding's persistence in this case caused a voluntary shift in the government's sputtering response to the initial FOIA requests. Even absent final judgment on the merits, a plaintiff can "substantially prevail" by "caus[ing] a change in the agency's position regarding the production of requested documents." *Grand Canyon Tr. v. Bernhardt*, No. 18-5232, 2020 WL 253019, at *4 (D.C. Cir. Jan. 17, 2020) (per curiam); *see also Brayton*, 641 F.3d 521, 524–25 (D.C. Cir. 2011) (describing congressional reinstatement of the "catalyst theory" through 5 U.S.C. § 552(a)(4)(E)). Such was the case here. Prior to the initiation of this lawsuit, and for some time thereafter, the government Departments named as defendants had produced *zero* documents in response to King & Spalding's April 2016 FOIA requests despite King & Spalding's very manageable and reasonable FOIA requests. *See* ECF No. 13 ¶ 9. Indeed, not until

December 2016—four months after King & Spalding filed suit and eight months after the initial FOIA requests—did the government begin producing the hundreds of pages of documents unquestionably due to King & Spalding under FOIA. *See* ECF No. 14 ¶ 6b; ECF No. 18 ¶ 4; Exhibits C–F. It then supplemented those documents with an additional production in April 2017. *See* ECF No. 29 ¶ 4; Exhibit G. Thus, even before King & Spalding won judgment on the remainder of the contested requests, it had already "substantially prevailed" for purposes of FOIA fee-shifting.

In sum, King & Spalding's initial success and ultimate victory make it eligible for an award of attorneys' fees and costs under the statute.

II. King & Spalding Deserves an Award of Reasonable Fees, Costs, and Expenses.

In addition to being fee-eligible, King & Spalding has *earned* a fee award by forcing government transparency in the face of government intransigence. In determining whether an eligible FOIA plaintiff should actually receive fees and costs, this Court must consider "'(1) the public benefit derived from the case; (2) the commercial benefit to the plaintiff; (3) the nature of the plaintiff's interest in the records; and (4) the reasonableness of the [government's] withholding' of the requested documents." *McKinley v. Fed. Hous. Fin. Agency*, 739 F.3d 707, 711 (D.C. Cir. 2014) (quoting *Tax Analysts v. DOJ*, 965 F.3d 1092, 1093 (D.C. Cir. 1992)). Here, the public will benefit substantially from learning the cozy relationship that prompted the government to investigate Abiomed. And even if King & Spalding had some private stake in this litigation (as most plaintiffs do) that fact cannot preclude an award under this Circuit's precedents. This is especially true where, as here, the government has multiplied the costs of litigation—to both the plaintiff and the public—by stubbornly protracting it over the course of several years and multiple rounds of merits briefing. In light of these circumstances, the Court should grant King & Spalding's fee request.

A. This Lawsuit Benefits the Public.

King & Spalding's pursuit of information related to the 2012 Abiomed investigation benefits the public at large. This Court's public-benefit consideration "requires an *ex ante* assessment of the potential public value of the information requested." *Morley v. CIA*, 810 F.3d 841, 844 (D.C. Cir. 2016). Such potential value depends on the likelihood that the requested information will bear on matters of public concern. *See Cotton v. Heyman*, 63 F.3d 1115, 1120 (D.C. Cir. 1995). Those matters include the exercise of prosecutorial judgment, which is a core executive function. *See Citizens for Responsibility & Ethics in Washington v. DOJ*, 142 F. Supp. 3d 1, 7 (D.D.C. 2015); *cf. People for Ethical Treatment of Animals v. NIH*, 745 F.3d 535, 545 (D.C. Cir. 2014) ("[T]he circumstances would directly implicate the cognizable public interest in shedding light on NIH's investigatory processes.").

In this case, King & Spalding sought information likely to bear on that very concern. As mentioned above, this case began with requests for information regarding the 2012 Abiomed investigation. *See* ECF No. 20 ¶¶ 2, 10. Specifically, King & Spalding wanted to know what persons or entities communicated with the government about Abiomed prior to the investigation, as well as what information those persons or entities relayed. *See id.* From the very beginning, there was a substantial likelihood that this information would show the impetus for the investigation or, at the very least, the type of fact-gathering government regulators and attorneys were engaged in.

This was no goose chase, either. The information made public as the result of this lawsuit shows that federal prosecutors initiated a multi-year, costly, and ultimately unavailing investigation at the behest of their former colleague. Exhibit H, Items 1, 9, 10, 11, 12, & 16. That colleague's firm acted on behalf of a still unnamed third party, most probably a competitor of Abiomed. *Id.*, Item 12 (Letter to FDA dated December 21, 2010). Important standing alone,

this information takes on added significance and public consequence in light of the increased short-selling of Abiomed stock just prior to the public announcement of the investigation. ECF No. 22 at 7–8. This information offers a troubling peek behind the curtain of the Justice Department and the manner in which third parties can influence enforcement and cause reputational and financial damage to a competitor simply through an investigation.

B. King & Spalding's Personal Interests Do Not Preclude Relief.

Although King & Spalding had some private interest in these records and may reap some individual benefit from their release, those considerations still support a fee award here. In exercising FOIA fee-shifting authority, courts typically consider the plaintiff's private interests and benefits together. *See, e.g.*, *Davy v. CIA*, 550 F.3d 1155, 1160 (D.C. Cir. 2008). This makes good sense, as both concerns aim to "assess whether a plaintiff has 'sufficient private incentive to seek disclosure' without attorney's fees." *Id.* (quoting *Tax Analysts*, 965 F.2d at 1095). Of course, many—if not most—FOIA plaintiffs have *some* private interest in the records they seek and stand to gain *some* commercial benefit from disclosure. *See, e.g.*, *id.* Courts must therefore take care to weigh those interests in their appropriate context, accounting for the strength (or weakness) of any private incentive, the overall cost of the litigation, and the relative importance of other factors. *Cf. Reyes v. U.S. Nat'l Archives & Records Admin.*, 356 F. Supp. 3d 155, 165–66 (D.D.C. 2018) (finding the plaintiff's limited financial incentives, considered in context, minimized the importance of the private-interest factors).

In this case, context councils in favor of giving minimal weight to King & Spalding's private incentives. As explained more fully below, this lawsuit has required significant investments of time and attention over its long duration. *See infra* Part III. It need not have been so costly, but the government ensured that it was. *See infra* Part II.C. Thus, whereas the firm did eventually carry through and prevail, it is far from clear that future parties in King &

Spalding's situation will have proper incentives to do so absent some prospect of a fee award. Indeed, if the government is allowed to protract a FOIA suit like this one without any risk of fee-shifting, it will always enjoy the option to price all but the most selfless and deep-pocketed private interests out of FOIA's entitlements. This Court should avoid setting such a precedent, which would clearly undercut FOIA's basis purpose.

C. The Government's Evasions and Foot-Dragging Warrant Fee Shifting.

Finally, the government's intransigence justifies a fee award, especially in light of King & Spalding's reasonable FOIA requests that were for a finite time, avoided any deliberative materials, and excluded Abiomed's correspondence with the government. The Court's last fee-shifting consideration should account for the government's conduct. *See, e.g.*, *Reyes*, 356 F. Supp. 3d at 166–68. To be sure, courts generally will not fault the government for attempting to withhold information under "reasonable" exemption claims. *Davy*, 550 F.3d at 1162 (quoting *Tax Analysts*, 965 F.2d at 1096). But the law also does not abide government "recalcitrant[ce] in opposition to a valid claim" or any other "obdurate behavior," especially here with such reasonable requests. *Id.* (quoting *LaSalle Extension Univ. v. FTC*, 627 F.2d 481, 486 (D.C. Cir. 1980)). The government has exhibited such obdurateness here.

To begin, this matter might not have required litigation at all but for the government's lack of responsiveness to King & Spalding's narrowly-tailored FOIA requests. Indeed, King & Spalding waited nearly four months between submitting the requests and filing suit. *See* ECF No. 1; ECF No. 20 at ¶¶ 2, 10. In that window, the government offered no basis for withholding documents aside from asserting that the Abiomed investigation was ongoing—a claim that was obviously false and eventually abandoned. *See* ECF No. 1 ¶ 12, ECF No. 10 ¶ 12.

Then, after the suit was filed, the government's delay tactics began in earnest. The government first sought an eighteen-day extension of time to answer the complaint. *See* ECF No. 9. It then asked for more time to file the initial joint status report. *See* ECF No. 12. When the parties finally did produce the report in late October 2016, the government refused to commit to a production deadline and instead asked to file another status report in forty-five days. *See* ECF No. 13 ¶ 8; *see also id.* ¶ 9 (noting King & Spalding's opposition to the delay). In that next report, the government for the first time asserted that King & Spalding had failed to exhaust its administrative remedies with respect to some of the requests. *See* ECF No. 14 ¶¶ 4, 11. At the same time, the government requested another thirty-day extension to produce responsive documents. *See* ECF No. 15. In the end, it was not until April 2017—a full year after the initial FOIA requests—that King & Spalding finally received all of the documents the government *agreed* King & Spalding was entitled to under FOIA. *See* ECF No. 29 ¶ 4.

The government then continued to draw this litigation out with respect to the contested redactions. In the January 2017 status report, the government requested a summary judgment briefing schedule nearly two months longer than the one King & Spalding asked for. *See* ECF No. 18 ¶¶ 7, 8. Then, following a full round of summary judgment briefing, the Court recognized that the government had not supplied the factual details necessary to support its exemption claims. *See* ECF No. 28 at 1 ("Because [the government's] affiants do not answer th[e] question [of whether the source of redacted records is an entity or an individual], the court cannot assess whether the … withholdings are appropriate at this time."). Of course, permitting the government to supplement the record only led to more delays. The government asked for a new briefing schedule nearly three months beyond what King & Spalding requested. *See* ECF No. 29 ¶¶ 12, 19. When the Court struck a compromise, the government then asked for a thirteen-day extension

on *that* schedule. *See* ECF No. 30. Then, after the second round of summary judgment briefing, the Court held that the government's evidence still could not justify redacting the name of any private law firm associated with the Abiomed investigation. *See* ECF No. 38 at 31–32. This bears repeating: Nearly *two-and-a-half years* after King & Spalding submitted these FOIA requests, the government *still had yet to establish factual predicates* for some of the principal exemptions it claimed should apply.

Even if those exemptions had been valid, it still could not excuse these persistent evasions. Indeed, the attorney and law firm names represent an extremely narrow slice of the information that the government wrongly withheld. *Cf. Reyes*, 356 F. Supp. 3d at 167–68 (finding that staffing issues and administrative delays cannot excuse a government failure to produce uncontested documents); *Piper v. DOJ*, 339 F. Supp. 2d 13, 23 (D.D.C. 2004) (looking to all of the released documents to determine the reasonableness of the government's conduct). And when this Court finally did order the information released, the government took nearly *six more months* to do so, opting instead to force King & Spalding into briefing a needless motion to amend the judgment that just rehashed the government's same tired arguments. *See* ECF Nos. 66–70.

The reasonableness of the government's legal position thus pales in comparison to its unreasonable and obdurate stall tactics. Those tactics will go unchecked unless this Court awards King & Spalding reasonable fees and costs for its trouble.

III. King & Spalding Has Requested a Reasonable Fee Award.

King & Spalding requests an award of $664,955.87 in fees and $5,925.67 in costs and expenses, which is reasonable under the circumstances of this case. Under FOIA, a reasonable fee award must account for (1) the number of hours reasonably expended; (2) the reasonable hourly rate; and (3) incorporation of appropriate multipliers. *Save Our Cumberland Mountains, Inc. v. Hodel*, 857 F.2d 1516, 1517 (D.C. Cir. 1988). This includes the time and effort expended

requesting the fees themselves. *See, e.g.*, *Noxell Corp. v. Firehouse No. 1 Bar-B-Que Rest.*, 771 F.2d 521, 528 (D.C. Cir. 1985); *Judicial Watch*, 878 F. Supp. 2d at 240. King & Spalding thus requests such reasonable amounts as follows:

- $664,955.87 for attorneys' fees incurred during three-and-a-half years of litigation, through January 2020, before this Court, including multiple rounds of summary judgment briefing, and work on recovering attorneys' fees;
- $5,925.67 for litigation costs incurred during litigation before this Court; and
- Additional reasonable fees and expenses incurred and projected to incur to litigate this motion, include billing in February 2020 onward, to be determined at the conclusion of proceedings.

In support of these figures, King & Spalding will move to file sealed documents detailing the attorneys, rates, tasks, time, and other costs and expenses devoted to this litigation over the course of its long history.

CONCLUSION

For the foregoing reasons, King and Spalding respectfully requests Court grant this motion for reasonable attorneys' fees and costs under FOIA.

Dated: February 3, 2020

Respectfully submitted,

/s/ John C. Richter
John C. Richter, D.C. Bar No. 1014001
KING & SPALDING LLP
1700 Pennsylvania Ave., NW
Suite 200
Washington, DC 20006
Telephone: (202) 626-5617
Counsel for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on February 3, 2020, I electronically filed the foregoing Motion For Attorneys' Fees and Expenses, and the proposed order, and accompanying exhibits with the Clerk of Court using the CM/ECF system, which will send a notice of electronic filing to all counsel of record who have consented to electronic notification.

/s/ John C. Richter
John C. Richter, D.C. Bar No. 1014001
KING & SPALDING LLP
1700 Pennsylvania Ave., NW
Suite 200
Washington, DC 20006
Telephone: (202) 626-5617
Counsel for Plaintiff

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KING & SPALDING LLP **Plaintiff,** **v.** **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.** **Defendants.**	**Case No. 16-cv-01616 (APM)**

[PROPOSED] ORDER

This matter is before the Court on the motion of plaintiff King & Spalding LLP for attorneys' fees and expenses. This matter having been considered by the Court, the motion is GRANTED.

It is hereby ORDERED that King & Spalding is awarded _____ in attorney fees.

It is hereby ORDERED that King & Spalding is awarded _____ in costs.

Signed this _____ day of _____, 2020.

_____

Amit P. Mehta
UNITED STATES DISTRICT JUDGE

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT A
To Motion for Attorneys' Fees

FILED UNDER SEAL

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT B
To Motion for Attorneys' Fees

FILED UNDER SEAL

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT C
To Motion for Attorneys' Fees

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs /Freedom of Information Group

Refer to: Control Number 042220167001 and PIN KYMJ

DEC 0 5 2016

Alexander Haas
King & Spalding, LLP
1700 Pennsylvania Ave., NW Ste. 200
Washington, DC 20006

Dear Mr. Haas:

This is an interim response to your April 18, 2016 Freedom of Information Act (FOIA) request for the following records:

1. All documents Between January 1, 2013 and October 31, 2012, provided to any agency of the Federal Government from any individual, corporation, or other private party other than Abiomed, Inc ("Abiomed") that concern, discuss or refer to Abiomed;
2. All documents between January 1, 2012 and October 31, 21012, provided by Department of Health and Human Services ("HHS"),including(i) the HHS Ofifice of Inspector General, (ii) the Food and Drug Administration ("FDA"), or (iii) any HHS or FDA employee affiliated with the HEAT task force for DOJ or HHS Medicare Fraud Strike Force, to the U.S. States Attorney's Office for the District of Columbia, the Civil Division of the Department of Justice, or any other office component or office within DOJ, that were initially obtained or received from any individual, corporation, or other private party other than Abiomed, Inc ("Abiomed") that concern, discuss or refer to Abiomed;
3. All documents Between January 1, 2013 and October 31, 2012, provided to any agency of the Federal Government from any individual, corporation, or other private party other than Abiomed, related in whole or in part to the issuance of Health insurance Portability and Accountability Act subpoena issued by the U.S. States Attorney's Office for the District of Columbia to Abiomed from January 1, 2012 and October 31, 21012.

Our agency initiated a search for records falling within the scope of your request, and located the 57 pages on the enclosed disk. To ensure that we have fully complied with the request, CMS is continuing to confirm that its search for responsive documents is complete
We are releasing this portion of the responsive records to you in their entirety, without deletions.

Sincerely yours,

Joseph Tripline

Joseph Tripline
Director, Division of FOIA Analysis – A
Freedom of Information Group

Enclosure

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT D
To Motion for Attorneys' Fees

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs /Freedom of Information Group

Refer to: Control Number 042220167001 and PIN KYMJ

December 8, 2016

Alexander Haas
King & Spalding, LLP
1700 Pennsylvania Ave., NW Ste. 200
Washington, DC 20006

Dear Mr. Haas:

This is the final response to your April 18, 2016 Freedom of Information Act (FOIA) request for the following records:

1. All documents Between January 1, 2013 and October 31, 2012, provided to any agency of the Federal Government from any individual, corporation, or other private party other than Abiomed, Inc ("Abiomed") that concern, discuss or refer to Abiomed;
2. All documents between January 1, 2012 and October 31, 21012, provided by Department of Health and Human Services ("HHS"),including(i) the HHS Office of Inspector General, (ii) the Food and Drug Administration ("FDA"), or (iii) any HHS or FDA employee affiliated with the HEAT task force for DOJ or HHS Medicare Fraud Strike Force, to the U.S. States Attorney's Office for the District of Columbia, the Civil Division of the Department of Justice, or any other office component or office within DOJ, that were initially obtained or received from any individual, corporation, or other private party other than Abiomed, Inc ("Abiomed") that concern, discuss or refer to Abiomed;
3. All documents Between January 1, 2013 and October 31, 2012, provided to any agency of the Federal Government from any individual, corporation, or other private party other than Abiomed, related in whole or in part to the issuance of Health insurance Portability and Accountability Act subpoena issued by the U.S. States Attorney's Office for the District of Columbia to Abiomed from January 1, 2012 and October 31, 21012.

Our agency initiated a search for records falling within the scope of your request, and located the 20 pages on the enclosed disk. To ensure that we have fully complied with the request, CMS is continuing to confirm that its search for responsive documents is complete
We are releasing this portion of the responsive records to you in their entirety, without deletions.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

Michael Bell
HHS FOIA Public Liaison
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Telephone: (202) 260-0793
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

Sincerely yours,

Joseph Tripline

Joseph Tripline
Director, Division of FOIA Analysis – A
Freedom of Information Group

Enclosure

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT E
To Motion for Attorneys' Fees

U.S. Department of Justice

Executive Office for United States Attorneys

Freedom of Information and Privacy Staff

Suite 7300, Bicentennial Building
600 E Street, NW
Washington, DC 20530

(202) 252-6020
FAX (202) 252-6047

December 23, 2016

John Richter
King & Spalding LLP
1700 Pennsylvania Ave., NW
Ste. 200
Washington, District of Columbia 20006

Re: Request Number: FOIA-2016-02264
Date of Receipt: April 14, 2016
Subject of Request: Abiomed/DC

IN LITIGATION

Dear Mr. Richter:

Your request for records under the Freedom of Information Act/Privacy Act has been processed. This letter constitutes a reply from the Executive Office for United States Attorneys, the official record-keeper for all records located in this office and the various United States Attorneys.

To provide you with the greatest degree of access authorized by the Freedom of Information Act and the Privacy Act, we have considered your request in light of the provisions of both statutes.

The records you seek are located in a Privacy Act system of records that, in accordance with regulations promulgated by the Attorney General, is exempt from the access provisions of the Privacy Act. 28 CFR § 16.81. We have also processed your request under the Freedom of Information Act and are making all records required to be released, or considered appropriate for release as a matter of discretion, available to you. This letter is a [X] partial [ ] full denial.

Enclosed please find:

344 page(s) are being released in full (RIF);
_____ page(s) are being released in part (RIP);
51 page(s) are withheld in full (WIF). **The redacted/withheld documents were reviewed to determine if any information could be segregated for release.**
8 page(s) were found to be duplicates.

The exemption(s) cited for withholding records or portions of records are marked below. An enclosure to this letter explains the exemptions in more detail.

(B)(5)
(B)(6)
(B)(7)(c)
(B)(7)(d)

[ ] In addition, this office is withholding grand jury material which is retained in the District.

[ ] A review of the material revealed:

[ ] Our office located records that originated with another government component. **These records were found in the U.S. Attorney's Office files.** These records will be referred to the following component(s) listed for review and direct response to you:

[ ] There are public records which may be obtained from the clerk of the court or this office, upon specific request. If you wish to obtain a copy of these records, you must submit a new request. These records will be provided to you subject to copying fees.

[ ] Please note that your original letter was split into separate files ("requests"), for processing purposes, based on the nature of what you sought. Each file was given a separate Request Number (listed below), for which you will receive a separate response:

[X] See additional information attached.

If you are not satisfied with my response to this request, you may administratively appeal by writing to the Director, Office of Information Policy (OIP), United States Department of Justice, Suite 11050, 1425 New York Avenue, NW, Washington, DC 20530-0001, or you may submit an appeal through OIP's FOIAonline portal by creating an account on the following web site: https://foiaonline.regulations.gov/foia/action/public/home. Your appeal must be postmarked or electronically transmitted within ninety (90) days of the date of my response to your request. If you submit your appeal by mail, both the letter and the envelope should be clearly marked "Freedom of Information Act Appeal."

You may contact our FOIA Public Liaison at the telephone number listed above for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Sincerely,

Kevin Krebs
Assistant Director

Enclosure(s)

Form No. 021nofee – 12/15

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT F
To Motion for Attorneys' Fees

U.S. Department of Justice

Executive Office for United States Attorneys

Freedom of Information and Privacy Staff

Suite 7300, Bicentennial Building
600 E Street, NW
Washington, DC 20530

(202) 252-6020
FAX (202) 252-6047

December 23, 2016

John Richter
King & Spalding LLP
1700 Pennsylvania Ave., NW
Ste. 200
Washington, District of Columbia 20006

Re: Request Number: REFF-2016-02987
Date of Receipt: June 7, 2016
Subject of Request: Abiomed, Inc.

Dear Mr. Richter:

Your request for records under the Freedom of Information Act/Privacy Act has been processed. This letter constitutes a reply from the Executive Office for United States Attorneys, the official record-keeper for all records located in this office and the various United States Attorneys.

To provide you with the greatest degree of access authorized by the Freedom of Information Act and the Privacy Act, we have considered your request in light of the provisions of both statutes.

The records you seek are located in a Privacy Act system of records that, in accordance with regulations promulgated by the Attorney General, is exempt from the access provisions of the Privacy Act. 28 CFR § 16.81. We have also processed your request under the Freedom of Information Act and are making all records required to be released, or considered appropriate for release as a matter of discretion, available to you. This letter is a [x] partial [ ] full denial.

Enclosed please find:

27 page(s) are being released in full (RIF);
_____ page(s) are being released in part (RIP);
16 page(s) are withheld in full (WIF). **The redacted/withheld documents were reviewed to determine if any information could be segregated for release.**

The exemption(s) cited for withholding records or portions of records are marked below. An enclosure to this letter explains the exemptions in more detail.

(B)(5)

(B)(6)
(B)(7)(c)
(B)(7)(d)

[ ] In addition, this office is withholding grand jury material which is retained in the District.

[ ] A review of the material revealed:

[ ] Our office located records that originated with another government component. **These records were found in the U.S. Attorney's Office files.** These records will be referred to the following component(s) listed for review and direct response to you:

[ ] There are public records which may be obtained from the clerk of the court or this office, upon specific request. If you wish to obtain a copy of these records, you must submit a new request. These records will be provided to you subject to copying fees.

[ ] Please note that your original letter was split into separate files ("requests"), for processing purposes, based on the nature of what you sought. Each file was given a separate Request Number (listed below), for which you will receive a separate response:

[x] See additional information attached.

If you are not satisfied with my response to this request, you may administratively appeal by writing to the Director, Office of Information Policy (OIP), United States Department of Justice, Suite 11050, 1425 New York Avenue, NW, Washington, DC 20530-0001, or you may submit an appeal through OIP's FOIAonline portal by creating an account on the following web site: https://foiaonline.regulations.gov/foia/action/public/home. Your appeal must be postmarked or electronically transmitted within ninety (90) days of the date of my response to your request. If you submit your appeal by mail, both the letter and the envelope should be clearly marked "Freedom of Information Act Appeal."

You may contact our FOIA Public Liaison at the telephone number listed above for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Sincerely,

Kevin Krebs
Assistant Director

Enclosure(s)

Form No. 021nofee – 12/15

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT G
To Motion for Attorneys' Fees

U.S. Department of Justice

Executive Office for United States Attorneys

Freedom of Information and Privacy Staff

Suite 7300, Bicentennial Building
600 E Street, NW
Washington, DC 20530

(202) 252-6020
FAX (202) 252-6047

April 5, 2017

John Richter
King & Spalding LLP
1700 Pennsylvania Ave., NW
Ste. 200
Washington, District of Columbia 20006

Re: Request Number: FOIA-2016-02264
Date of Receipt: April 14, 2016
Subject of Request: Abiomed/DC

Dear Mr. Richter:

Recently, additional records were located that are responsive to the above-referenced Freedom of Information Act/Privacy request. These records have been reviewed for a supplemental release to you. This letter constitutes a reply from the Executive Office for United States Attorneys, the official record-keeper for all records located in this office and the various United States Attorneys.

To provide you with the greatest degree of access authorized by the Freedom of Information Act and the Privacy Act, we have considered your request in light of the provisions of both statutes.

The records you seek are located in a Privacy Act system of records that, in accordance with regulations promulgated by the Attorney General, is exempt from the access provisions of the Privacy Act. 28 CFR § 16.81. We have also processed your request under the Freedom of Information Act and are making all records required to be released, or considered appropriate for release as a matter of discretion, available to you. This letter is a [X] partial [ ] full denial.

Enclosed please find:

__46__ page(s) are being released in full (RIF);
__33__ page(s) are being released in part (RIP);
__0__ page(s) are withheld in full (WIF). **The redacted/withheld documents were reviewed to determine if any information could be segregated for release.**

A portion of one of the records that is being released in part, and five additional pages, were reviewed and found to be duplicates of records that were previously withheld.

The exemption(s) cited for withholding records or portions of records are marked below. An enclosure to this letter explains the exemptions in more detail.

(B)(4)
(B)(5)
(B)(6)
(B)(7)(c)
(B)(7)(d)

[ ] In addition, this office is withholding grand jury material which is retained in the District.

[X] A review of the material revealed:

[ ] Our office located records that originated with another government component. **These records were found in the U.S. Attorney's Office files.** These records will be referred to the following component(s) listed for review and direct response to you: Department for Health and Human Services/Food and Drug Administration.

[ ] There are public records which may be obtained from the clerk of the court or this office, upon specific request. If you wish to obtain a copy of these records, you must submit a new request. These records will be provided to you subject to copying fees.

[X] Our office located records in which contained information that is of interest to other agencies/components of the Department of Justice. Those records consisted of 48 pages, which were submitted to the Department for Health and Human Services/Food and Drug Administration, and four pages to the Civil Division Office for the Department of Justice. Upon completion of their review of these records, our office will directly respond to you. Pursuant to an email that was submitted by you to AUSA Jeremy Simon, at the U.S. Attorney's Office for D.C., you agreed that certain records, which were originally submitted to the FDA for its review, would not be responsive to your request. Therefore, those pages were not processed and are not a part of this release.

[ ] Please note that your original letter was split into separate files ("requests"), for processing purposes, based on the nature of what you sought. Each file was given a separate Request Number (listed below), for which you will receive a separate response:

[X] See additional information attached.

If you are not satisfied with my response to this request, you may administratively appeal by writing to the Director, Office of Information Policy (OIP), United States Department of Justice, Suite 11050, 1425 New York Avenue, NW, Washington, DC 20530-0001, or you may submit an appeal through OIP's FOIAonline portal by creating an account on the following web site: https://foiaonline.regulations.gov/foia/action/public/home. Your appeal must be postmarked or electronically transmitted within ninety (90) days of the date of my response to your request. If you submit your appeal by mail, both the letter and the envelope should be clearly marked "Freedom of Information Act Appeal."

You may contact our FOIA Public Liaison at the telephone number listed above for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Sincerely,

Kevin Krebs
Assistant Director

Enclosure(s)

Form No. 021nofee – 12/15

King & Spalding v. HHS, et al. **(Case No. 16-cv-1616)**

EXHIBIT H
To Motion for Attorneys' Fees

U.S. Department of Justice

Executive Office for United States Attorneys
Freedom of Information Act & Privacy Act Staff

Bicentennial Building
600 E Street, NW, Suite 7300
Washington, DC 20530

(202) 252-6020
(202) 252-6047 Fax

January 22, 2020

VIA FEDERAL EXPRESS/ELECTRONIC MAIL
John Richter
King & Spalding LLP
1700 Pennsylvania Ave., NW
Ste. 200
Washington, District of Columbia 20006
jrichter@kslaw.com>

Re: Request Numbers: FOIA-2016-02264/ REFF-2016-02987
Dates of Receipt: April 14, 2016/ June 7, 2016
Subject of Request: Abiomed/DC

Dear Mr. Richter:

We are writing this letter to provide you with a supplemental release of records consistent with the Court's Memorandum and Opinion Orders of September 7, 2018 and July 24, 2019. Pursuant to those decisions, redactions pursuant to Exemptions (b)(6) and (b)(7)(C) of the FOIA will remain in place to protect the names and identifying information of government personnel, third parties (not including the names and identifying information of the private attorney and law firm discussed in the Court's decision of July 24, 2019), and a telephonic passcode. The names of third parties and government personnel that are contained on records that are publicly available are being released (e.g. items retrievable on the internet).

FOIA-2016-02246

Pursuant to this FOIA request, this release includes the 51 pages that were previously withheld in full, as referenced in the release letter dated December 23, 2016, which were also captured as Items 1-12 on EOUSA's Corrected and Supplemental Vaughn Index. Regarding the document referenced as Item Two in this packet – an email dated March 1, 2012 from "Perfmail digest – you will see a redaction at the top that document. That redaction was not made by EOUSA.

As to EOUSA's release on April 5, 2017, which is captured as Items 13-16 on EOUSA's Corrected and Supplemental Vaughn Index, please note that EOUSA is re-releasing a single-paged email, dated September 20, 2012, with regard to Item Thirteen, which consists of an additional redaction of the name of a government employee that was inadvertently included in

the original production. Regarding the 27 pages of attachments described at Item 13 on the Corrected and Supplemental Vaughn Index, those pages do not contain any redactions ordered to be removed by the Court's decisions; therefore, EOUSA is not reproducing here.

Regarding the Items previously referenced as Items 14 to 16 on EOUSA's Corrected and Supplemental Vaughn Index, we have removed the redactions that were previously made pursuant to the FOIA that once protected the name and contact information of the private attorney and the name of law firm, as ordered by the Court.

For your convenience, each document is separated by a cover page, which corresponds to numerical order of how the document appears on EOUSA's Corrected and Supplemental Vaughn Index (e.g. the first document is referenced as "Item One").

REFF-2016-02987

On December 23, 2016, we stated in our release letter that EOUSA was fully releasing 27 pages, and fully withholding 16 pages. Today, we discovered an administrative error showing that two pages which were previously withheld in full should have been fully released to you in the original production. Accordingly, 29 pages should have been released to you in full, and 14 pages should have been withheld in full on December 23, 2016. The two pages that were erroneously withheld in that production are now being provided to you pursuant to this FOIA request number. They may be found behind the cover page "REFF-2016-02987 – Additional Pages." Also, we note that these two pages were already released to you on December 23, 2016, in FOIA-2016-02242. Regarding the 14 pages previously withheld in full in this referral on December 23, 2016, those records are among the 51 pages now being released to you in FOIA-2016-02264 (Items One through Three). Nevertheless, we are releasing them to you in this FOIA request number (REFF-2016-02987) with the same redactions pursuant to Exemptions (b)(6) and (b)(7)(C) of the FOIA. These records may be found under the cover page "REF-2016-02987 – Release in Full."

In total, the enclosed release consists of 79 pages (excluding the cover pages), with 26 pages being fully released, and 53 pages with redactions in part pursuant to Exemptions (b)(6), (b)(7)(C) (EOUSA) and an additional redaction pursuant to (b)(7)(F) (pursuant to redactions made by the FDA on Item Fourteen, which was produced to you on April 5, 2017). If you have any comments regarding the content of this production, please contact our litigating attorney, AUSA Jeremy Simon, at (202) 252-2528.

Sincerely,

Kevin Krebs
Assistant Director

Enclosure(s)

ITEM ONE

McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
Phone: 312.849.8100
Fax: 312.849.3690
www.mcguirewoods.com

David J. Pivnick
Direct: 312.750.3585

McGUIREWOODS

dpivnick@mcguirewoods.com
Direct Fax: 312.698.4539

May 18, 2012

VIA EMAIL AND FEDERAL EXPRESS

(b) (6), (b) (7)
Assistant United States Attorney
Criminal Division
555 Fourth Street, NW
Washington, DC 20530
Email: (b) (6), (b) (7)(C)

Re: Update on Abiomed's Activities

Dear (b) (6),

We write to provide you with an update on Abiomed's activities subsequent to our meeting in February, as well as provide you with some additional materials that we obtained after that meeting. This letter attaches and provides a brief description of those materials. We believe that the materials reflect Abiomed's off-label promotion of the Impella and its emphasis on the reimbursements that are purportedly attainable through the use of the Impella®.

1. CGS Guidance on Coding

On May 10, 2012, CGS, which is the Medicare carrier for Kentucky and Ohio, issued guidance relating to the coding for the Impella®. This guidance noted that the CGS Administrators Medical Review Department has seen claims billed with code 33799 for the insertion of the Impella®. The CGS guidance noted that the Impella® "is not a ventricular assist device designed to provide transition to implant; it is designed to assist during revascularization procedures for a short term (6-8 hours)." In light of the intended short term use of the Impella®, CGS instructed providers to use CPT code 92970 in reporting the insertion of the Impella®. The CGS guidance then noted that "**Impella® procedures coded under any other CPT code will be denied as a billing error.**" The CGS guidance also noted that there was no separate reimbursement for the removal of the Impella® in light of its short-term nature.

2. Abiomed's May 2012 PowerPoint Presentation

This document reflects coding and reimbursement information that we understand was disseminated by Abiomed as well as a recent PowerPoint presentation we understand was given by Abiomed. The coding and reimbursement document provides information on the various codes that can be used with Impella® and the reimbursements associated with those codes, the

MCC's and CC's that are commonly used with the Impella® 2.5, and the CPT codes that can be used in connection with the insertion and removal of the Impella®.

The PowerPoint presentation includes a general description of the Impella® and its function. The presentation also includes a discussion of hospital reimbursements with the Impella®, including a slide that notes: "Payer mix: majority are Medicare. . . ." That same slide includes what appears to be information regarding the reimbursement for PCI procedures – which are procedures that are outside of Abiomed's FDA clearance for the Impella®. Similarly, there are other discussions of what appear to be off-label uses of the Impella®, including the discussion of prophylactic uses of the Impella. The PowerPoint also includes several slides that relate to the Protect II study, which appear to have originated at the 2011 TCT conference. These slides again provide data on the purported results of the Protect II, including at 90 days, despite the trial's primary endpoint being at 30 days. Abiomed is seemingly continuing to rely on this study for promotional purposes even though the study did not meet its 30 day primary endpoint and was terminated in or around December 2010. These points are not disclosed in the presentation. Further, the slides contain reimbursement information that appears to conflict with the recent guidance from CGS above (e.g., coding for removal of the Impella® and coding for a ventricular assist device (VAD) as opposed to the code for a short term percutaneous catheter).

3. Abiomed's May 2012 Financial Reports

On May 16, 2012, Abiomed announced its fourth quarter results for fiscal 2012, which included revenue of $37.3 million, which was a 31% increase over the fourth quarter of fiscal 2011. Abiomed also noted that it had achieved profitability for the fiscal year. Abiomed's numbers were largely driven by the Impella®. The Impella® had worldwide revenue of $106.9 million ($99.1 million in the U.S.) during fiscal 2012, which represented a 37% increase over the prior year. There was also a 44% increase in U.S. Impella® revenue during the fourth quarter of fiscal 2012 as compared to that period in fiscal 2011. The article also indicates that Abiomed expects substantial increases in revenues during fiscal year 2013.

Separately, it is notable that Abiomed's stock price has dramatically risen to over $23.00.

4. February 2012 Perfmail Digest

This is a copy of an email chain from an online forum discussing perfusion and the use of the Impella®. We found a few of the comments to be interesting, particularly the comments that were made by (b) (6), (b) (7) (b) (6), (b) (7) commented on the short-term use of the Impella®, but also discussed Abiomed's approach in promoting and selling the device. Specifically, [redacted] (b) (6), (b) stated that Abiomed's sales representative focused the presentation on billing and coding and emphasized the reimbursements that were available through the use of the Impella®. (b) (6), (b) (7) also noted that there was information provided about the opportunity to purchase 5 Impella® catheters and then obtain the controller for free. (b) (6), (b) (7) summarized by stating that "[t]he primary pitch is that if cardiology has the right patient mix and if it is coded correctly they will make $25-$35K per procedure." There are other emails in the chain that are also

notable in the manner in which they discuss the use of the Impella®. We have redacted the internal portions of the email chain that came after the email on March 1, 2012.

5. Abiomed Schedule of Events at the 2012 ACC Conference

Abiomed continued its comprehensive marketing of the Impella® at the American College of Cardiology 2012 Scientific Sessions, which were held in Chicago, Illinois from March 24-26, 2012. The schedule of events reflects that Abiomed had scheduled sessions related to patients treated with PCI and patients who were suffering from cardiogenic shock. There appears to have also been at least one session that was directly related to the PROTECT II Study.

6. Additional Materials Received from the FDA

After our meeting, we also received some additional materials from the FDA in response to previously submitted FOIA requests. We understand that you have likely already seen these materials, but we wanted to provide them to be sure.

Please do not hesitate to ask if you have any questions regarding these documents or if you require any additional information.

Sincerely,

David J. Pivnick

David J. Pivnick

cc: J. Patrick Rowan

ITEM TWO

---- Forwarded Message ----
From: Perfmail digest <perfmail@lists.perfusion.com>
To: perfmail digest recipients <perfmail@lists.perfusion.com>
Sent: Thursday, March 1, 2012 12:00 AM
Subject: perfmail digest: February 29, 2012

PERFMAIL Digest for Wednesday, February 29, 2012.

1 (b) (6)
2. Saint Thomas Solution
3. Re: IMPELLA perfusion coverage
4. Re: IMPELLA perfusion coverage
5. Re: IMPELLA perfusion coverage
6. Perfusion.com Jobs Search Results - Email Alert
7. Re: IMPELLA perfusion coverage

Subject: (b) (6) MD
From: <orders@perfusion.com>
Date: 28 Feb 2012 13:26:01 -0500

X-Message-Number: 1

****

Name: (b) (6)
Email: (b) (6)
Subject: (b) (6) MD

Message:

(b) (6) is heading to Albuquerque, NM and any information regarding (b) would be appreciated. (b) is coming from Jackson Memorial Hospital in Miami. We hope to make (b) transition smooth.

Subject: Saint Thomas Solution
From: (b) (6)
Date: Mon, 27 Feb 2012 15:16:34 -0000
X-Message-Number: 2

Hi, everybody!

I would like to know if someone has something about this type of cardioplegic solution. I'm helping in a work about this type of solution.
My personal e-mail is (b) (6)

Thank you all!

Have a great week!

(b) (6)
Cordis Perfusionist, Brazil.

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) net>
Date: Sun, 26 Feb 2012 11:19:02 -0600
X-Message-Number: 3

One needs to clarify between the Impella 2.5 which is sold to the cath =
lab/cardiologist and the 5.0 which is sold to surgeons. In either case =
the DFU states the same time frame (this is from the 5.0):
"The ImpellaR 5.0 Circulatory Support System is intended for circulatory =
support using an

extracorporeal bypass control unit, for periods up to 6 hours. It is =
also intended to be used

to provide circulatory support (for periods up to 6 hours) during =
procedures not requiring

cardiopulmonary bypass."

In my institution when the Abiomed sales person made the presentation to =
the cath lab, perfusion was only added as an after thought. The main =
focus was on the cardiologist and a small subgroup of patients who were =
not candidates for PCI. The focus was, "...put the catheter in, do your =
proceedure, remove the device and make 30K."=20

Before some of you go well he is just complaining again. OK, when have =
you ever been in a "technical presentation" where billing and coding =
personnel were addressed specifically and at length? Abiomed told our =
hospital to buy 5 and get the controller for free. Well each catheter is =
about $25K and the final agreement was for 3 catheters! The primary =
pitch is that if cardiology has the right patient mix and if it is coded =
correctly they will make $25-$35K per procedure. How do you say =
manufacturer driven product pitching to a market that is desperate to =
find ways to stay competitive and a specialty that loves invasive =
devices?

To address the issue of perfusion coverage, finally, there shouldn't be =
any. If you follow Abiolmed's logic there is no need for specialized =
care. Put in the catheter, hook it up to the controller, prime and away =
you go. Then pull it in an hour. The surgeons I work with told =
cardiology that if they had a problem too bad. They were not consulted =
and this was an elective procedure on a patient, by definition, who was =
not a surgical candidate. Repair of femoral artery perhaps but not a =
surgical intervention on an emergent basis.=20

I'm not Abiomed bashing. I think it is a good product and from what I =
hear they are developing a right sided device. For those of use who have =
seen a patient die of right sided failure it would be a very welcomed =
addition to our product mix. I do think that their "comprehensive =
training program" for the 2.5 is aimed at cardiology and nursing with no =
thought, at all, toward perfusion. Unless you are specifically told to =
provide coverage for the device let the nursing staff handle it, after =
all that is what the manufacturer says is safe after their "training".

By the way, we did 6 and perfusion was never called and after a cost =
analysis we won't do anymore. I know that a lot of people are using them =
regularly and are making great money but that's my story and I'm =
sticking to it.

Definitely my 2 cents worth,

(b) (6) [redacted]

----- Original Message -----=20
From: "Perfmail" <perfmail@lists.perfusion.com>
To: "Perfmail" <perfmail@lists.perfusion.com>
Sent: Sunday, February 26, 2012 8:19 AM
Subject: Re: IMPELLA perfusion coverage

Appropriate training for nursing staff should require your Perfusionists =
to NOT have to monitor Impella patients. Abiomed brings a comprehensive =
training program for all clinicians who will be caring for patients with =
Impellas. From Cath Lab to OR to ICU, all parties will be =
appropraitely trained so that it does not become a 24/7 Perfusion =
coverage type thing.
(b) (6)

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) .com>
Date: Sun, 26 Feb 2012 19:20:53 -0500
X-Message-Number: 4

--e89a8f83a4ef85c0bb04b9e716d3
Content-Type: text/plain; charset=ISO-8859-1

(b) (6)

Your comment "*We will 'advise'---if we can remember after months of not even noticing the console in our office. I think we will wind up calling the cath lab and asking if anyone there remembers how to do it.*" bothers me a bit. It is our responsibility to be up to speed on each of the devices we are responsible for operating. We have a number of systems that we use on occasion, and considering the number of staff we have, a particular staff member may not see one of these systems for a number of months. It is our responsibility, through competency maintenance and personal efforts, to stay current on every system we employ. Having used the Impella, as I have, I would be surprised if you felt it was as simple to competently insert and operate as an IABP. I personally believe the direction companies who market these and other percutaneous systems are going is unwise. An apparent decrease in complexity does not change how the system interacts with the patient and the complications that may arise. Simply because a device is inserted percutaneously, the design is different, or the interface has changed doesn't change what the device does. IMO, those who deal with extracorporeal systems every day are the best prepared to manage these devices, perfusionists. AmSECT has published a position statement on this topic. One place to read it is here<http://pennperf.org/wp-content/uploads/2011/12/0021.pdf>

Respectfully,

(b) (6)

On Sun, Feb 26, 2012 at 1:13 PM, Perfmail
<perfmail@lists.perfusion.com>wrote:

> Okay, I've stopped laughing. Whew! What a gag.
> Impella: We have two sizes. The 2.5 was used by the cath lab, and no one
> even mentioned it to the perfusionists until after several had been
> inserted and they (cardiology) wanted the O.R. to have the 5.0 "just in
> case". After using it in the cath lab, it was usually withdrawn. At least
> one time the patient was sent to the intensive care unit, and at least one
> patient was sent out for further intervention. We have not heard about it
> in months.
>
> After a meeting of the heavy guns (and a few peons, like me), it was
> decided to equip the O.R. with 5.0 cannulae and one of the two consoles
> that cardiology had. It sits in my office, collecting dust. The cannula
> has faced expiration at least once and was exchanged. The O.R./purchasing
> complex has charge of it. The plan is that the perfusionist will be
> running the pump and will only be able to spare a small amount of attention
> to Impella insertion, which is a surgeon/PA/nurse task. We will
> 'advise'---if we can remember after months of not even noticing the console
> in our office. I think we will wind up calling the cath lab and asking if
> anyone there remembers how to do it.
>
> Certainly we do not have a mandate to babysit it in the unit. That task
> has already been laid on the nursing staff. We are perhaps 'resource
> persons' if they get into trouble, just as we are for the IABP. We did
> 24/7 in Unit coverage of that for 15-20 years, but for at least the past
> decade the ICU staff has handled it, and I have reached the point where,
> when I do my daily check, I tell the attending nurse that if there is a
> problem, "fix it and let me know how it went". They have been superb
> balloon sitters. Thank you very much, Datascope/Maquet for the training
> and in-servicings. BTW, we do 40 balloons / year +/-, decade in and decade
> out.
>
> In short, our experience with the Impella, as with the Angio-vac, mirrors
> that of many institutions: initial enthusiasm followed by total apathy. As
> with burn out---the first stage is enthusiasm.
>
> (b) (6) org

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) com
Date: Sun, 26 Feb 2012 20:52:31 -0500 (EST)
X-Message-Number: 5

This is a multi-part message in MIME format.
----------MB_8CEC3099A769D8D_3C0_31F80_webmail-d076.sysops.aol.com

Content-Transfer-Encoding: quoted-printable
Content-Type: text/plain; charset="us-ascii"

(b) (6)

I think you already know that we have already have 24/7 in-house coverage. =
With the Impella 2.5, we are there for the insertion. After the patient is =
transported to critical care, we are available for trouble-shooting. We hav=
e not yet inserted the 5.0 Impella, but will cover it the same way. Unlike =
many of the responses, we became involved with the Impella during one of th=
e early clinical trials.

(b) (6)
Riverside Hospital
Columbus, OH=20

-----Original Message-----
From: Perfmail <perfmail@lists.perfusion.com>
To: Perfmail <perfmail@lists.perfusion.com>
Sent: Sun, Feb 26, 2012 8:13 am
Subject: IMPELLA perfusion coverage

Could anyone share how perfusion coverage for IMPELLA catheters works=20
ost insertion at their institutions. I'm trying to match patient=20
afety with cost of 24/7 coverage.
(b) (6)

Subject: Perfusion.com Jobs Search Results - Email Alert
From: (b) (6) <services@perfusion.com>
Date: Tue, 28 Feb 2012 11:50:17 -0500
X-Message-Number: 6

Perfusion.com Jobs has found the following jobs for you:

Job Title, Organization, Location, Url

Perfusionist, Charleston Area Medical Center, Charleston
http://www.perfusion.com/jobs/jobdetails.aspx?id=3188

NEW FEATURE:

Perfusion.com Premium members can receive daily email updates with links
to all new jobs posted that meet their exact specifications!

Sign-up online at: http://www.perfusion.com/member/premium_signup.asp

All Job Links:

http://www.perfusion.com/jobs/jseeker/

This is an automated response. Please do NOT reply.

PDC Employment Services
http://www.perfusion.com/jobs
Toll Free: (866) 499-5672
jobs@perfusion.com

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) (b) (6) .net>
Date: Sun, 26 Feb 2012 19:22:07 -0800 (PST)
X-Message-Number: 7

---2114655128-1036549839-1330312927=:84560
Content-Type: text/plain; charset=iso-8859-1
Content-Transfer-Encoding: quoted-printable

=A0=A0 At one of our institutions our Perfusion team has taken charge of th=
e Impella.=A0 Mostly because there were too many Cath Lab personnel to
stay=
competent. We set it up and operate it in the Cath Lab. Usually the Impell=
a is put in as support for a high risk PCI, then removed at the end of the =
procedure. Some are put in emergently and the patient needs to be supported=
in the ICU. AbioMed has spectacular Reps and training programs. We hand th=
e Impella off to the ICU staff. If they aren't comfortable the Reps or our =
Perfusion staff will give them an in-service, etc. We are available to be c=
ontacted for trouble shooting, but the AbioMed Reps make that a very rare e=
vent. We bill it as any Ventricular Assist Device. It is very expensive, bu=
t the reimbursement to the hosp[ital is also very good.
=A0=A0 At our other institution the Cath Lab is completely autonamous from
=
the Perfusion Team and we only hear about use from the Reps at the other Ho=
spital. I think in most cases=A0 it comes down to the role of Perfusion in =
the Cath Lab before the Impella is put in practice.=20
(b) (6) CCP

--- On Sun, 2/26/12, Perfmail <perfmail@lists.perfusion.com> wrote:

From: Perfmail <perfmail@lists.perfusion.com>
Subject: Re: IMPELLA perfusion coverage
To: "Perfmail" <perfmail@lists.perfusion.com>
Date: Sunday, February 26, 2012, 10:29 AM

While I agree that perfusion bedside 24/7 monitoring is not needed for any

MCS/VAD system, Abiomed will train anyone to operate the Impella.

Now, I don't subscribe to this particular course.=A0 I believe perfusionist=
s
are the best equipped to provide optimal care for these patients and would highly recommend that your perfusion department be actively involved in any MCS system implanted at your institution.

(b) (6)

ITEM THREE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

APR 20 2010

(b) (6)
Sr. Vice-President, Global Product Operations
Abiomed, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Dear (b) (6):

The purpose of this letter is to acknowledge receipt of your April 7, 2010 correspondence addressed to (b) (6), (b) (7)(C) Your correspondence was in response to our March 29, 2010 letter addressing your proposed corrective actions to an Untitled Letter that was issued to you on January 28, 2010.

You took additional corrective actions to address the concerns we noted in our March 29, 2010 letter to you. These additional actions included:

- removing the brochure with the referenced charts and graphs from the website,
- providing screenshots to document the removal of the brochure and the press release from your website, and
- providing us with the standard operating procedure (SOP) and routing form for Customer or External Communication.

In reviewing your website, however, it was discovered that a copy of the brochure was still available under the heading of "Brochures" under the "Product" tab. You were notified of this oversight on April 16, 2010 via telephone call. You promised to remove that brochure by the end of the day. The removal of this brochure was documented, by you, via e-mail on April 16, 2010.

Your response appears adequate. No response to this letter is necessary.

The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website.

The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address: http://www.fda.gov/Training/CDRHLearn/ucm162015.htm.

Sincerely yours,

(b) (6), (b) (7)(C) [redacted]

Chief, Special Investigations Branch
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health

CC:

(b) (6) [redacted]

Chief Medical Officer
ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Indications for Use

510(k) Number (If known): K063723

Device Name: IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System

Indications for Use:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(b) (6) [redacted]

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063723

ITEM FOUR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Abiomed, Inc.
c/o (b) (6)
22 Cherry Hill Drive
Danvers, MA 01923

Re: K063723
Impella® Recover® LP 2.5 Percutaneous Cardiac Suppport System
Regulation Number: 21 CFR 870.4360
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Catheter, Cannula and Tubing Vascular, Cardiopulmonary Bypass
Catheter, Intravascular, Diagnostic
Regulatory Class: Class III (three)
Product Code: KFM, DWF, DQO
Dated: May 15, 2008
Received: May 19, 2008

Dear (b) (6)

This letter corrects our substantially equivalent letter of May 30, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

(b) (6) [redacted]

(b) (6), (b) (7)(C) [redacted]

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosur

ABIOMED'S OFF LABEL PROMOTION OF THE IMPELLA

Indications for Use

510(k) Number (if known): K063723

Device Name: IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System

Indications for Use:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(b) (6)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063723

K063723

MAY 30 2008

510(k) Summary (Prepared in accordance with 21 CFR Part 807.92)

a. Submitted

Applicant Name:	ABIOMED, Inc. 22 Cherry Hill Drive, Danvers, MA 01923
Contact Person:	(b) (6)
Date Summary Prepared:	May 15, 2008

b. Device Information

Trade Name:	IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System
Common Name:	Percutaneous Cardiac Support System
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, non roller type (classified under 870.4360) Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass (classified under 870.4210) Diagnostic Intravascular catheter (classified under 870.1200)
Product Code:	74KFM, 74DWF, 74DQO

c. Legally Marketed Predicate Devices

- TandemHeart PTVA System – K991783, K052570 ,K924642 , K924643
- Vascular Solutions Langston Dual Lumen Catheter – K050168

d. Device Description:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System (IMPELLA RECOVER LP 2.5 System) provides circulatory support with the ability to deliver anticoagulant through an infusion system. The System is comprised of: 1) a catheter which contains an integrated pump motor/infusate lumen, integrated intravascular pressure lumen and integral cannula, 2) a controller/console and 3) infusion system designed to work together, and 4) accessories.

e. Intended Use:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure.

f. Technological Characteristics and Comparison to Predicate Device(s):

The technological characteristics of the IMPELLA RECOVER® LP 2.5 are the same as the TANDEM HEART systems and the Vascular solutions Langston catheter with the exception of the following differences:

- pump location
- certain materials of construction
- pump speed

g. Test Results:

Pre – Clinical:

To validate the device design of the IMPELLA RECOVER® Percutaneous Cardiac Support System, ABIOMED performed the following *in vitro* testing:

With regard to sterilization, packaging, and shelf-life, the IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is sterilized using EtO gas with a SAL of 10^{-6}. The sterilization method/cycle was validated using EN 550 "*Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization.*" The EtO sterilization residual values for EO and ECH and are within the allowable limits of ISO 10993-7. The LAL test was used to ensure a pyrogen free determination. The packaging material has been validated to ensure its integrity.

Biocompatibility testing of all patient contacting materials was conducted on the finished sterilized devices in accordance with ISO-10993, "*Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*". All testing results are acceptable.

The design and testing validation of the software contained in the IMPELLA MCS was conducted in compliance with the FDA 2005 guidance document entitled "*Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*"

With regard to electromagnetic compatibility and electrical safety, the IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System was tested in accordance with EN 60601 and EN 61000 and their applicable subparts. The testing results demonstrate that the device is in conformance with these FDA recognized standards.

With regard to In vitro performance testing, ABIOMED conducted a full range of testing demonstrating that the entire IMPELLA RECOVER® LP 2.5 System operates as intended. All tests were acceptable.

Clinical :

Abiomed provided a detailed analysis based on a clinical data collected from a combination of 109 OUS and 20 US patients used to address patient safety.

h. Conclusion:

The ABIOMED IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is substantially equivalent to the TandemHeart PTVA System and Control system (K991783), the TandemHeart Transseptal Cannula (K052570), the Medtronic Biomedicus 15F arterial cannula and introducer (K924642, K924643) and the Vascular Solutions Langston Dual Lumen Catheter – K050168

ITEM FIVE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993-0002

JAN 28 2010

(b) (6) [redacted]

Chief Medical Officer
ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Dear (b) (6) [redacted]:

This letter is to inform you of objectionable promotional activities the Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) has observed related to Abiomed's promotion of the Impella Recover LP 2.5 Percutaneous Cardiac Support System. CDRH has reviewed a copy of your advertisement, published in the September 2009 CARDIAC INTERVENTIONS MAGAZINE (advertisement), as well as information contained in a September 2009 Press Release in BUSINESS WIRE (press release). This letter requests prompt corrective action to address the violations cited.

Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), the Impella Recover LP 2.5 Percutaneous Cardiac Support System is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. This device was cleared in May 2008 for partial circulatory support using an extracorporeal bypass control unit, for periods up to six hours, and to provide partial circulatory support for periods up to six hours during procedures not requiring cardiopulmonary bypass.

You have been granted two separate Investigational Device Exemptions (IDE) for the Impella 2.5. The first IDE was granted in February 2005 for high risk Percutaneous Coronary Intervention ("high risk PCI"), G050017; the second IDE was granted in March 2008 for Acute Myocardial Infarction ("AMI"), G080021. The high risk PCI and AMI indications are investigational and outside the existing clearance for Impella 2.5. Our review of your advertisement and press release finds that Abiomed is promoting the Impella 2.5 for high risk PCI and AMI, in violation of 21 CFR 812.7(a) and (d), which provide that you may not promote or test market an investigational device, until after FDA has approved the device for commercial distribution, and you may not represent that the Impella 2.5 is safe and effective for the purposes for which it is being investigated. The high risk PCI and AMI are also adulterated under section 501(i) of the Act (21 U.S.C. § 351) for failing to comply with a requirement prescribed by or under section 520(g) of the Act, specifically 21 CFR 812.7(a) and (d).

Further, Abiomed is promoting the Impella 2.5 for high risk PCI and AMI, which are new intended uses which the agency has not cleared or approved. Such promotion renders the Impella 2.5 misbranded within the meaning of section 502(o) because no notice or other information respecting the device was submitted as required by section 510(k) of the Act (21 U.S.C. 360(k)) and there is no premarket approval application under section 515 of the Act or petition to reclassify under section 513(f) of the Act pending before FDA (see 21 CFR 807.81(b)(1)).

In reviewing Abiomed's promotional materials, CDRH noted the following violations:

i. Advertisement

- "Demonstrated hemodynamic superiority to IABP" (Intra Aortic Balloon Pump). This comparison statement can be interpreted as an efficacy statement regarding the superiority of Impella to IABP. Currently, the Impella 2.5 is under an approved IDE to compare the efficacy of Impella 2.5 to IABP for an AMI population. Accordingly, this statement is in violation of 812.7(d), which prohibits the representation that a device is safe and effective for the purposes being studied under the investigation.

- The advertisement shows that Impella 2.5 has been used in high risk PCI and AMI. As the Impella 2.5 is an investigational device currently being studied for high risk PCI and AMI, this is a violation of 812.7(a), which prohibits the promotion of an investigational device.

ii. Press Release:

- Abiomed represents in the press release that Impella 2.5 is safe and effective for use in high risk PCI in violation of 21 CFR 812.7(d). Specifically, the press release states that "USpella is the largest IRB registry reported so far for Impella 2.5 that confirms prior positive study results. Impella is safe and easy to use, provides excellent support to stabilize the patients during high risk PCI and restores the hemodynamics in unstable conditions refractory to conventional therapies" (emphasis added). Since the use of the Impella 2.5 for high risk PCI is currently being studied under an IDE, the statement that the high risk PCI is "safe" and "provides excellent support" is a violation of 21 CFR 812.7(d).

The violations described above are not intended to be an all inclusive list of problems that may exist with your promotional activities. It is your responsibility as a study sponsor to ensure compliance with the Act and applicable regulations. The specific violations noted in this letter may also be reflected in other promotional materials used by your firm. You

are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

We request written documentation within thirty (30) working days of receiving this letter of the actions you have taken or will take to correct these violations and prevent the recurrence of similar violations. Please provide written documentation of the actions you have taken or will take to correct these violations and prevent the recurrence of similar violations in current or future studies for which you are the study sponsor. Your response should be sent to: Attention: (b) (6), (b) (7)(C) JD, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 10903 New Hampshire Ave., WO66-3504, Silver Spring, MD, 20993-0002.

The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address: http://www.fda.gov/Training/CDRHLearn/ucm162015.htm.

If you have any questions, please contact (b) (6), (b) (7)(C) at (b) (6), (b) (7)(C) or at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)
Director
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health

CC:

(b) (6)
Senior Vice President
ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

(b) (6) JD

Food and Drug Administration

Center for Devices and Radiological Health

Office of Compliance, Division of Research Biomonitoring

10903 New Hampshire Ave

WO66-3504

Silver Spring MD 20993-0002

Dear (b) (6),

This letter is to provide a written response to the Untitled Letter received by Abiomed date January 28, 2010. In a subsequent conversation with you due to the closure of the FDA during a series of snow storms our 30 working day limit was extended to March 5th . We appreciated the extra time and worked to put it to good use.

As a first point, FDA's Untitled Letter referred to an Advertisement and a Press Release. The Advertisement was identified in the Untitled Letter as appearing in the September 2009 issue of Cardiac Interventions Magazine. The Press Release referred to was also dated September 2009.

We provided a set of questions based on this information and I think that there was some general confusion about the Advertisement. When we received the Untitled Letter we immediately looked through the Cardiac interventions Magazine - Sept 2009 and could not find any Advertisement about the Impella® 2.5or the wording quoted in the Untitled Letter under section "i. Advertisement". I appreciate you taking the time to have a follow up discussions in which you provided specific guidance around something called "Cardiac Sciences" combined with a case study you referenced and read the wording of the Advertisement. From there I was able to track down the Advertisement. The Advertisement that was described in the Untitled Letter was actually in "Cath Lab Digest Magazine – Sept. 2009", just for the record. Therein lies the confusion and the reasons for some of our initial questions.

I would like to address the violations and what our proposed corrective actions are:

"i. Advertisement

- *"Demonstrated hemodynamic superiority to IABP" (Intra Aortic Balloon Pump). This comparison statement can be interpreted as an efficacy*

statement regarding the superiority of Impella to IABP. Currently the Impella 2.5 is under an approved IDE to compare efficacy of the Impella 2.5 to IABP for an AMI population. Accordingly this statement is in violation of 812.7(d), which prohibits the representation that a devices is safe and effective for the purpose of being studied in the investigation.

- *The advertisement shows that Impella 2.5 has been used in High risk PCI and AMI. As the Impella 2.5 is an investigational device being studied for high Rick PCI and AMI, this is a violation of 812.7(a) which prohibits the promotion of an investigational device."*

ABIOMED RESPONSE:

Abiomed now recognizes that the use of the term "Demonstrated" is viewed as a term reflecting proven efficacy. As mentioned in our first response this was not viewed as a statement of efficacy since "hemodynamic superiority" has not been allowed to be a primary end point by FDA in the IDE studies we are presently conducting. With that said the corrective action we propose would be to eliminate the term "Demonstrated" from that statement in any materials that Abiomed has in its possession. This includes a review of the entire website to eliminate this bulleted phrase from the advertisement as well as any existing marketing materials containing the bulleted phrase.

Abiomed has strengthened its review process as well since that timeframe. Since Nov 2009 our SOP has been updated to include additional requirements for independent review and sign off on all promotional materials, including anything on the website.

On bullet 2, Abiomed understands that the concern is the combination of the bulleted items in the Ad with the bar graphs relating to the profile of general use of the device under the 510k. What may not be clear in the advertisement is that these charts reflect the data from our voluntary registry collected under IRB for the use of the device under our 510(k) indication. These charts in and of themselves are just data, if they are divorced from the claims.

Therefore we propose as a corrective action that any promotional materials that Abiomed produces that have this type of data profiling the use of the Impella 2.5 in its general use will not be associated with any claims for use of the device. In addition we would remove any materials that are in our possession presently in our website or marketing materials that combine these charts with claims about the device.

"ii. Press Release:

Abiomed represents in the press release that the Impella 2.5 is safe and effective for use in high risk PCI in violation of 21 CFR 812.7(d). Specifically, the press release state that USpella is the largest IRB registry reported so far for Impella 2.5 that confirm prior positive study results. Impella is safe and easy to use, provides excellent support to stabilize patients during high risk PCI and restores hemodynamics in unstable

conditions refractory to conventional therapies" (emphasis added). Since the use of the Impella 2.5 for high risk PCI is currently being studied under an IDE, the statement that high risk PCI is "safe" and provides "excellent support" is a violation of CFR 812.7(d)."

Abiomed Response:

Abiomed now understands that this physician's quotation could have been stated in a way to not claim the device is "safe" or that it provides "excellent support". As a corrective action Abiomed has completed a full review of its website and its collateral materials and will remove materials claiming the device is "safe" or that it" provides excellent support". Abiomed will also remove the Press Release from its website.

As mentioned above the SOP controlling the release of promotional materials from the company has been strengthened since last November and we believe this new process should address the integration of this feedback into our review process.

We hope that this response from Abiomed has adequately addressed FDA concerns expressed in the Untitled Letter. We appreciate the time you have allowed us to respond. In this time we have reviewed our website and our existing promotional materials. The required changes to address your concerns are being implemented as I write this letter. We expect closure on all items within 30 calendar days.

Sincerely,

(b) (6) [redacted]

Sr. Vice-President, Global Product Operations

Abiomed Inc.

CC: (b) (6) [redacted]

Inspections, Compliance, Enforcement, and Criminal Investigations

Abiomed, Inc.

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 10, 2011

WARNING LETTER

VIA UNITED PARCEL SERVICE

Michael R. Minogue
President and Chief Executive Officer
ABIOMED, Incorporated
22 Cherry Hill Drive
Danvers, Massachusetts, 01923-2575

Re: IMPELLA RECOVER LP 2.5 Percutaneous Cardiac Support System
Refer to: GEN1100068

Dear Mr. Minogue:

The Food and Drug Administration (FDA) has learned that your firm is marketing the IMPELLA RECOVER LP 2.5 Percutaneous Cardiac Support System (IMPELLA RECOVER LP 2.5) device in the United States without the required marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The product is a device within the meaning of section 201(h) of the Act, 21 U.S.C. § 321(h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or it is intended to affect the structure or function of the body.

Your firm obtained the following 510(k) clearance for this device: for "partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass. The IMPELLA RECOVER LP 2.5 also provides pressure measurements which are useful in determining intravascular pressure."

The Office of Compliance (OC) in the Center for Devices and Radiological Health (CDRH) reviewed an advertisement, labeling pieces, and your firm's website at www.abiomed.com the IMPELLA RECOVER LP 2.5 device on May 12, 2011. Our review of your firm's promotional materials indicate that ABIOMED is making claims that we stated were inappropriate in a January 28, 2010, letter to your firm. These claims represent a major modification to both the intended use and the indications for use of the device. The objectionable claims include the following: for

- An advertisement placed in the September, 2010, Cath Lab Digest (vol. 18, no.9). The advertisement shows a hand puncturing a red balloon with a pin. Printed on the balloon is text that reads, "Old ideas about heart recovery." The caption below the balloon reads in part, "After 40 years, there is something other than the intra-aortic balloon [pump] (IABP) for circulatory support in the Cath lab . . . Cardiac Power Output (CPO) is the #1 correlate to mortality for [acute myocardial infarctions] (AMI) in cardiogenic shock patients . . . In the latest USPELLA registry, the CPO of shock patients was observed to increase 120% from 0.5± 0.2 prior to IMPELLA to 1.1±0.2 on IMPELLA (p=0.02)."

As we stated in our January 28, 2010, letter, "comparative statements can be interpreted as efficacy statements regarding the superiority of the IMPELLA RECOVER LP 2.5 to IABP." When we sent you the January, 2010, letter, ABIOMED had an ongoing investigational device study, G050017, and we advised your firm that the claims violated the regulations at 21 CFR 812.7(d), which prohibit the representation that a device is safe and effective for the purposes being studied. Although the study has since been terminated, the unsupported comparative claims violate 21 CFR 801.6.

- On page 9 of your firm's presentation to the 2010 Transcatheter Cardiovascular Therapeutics meeting, your firm claimed that use of the IMPELLA RECOVER LP 2.5 in AMI Shock patients improves hemodynamics, and on page 10 your firm states that the use of the IMPELLA RECOVER LP 2.5 improves cardiac output, which is then linked to lower mortality rates. Both of these indications would need to be supported with an appropriately designed clinical study performed under an Investigational Device Exemption (IDE).
- On the ABIOMED website and in the aforementioned advertisement, your logo includes the tag line, "Recovering Hearts, Saving Lives." This is another claim that would require a randomized clinical study performed under an IDE specifically to evaluate whether the device could salvage heart tissue and muscle.

Statements such as the ones cited above represent a major change or modification in the intended use of your firm's device that requires a new premarket notification. 21 CFR 807.81(a)(3)(ii). Therefore, the IMPELLA RECOVER LP 2.5 device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C.C. 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an IDE under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because your firm did not notify the agency of its intent to introduce it into commercial distribution for the intended uses discussed above, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b). The kind of information your firm must submit in order to obtain approval or clearance of its device is available through the Internet at http://www.fda.gov/cdrh/deviceadvice/3122.html [1]. The FDA will evaluate the information submitted and decide whether your firm's product may be legally marketed.

The Office of Compliance requests that ABIOMED, Inc., immediately cease marketing the IMPELLA RECOVER LP 2.5 for unapproved uses such as those described

above. Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. Such action includes, but is not limited to, seizure, injunction, and/or civil money penalties. U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Request for Certificates to Foreign Government will not be granted until the violations related to the subject device are corrected.

Please notify this office in writing within 15 working days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations from occurring again. Include documentations of the corrective actions taken. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please provide a translation of documentation not in English to facilitate our review. Your response should be sent to:

Terri T. Garvin
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
10903 New Hampshire Avenue
WO66-3521
Silver Spring, MD 20993

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. Your firm should investigate and determine the causes of the violations and take prompt steps to correct the violations and to bring your firm's products into compliance.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Links on this page:

1. http://www.fda.gov/cdrh/deviceadvice/3122.html

Change to Labeling- Instructions for Use Manual

The Instructions for Use Manual in the following section for the IMPELLA LP 2.5 Percutaneous Cardiac Support System is identical to that submitted in the original 510k submission with the one exception. Specifically, as requested by the FDA, the page in the Instructions for Use containing the Indications for Use (Page 2.2) has been replaced to the final version:

> "The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.
>
> The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure."

ITEM SIX

6.0 TRUTHFUL AND ACCURACY STATEMENT

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR §807.87 (j)]

I certify that, in my capacity as Vice President, QA and RA, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6) [redacted]

Vice President, QA and RA
ABIOMED, Inc.

Dec. 9, 2006
Date

K063723
(Premarket Notification [510(k)] Number)

Indications

The Impella® RECOVER LP2.5 Percutaneous Cardiac Support System is intended for circulatory support using an extracorporeal bypass control unit. Intended duration of use is for periods appropriate to cardiopulmonary bypass, up to 6 hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to 6 hours) for procedures not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, surgery of the aorta, high risk cardiac surgery, high risk patients undergoing non-surgical cardiac procedures, etc).

The Impella RECOVER LP2.5 Percutaneous Cardiac Support System also provides for pressure measurements which are useful in determining intravascular pressure.

Contraindications

- Mechanical aortic valve or heart constrictive device.
- Aortic stenosis (graded as $\geq +2$ equivalent to an orifice area of 1.5 cm^2 or less).
- Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as $\geq +2$).
- Severe peripheral arterial obstructive disease that would preclude LP2.5 System device placement.

Potential Adverse Events

- Death
- Cerebral vascular accident (CVA) / Stroke
- Aortic insufficiency
- Aortic valve injury
- Arrhythmia

0127

Warnings

NOTE: A warning indicates a situation that could result in injury or death.

- The LP2.5 System is intended for use only by personnel trained in accordance with the Abiomed Training Program.
- The sterile components of the LP2.5 System can be used only if the sterilization indicators show that the contents have been sterilized, the packaging is not damaged, and the expiration date has not elapsed.
- Do ***NOT*** resterilize or reuse the LP2.5 Catheter. It is a disposable device and is intended for single use only. Do ***NOT*** autoclave the Catheter.
- Retrograde flow will occur across the aortic valve if the pump is set at performance level P0.
- Fluoroscopy ***MUST*** be used for the insertion of the Impella guidewire and LP2.5 Catheter.
- To prevent failure of the 13F peel away introducer, remove the 13F peel away introducer prior to transport. The ACT should also be less than 150 seconds to ensure that the patient is not anticoagulated.
- The Braun Vista® basic Infusion Pump provided by Abiomed must ***NOT*** be used in conjunction with any products other than Impella products.
- Do ***NOT*** use an LP2.5 System if any part of the System is damaged.
- Take care to avoid over-inserting the Catheter and possibly impinging the Catheter tip against the vessel/ventricular/atrial walls.

Overview

The LP2.5 System consists of the following components:

- LP2.5 Catheter (Catheter)
- Impella® Power Supply
- Impella® Mobile Pump Console (MPC)
- Braun Vista® basic Infusion Pump (Vista basic)

LP 2.5 Catheter

The LP 2.5 Catheter (see Figure 1) is an intravascular microaxial blood pump that delivers up to 2.5 liters of blood per minute from the left ventricle and into the aorta.

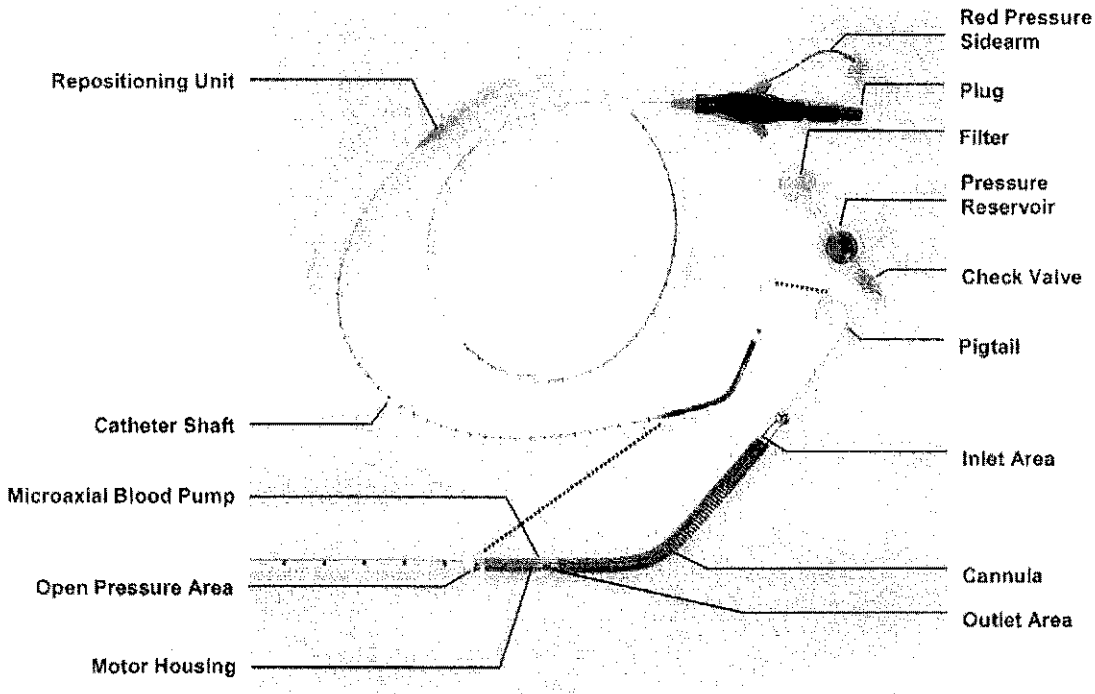

Figure 1 RECOVER LP 2.5 Catheter

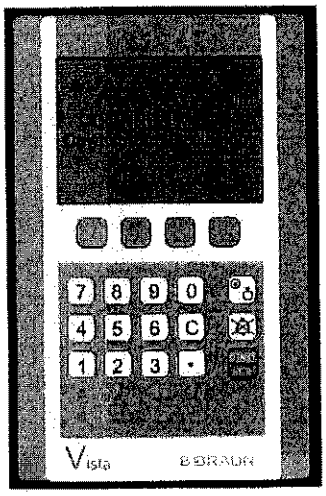

Figure 40 Downstream Occlusion Alarm

Patient Weaning

Weaning the patient from the LP 2.5 System is at the discretion of the physician.

The following weaning protocol is provided as ***guidance only***.

0173

1223

Pump Parameters

Speed range	0 to 51,000 rpm
Power consumption	less than 0.99 A
Voltage	max. 18 V
Flow-Maximum	2.3 ± 0.3 L/min
Purging the LP 2.5 Catheter	
Recommended purge fluid	20% Dextrose solution with heparin concentration of 50 I.U. per mL
Purge pressure	300 to 700 mmHg
Infusion rate	4 to 12 mL/h
Dimensions of LP 2.5 Catheter	
Length of invasive portion (w/o catheter)	130 ± 3 mm
Diameter	max. 4.2 mm (nom. 4.0 mm)
Classification per DIN EN 60601-1	Safety class II, degree of protection: CF (MPC and pump)
Classification per MDD/93/42/EEC	Class III

ITEM SEVEN

Economic Study Analysis:

In PROTECT II, Impella significantly reduced out-of-hospital major adverse events by 56% (p=0.002) over the IABP arm. As of today's latest release, the economic study includes additional patients and readmission data (n=249) from the initial PROTECT II presentation at the American College of Cardiology (ACC) Scientific Session in April 2011.

Hospital charges for all PROTECT II patients at 90 days averaged approximately $165,000 per patient for the IABP and approximately $146,000 for Impella, resulting in $19,000 lower charges with Impella support. Hospital charges for survivors only averaged approximately $156,000 per patient for IABP and approximately $134,000 for Impella, resulting in $22,000 lower charges with Impella support, excluding device costs.

Overall Hospital Charges at 90 Days Without Device Costs

	Impella	IABP
All Patients	$146K	$165K
Survivors Only	$134K	$156K
Reduction in Hospital Charges	***$19K to $22K lower charges with Impella support***	

Impella's reduction of overall hospital charges were driven by the following:

- 47% reduction in repeat revascularization for Impella patients at 90 days;
- 67% lower charges per readmission for Impella patients at 90 days.

The device costs were subtracted out of the economic study data and added back in at hospital cost assumptions. With device costs included ($20,000 for Impella, $800 for IABP), the hospital charges become equivalent at 90 days. Additional economic study information will be presented at a later date. This economic study was conducted by Presscott Associates, Ltd., an independent health economics organization. Analysis included third-party collection and analysis of medical billing data from actual claims submitted to payers.

"Reducing relevant clinical adverse events and lowering repeat revascularization rates unquestionably impacts readmissions at 90 days. These data represent a mutually beneficial scenario for the patients and payers, during a time when hospitals are continually scrutinized under new health reform payment models," said Michael R. Minogue, Chairman, President, and Chief Executive Officer, Abiomed.

"National delivery and payment reforms will accelerate the need for healthcare providers to show that clinical therapies improve quality and the use of healthcare resources," said David A. Gregory, MPA, FACHE, Executive Vice President, Presscott Associates, Ltd. "These economic findings demonstrate that the Impella therapy as compared to the IABP are powerful, in that they show Impella reduced the need for the patient to repeat the PCI procedure, which is a benefit to hospitals, payers, and certainly to the patient from a quality of life perspective."

These data reported have been collected, monitored and analyzed by a third party academic research organization and Presscott Associates, Ltd.

References:

1. MACCE is defined as Composite of Major Adverse Cardiac and Cerebrovascular Events, including Death/Stroke or TIA/MI/Repeat Revascularization in the PROTECT II study, using 8xULN for biomarkers or Q-wave for Peri-procedural MI (Stone et al Circulation 2001;104:642-647) and 2xULN for Spontaneous MI (PROTECT II definition).

2. The PROTECT II study was a prospective, multi-center, randomized controlled study of the Impella 2.5 versus the intra-aortic balloon pump (IABP) in patients undergoing non-emergent high-risk PCI requiring hemodynamic support. The purpose of the PROTECT II study was to determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an IABP during "high-risk" angioplasty procedures. The study protocol was for low ejection fraction (EF) patients with unprotected left main (EF ≤ 35%) or with triple vessel disease (EF ≤ 30%). The primary endpoint of the study is a composite of the following ten Major Adverse Events at 30 days or discharge: death, myocardial infarction, stroke, repeat revascularization (PCI/CABG), need for any cardiovascular operation, acute renal dysfunction, increase in aortic insufficiency, severe hypotension, CPR or arrhythmia requiring Trt, failure to adequately reopen the vessel. The thesis assumed major adverse event rates of ≥20% for Impella and ≥ 30% for IABP.

3. Coronary atherectomy, commonly referred to as rotablation, is a catheter-based procedure that includes a high-speed rotating metallic burr that abrades calcified (hardened) plaque that is blocking an artery and blood supply to the heart, rotating at speeds of up to 200,000 RPM. Complications listed per FDA labeling include: ventricular perforation, contrast media reaction, stroke, slow flow, no flow, myocardial infarction (Q-wave and non Q-wave), arrhythmia requiring treatment, cardiac tamponade, and death.

4. All of the adverse events of the study have been independently adjudicated by the third party academic research organization (ARO). However, the database is not locked as of the Society of Angiographic Cardiovascular Interventions (SCAI) Scientific Sessions in May 2011.

5. All economic data has been collected by Presscott Associates, Ltd. in unison with the ARO. Additional patients may be added in the future to the economic report. As of this press release, n=249 is comprised of patients that consented to the economic study and were in the United States.

6. Statistically Significant p value of p≤0.05 means that the likelihood that the phenomena tested occurred by chance alone is less than or equal to 5%.

ABOUT ABIOMED

Based in Danvers, Massachusetts, Abiomed, Inc., is a leading provider of medical devices that provide circulatory support to acute heart failure patients across the continuum of care in heart recovery. Our products are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping of the heart. For additional information please visit: www.abiomed.com.

FORWARD-LOOKING STATEMENTS

This Release contains forward-looking statements, including statements regarding the benefits of the Impella 2.5 over an IABP. Future patient outcomes and resulting hospital charges, may differ materially in the future and the Company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, including anticipated future losses, physician usage, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, future capital needs and uncertainty of additional financing, and other risks and challenges detailed in the Company's filings with the Securities and Exchange Commission, including the Annual Report filed on Form 10-K and most recently filed Quarterly Report on Form 10-Q. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this Release. The Company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this Release or to reflect the occurrence of unanticipated events.

Contacts

Abiomed, Inc.
Aimee Maillett, 978-646-1553
Corporate Communications Manager
ir@abiomed.com

ITEM EIGHT

Subject: ABIOMED ENDS PROTECT II STUDY AND ANNOUNCES INTERIM RESULTS, DETAILED CLINICAL ^NALYSIS TO BE PRESENTED AT ACC 2011

Hello Everyone,

I wanted to let you know that effective December 6, 2010, we have announced the conclusion of our Protect II clinical trial.

While the formal data from this trial will be presented at ACC in April, I am forwarding preliminary data to you today.

I wanted to highlight a few key points:

* For the entire study population, Impella significantly reduced out-of-hospital major adverse events by 52% compared to IAB for the duration of the monitoring of 90 days. This is key for the future of healthcare-where out-of-hospital results and readmissions will be metrics for cost effective treatment protocols.

* There was an overall positive trend in the majority of patients in the study at the interim analysis, in which Impella reduced the major adverse event rate by 26% over the IAB. Additionally, 125 patients have been enrolled since the midpoint and are not yet included in this interim analysis.

* Impella provided a 47% reduction in major adverse events over IAB in a subgroup that represents 70% of the protocol study population. A preliminary analysis of a "PROTECT" score, similar to a SYNTAX score, will be presented at the upcoming ACC conference in April.

* When using atherectomy, Impella significantly reduced repeat revascularization.

* The study was stopped based on a futility determination at the planned interim analysis regarding the primary endpoint, which the company views as likely to be due to unanticipated confounding variables related to the use of rotational atherectomy in the trial. The data revealed confounding variables in the treatment between the two arms with the most significant differences related to two times more frequent use (p=0.04) and two times the number of passes per use (p=0.003) of rotational atherectomy in the Impella arm compared to the IAB arm, accounting for 12% (n=38) of total PROTECT II patients at the interim. Use of atherectomy during PCI has been previously shown to increase CKMB release (heart enzyme) following PCI, triggering an endpoint in PROTECT II.

is is exciting news and I'd like to follow up with you shortly to discuss these results more detail. If you would like the Protect II PDF slides, you can request them from our medical affairs department at medical affairs@abiomed.com.

Thanks again for your continued support!

(b) (6)

Associate Cardiology Account Manager

ABIOMED, Inc.

22 Cherry Hill Drive | Danvers, MA 01923

Cell: (b) (6)

24-Hour Emergency: 800-422-8666

(b) (6) .com

www.abiomed.com

Recovering hearts. Saving Lives.(tm)

"Above all else, keep watch over your heart, for herein lie the wellsprings of life." - Proverbs

ITEM NINE

(b) (6), (b) (7)(C) (USADC)

From: Pivnick, David J. <DPivnick@mcguirewoods.com>
Sent: Monday, May 21, 2012 11:11 AM
To: (b) (6), (b) (7) (USADC)
Cc: Rowan, J. Patrick
Subject: RE: Abiomed
Attachments: May 10, 2012 CGS Impella Guidance.pdf; May 18, 2012 CGS Revised Impella Guidance.pdf

(b) (6), (b) (7)

I wanted to provide you with an update on one of the pieces of information that was provided with my letter last Friday. Specifically, the first item referenced in the letter (and attached as Exhibit 1) was a copy of CGS guidance from May 10, 2012 relating to the recommended billing and coding practices for the Impella. On Friday, CGS rescinded its prior guidance and suggested instead that unlisted code 33999 be used (instead of code 92970, which was recommended in the May 10, 2012 guidance).

I have attached copies of both pieces of CGS guidance for your review, but wanted to make sure that you had the update in a timely manner.

Sincerely,

David J. Pivnick
McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
312.750.3585 (Direct Line)
312.698.4539 (Direct FAX)
dpivnick@mcguirewoods.com

From: (b) (6), (b) (7) (USADC) [mailto:(b) (6)
Sent: Friday, May 18, 2012 4:17 PM
To: Pivnick, David J.
Cc: Rowan, J. Patrick
Subject: RE: Abiomed

David –

Thanks for the extra info. We actually have a conference call scheduled next Friday on this case. Would you be available to talk Friday morning, around 11 am?

(b) (6), (b) (7)(C)

From: Pivnick, David J. [mailto:DPivnick@mcguirewoods.com]
Sent: Friday, May 18, 2012 4:37 PM
To: (b) (6), (b) (7) (USADC)

Cc: Rowan, J. Patrick
Subject: Abiomed

(b) (6), (b) (7)(C)

We wanted to provide you with some follow-up information relating to Abiomed. Please see the attached letter and exhibits, which provide that information.

We would appreciate an opportunity to have a brief discussion regarding these materials at your convenience.

Sincerely,

David J. Pivnick
McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
312.750.3585 (Direct Line)
312.698.4539 (Direct FAX)
dpivnick@mcguirewoods.com

ITEM TEN

(b) (6), (b) (7)(C) (USADC)

From: Pivnick, David J. <DPivnick@mcguirewoods.com>
Sent: Friday, May 18, 2012 4:37 PM
To: (b) (6), (b) (7)(C) (USADC)
Cc: Rowan, J. Patrick
Subject: Abiomed
Attachments: Active_39332326_1_Letter to (b) (6), (b) (7)(C) (05-18-12).PDF

(b) (6), (b) (7)

We wanted to provide you with some follow-up information relating to Abiomed. Please see the attached letter and exhibits, which provide that information.

We would appreciate an opportunity to have a brief discussion regarding these materials at your convenience.

Sincerely,

David J. Pivnick
McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
312.750.3585 (Direct Line)
312.698.4539 (Direct FAX)
dpivnick@mcguirewoods.com

ITEM ELEVEN

(b) (6), (b) (7)(C) (USADC)

From: Rowan, J. Patrick <prowan@mcguirewoods.com>
Sent: Friday, February 10, 2012 6:08 PM
To: (b) (6), (b) (7)(C) (USADC)
Cc: Pivnick, David J.
Subject: Abiomed
Attachments: Active_37118640_1_Mad Money - Transcript with Mike Minogue.DOC

(b) (6),

Here is the link to the piece (http://www.cnbc.com/id/46303265). An informal transcript is attached. Thanks

Pat

J. Patrick Rowan
McGuireWoods LLP
2001 K Street, NW
Suite 400
Washington, DC 20006-1040
202.857.1758 (Direct Line)
202.828.3304 (Direct FAX)
prowan@mcguirewoods.com

http://www.mcguirewoods.com

ITEM TWELVE

(b) (6) (USADC)

From: Rowan, J. Patrick <prowan@mcguirewoods.com>
Sent: Friday, February 3, 2012 3:43 PM
To: (b) (6), (b) (7)(C) (USADC)
Cc: Pivnick, David J.
Subject: Abiomed
Attachments: Active_28459933_1_FDA - Proof of Receipt.PDF

(b) (6), (b) (7)

Thanks again to you and your colleagues for listening to our presentation yesterday. At one point, we were asked if we had corresponded with FDA and we said that we had. Enclosed is the letter that we sent to FDA in December, 2010. It references some attachments, which are not readily available to me. Obviously, the FDA will have them, but if you would like me to locate and forward a set, please let me know. We are happy to answer any questions you may have about this or other matters.

Pat

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Melissa Gilmore
Direct: 202.857.1724

mgilmore@mcguirewoods.com
Direct Fax: 202.828.3302

December 21, 2010

VIA MESSENGER DELIVERY

(b) (6)
Office of Compliance
Center for Devices and Radiologic Health
WO66-G609, Room 3414
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: False and Misleading Abiomed Advertising

Dear (b) (6)

My firm has been engaged to bring to your attention off-label, false and misleading advertising by Abiomed, Inc. (Abiomed) in connection with its restricted device, the Impella® LP 2.5 Percutaneous Cardiac Support System (Impella). As detailed below, Abiomed is actively, aggressively, and inappropriately marketing the Impella, creating a significant risk to the public and in a manner inconsistent with the Federal Food, Drug, and Cosmetic Act (the Act). We respectfully request that FDA cause Abiomed to immediately cease the dissemination of the violative promotional materials, modify its www.abiomed.com website accordingly, and take any other actions FDA deems appropriate.

Abiomed's materials omit and minimize the serious risks associated with the device, broaden and fail to present the limitations to the approved indication of the device, and present unsubstantiated superiority and effectiveness claims. Thus, the advertising misbrands the device in violation of the Act, 21 U.S.C. § 352, and FDA implementing regulations. Cf. 21 C.F.R. § 801. These violations are concerning from a public health perspective because they suggest that the Impella is safer or more effective than has been demonstrated, and they encourage the use of the Impella in circumstances other than those for which the device has been shown to be safe and effective.

BACKGROUND

According to the 510(k) for the Impella (Exhibit 1), the Impella is indicated for partial circulatory support using an extracorporeal bypass control unit for periods up to 6 hours. It is also intended to be used to provide partial circulatory support for periods up

to 6 hours during procedures not requiring cardiopulmonary bypass and provides pressure measurements which are useful in determining intravascular pressure.

The Impella has been associated with a number of Adverse Events in patients, including vascular injury, bleeding, thrombocytopenia, and thrombotic vascular (non-CNS) complication. A full list of potential Adverse Events is attached as Exhibit 2.

EXAMPLES OF ABIOMED'S FALSE AND MISLEADING ADVERTISEMENTS AND COMMUNICATIONS

Attached to this letter are several disturbing examples of Abiomed's false and misleading advertisements and communications. These include:

- Exhibit 3 is a full-page color advertisement (Advertisement) placed by Abiomed in the September 2010 Cath Lab Digest (vol. 18, no. 9) comparing its Impella product to intra-aortic balloon (IAB) catheters. Cath Lab Digest is widely distributed in the field of cardiac support and reaches interventional cardiologists that use both IABs and the Impella device.
- Exhibit 4 is a September 30, 2010 Abiomed press release (USpella Registry Press Release) discussing Abiomed's USpella registry purporting to include data for 352 patients on its Impella device.
- Exhibit 5 is a slideshow presented by Abiomed at the EuroPCR conference in May 2010 summarizing the data from Abiomed's USpella registry (Slide).
- Exhibit 6 contains screen shots of Abiomed's website as of December 8, 2010 (Website).
- Exhibit 7 is a transcript of one of Abiomed's earnings conference calls including statements by CEO Michael Minogue (CEO Transcript).

PROMOTION OF UNAPPROVED USE/BROADENING INDICATIONS FOR USE

The materials enumerated above misleadingly promote the Impella for intended uses and indications for use that are unapproved, for which safety and effectiveness have not been established, and for which there is no clinical evidence: recovering native heart tissue and saving lives.

Specifically, the Advertisement, Website, Press Release, and CEO Transcript promote the Impella's ability to help recover heart muscle and save lives:

- Press Release: see "better facilitate heart muscle recovery" in the first paragraph and similar language in the second, third, and fourth paragraphs.
- CEO Transcript: Abiomed's CEO spoke of the savings associated with "recovering heart muscle and discharging heart attack patients with their native heart potentially."

- Advertisement: see "old ideas about heart recovery" inside the red balloon and the "Recovering Hearts. Saving Lives" logo line below the Abiomed trademark to the left of the device photo in the lower left hand corner of the Advertisement
- Webpage: see logo line toward top of page, "Recovering hearts. Saving lives."

Abiomed's promotion of heart muscle recovery poses significant risk to the public; the unapproved claims may lead physicians to use the Impella as a prophylactic measure in the hope that it will help recover heart muscle. In fact, there is currently no device approved by FDA to recover heart muscle. Thus, patients who may not otherwise have received circulatory support will be placed on the Impella notwithstanding the long list of well-recognized dangers associated with the Impella. (See Adverse Events, above).

Although the Impella has been approved to provide partial circulatory support for patients whose hearts are under distress, each of these communications describe an outcome (heart muscle recovery) that has not been proven and for which the Impella is not approved. The FDA only recently approved a small 50 patient pilot study (MINI AMI) sponsored by Abiomed which is still ongoing, to specifically look at the Impella device's ability to reduce heart muscle damage. See Exhibit 8, Abiomed's own press release of December 2, 2010 (Reducing Heart Muscle Damage Press Release).

In addition, the Advertisement goes well beyond just promoting an unapproved indication and putting patients at risk, as it weaves a story the totality of which is utterly false and misleading. The Advertisement purports to show how much better off cardiac patients did after they were switched over from an IAB to the Impella.

The stage is set by referring to Cardiac Power Output (CPO) in the third paragraph of the Advertisement, which Abiomed refers to as the "#1 correlate to mortality for acute myocardial infarctions (AMI) in cardiogenic shock" and a doubling of which is stated to result in "a shock patient's risk of in-hospital death [decrease] from 60% to 30%." The Advertisement then points out that according to Abiomed's USpella registry, "the CPO of shock patients was observed to increase 120% from 0.5 ± 0.2 prior to Impella to 1.1 ± 0.2 on Impella ($p = 0.02$)" - implying a survival benefit to the patient, which is completely unsubstantiated. While it may be true that CPO is a correlate to mortality in shock patients, they have not shown any mortality benefit for these patients. Abiomed relies on observational data, which is not designed to evaluate outcomes. Abiomed's hemodynamic observations of the Impella device are designed to mislead clinicians into believing that the Impella improves mortality, when if fact there is no data to support this claim.

The Advertisement also lacks fair balance and is misleading because of what it leaves out. For example, if one is already looking at patient's blood pressures, the augmented diastolic pressure, which is not mentioned in the Advertisement, should also be considered as part of the patient's overall statistics. Further, the Advertisement

makes absolutely no mention of patient complications or adverse events that may go hand in hand with the highlighted "Improvement Gains" highlighted by the Advertisement.

MISLEADING, INADEQUATE, AND IMPROPERLY-SUBSTANTIATED COMPARATIVE ADVERTISING CLAIMS

Abiomed also claims the Impella's superiority over IABs in a manner that is misleading, inadequate, and unsupported.

First, the Advertisement misleadingly and inappropriately compares clinical parameters that are affected differently by IABs and the Impella because the devices work differently. The Advertisement points to an increase in systolic and diastolic blood pressures when transitioning between an IAB and the Impella, and implies a corresponding clinical benefit to the patient by referring to the increase as an "Improvement Gain." What Abiomed fails to disclose is that changes in systolic and diastolic blood pressures are not useful in comparing the clinical benefit to a patient on the IAB versus the Impella: while the Impella is placed in the left ventricle and is designed to increase systolic and diastolic blood pressure, IABs sit in the aorta just outside the heart and are designed to lower systolic and end diastolic blood pressures, but increase the Mean Arterial Pressure through augmentation of diastole. The devices by their design work differently. Therefore, using systolic and diastolic blood pressures to compare patient benefit as done in the Advertisement is deceptive.

Second, Abiomed makes improperly substantiated claims, based on inadequate data, between the Impella device and IABs by comparing the Impella to the whole of the IAB market, without conducting a "head to head" comparative study and without support from a clinical trial. In fact, Abiomed's most recent attempt to compare itself to IABs just failed: Abiomed recently stopped its clinical study comparing the Impella to the IAB because of a Data Safety Monitoring Board finding of futility. See Exhibit 9, Abiomed's own press release of December 6, 2010 (Finding of Futility Press Release). Instead, the comparison is based on non-randomized, non-peer reviewed, unpublished, observational data taken from a registry supported and funded by Abiomed (USpella registry, see Exhibit 5, Registry summary of results as presented at the Transcatheter Cardiovascular Therapeutics ("TCT") conference on September 23-25, 2010). Further, while the USpella registry is based on 251 patients (as of the date of the Advertisement), Abiomed's misleading conclusions are based on a handpicked, 18-member subset of this group (see "N=18" at the bottom of the Advertisement and the Slide).

Finally, the CEO Transcript shows inappropriate comparative claims as well: Abiomed's CEO stated "Impella provides better hemodynamic support compared to the intra-aortic balloon". However, hemodynamic measurements taken by Abiomed beyond

the initial thirty minute time frame demonstrate comparable levels of support for the IAB and Impella. (Exhibit 10, ISAR SHOCK trial).

In conclusion, Abiomed's advertising misbrands the Impella in violation of the Act, it fails to provide a fair balance of information, and is outright deceptive and misleading. Further, absent a new premarket notification, Abiomed's marketed intended use for the Impella as recovering heart muscle far exceeds it current indications for use. We ask that the FDA address these violative actions with Abiomed as soon as possible so as to minimize any resulting public damage.

Thank you for your attention, and please contact me freely at 202.857.1724 with any questions or comments.

Sincerely,

Melissa Gilmore

cc: Kristian Werling
Ann Simoneau
Timothy Ulatowski

ITEM THIRTEEN

(b) (6), (b) (7)(C) (USADC)

From: Schaefer, Kelsey <Kelsey.Schaefer@fda.hhs.gov>
Sent: Thursday, September 20, 2012 4:51 PM
To: Lash, Matthew J. (CIV); (b) (6), (b) (7) (USADC); (b) (6), (b) (7) (USADC)
Cc: (b) (7)(F)
Subject: Abiomed
Attachments: Draft Minutes Abiomed Meeting with Office of Compliance 07AUG2012 Final (2).doc; Abiomed Minutes Final 2012 08 07_acd edits.doc; Abiomed Minutes Final 2012 08 07 _acd edits-smp.doc; Abiomed EIR.pdf; Abiomed Brochure A.pdf; Abiomed Brochure B.pdf; K112892 510(k) Amendment for Change of Name of Device 23AUG2012.pdf

Attached are the following documents (b) (7) received from CDRH.

1. Abiomed's Draft Meeting Minutes with the Office of Compliance
2. Office of Compliance Meeting Minutes summarized by DOE B's Andrew Durfor
3. ODE's comments/edits of OC's Meeting Minutes
4. Abiomed's June 11th EIR
5. Promotional Brochure (A) for the Impella device collected by Owen Farris (ODE reviewer) at the May 10, 2012 Heart Rhythm Society Meeting.
6. Promotional Brochure (B) for the Impella device collected by Owen Farris (ODE reviewer) at the May 10, 2012 Heart Rhythm Society Meeting.
7. Copy of most recent 510(k) for the Impella. The name cVad that was proposed in this 510(k) was not made as a final name change for the device in the United States. It is still referred to as the Impella.

These documents may contain trade secret and confidential commercial information, personal privacy information, and/or may be subject to the attorney-client, deliberative process, and/or other privileges. Further disclosure of these documents could violate Federal laws and regulations. Any questions or requests for further disclosure should be raised with Kelsey Schaefer at FDA OCC.

Kelsey A. Schaefer
Associate Chief Counsel for Enforcement
Food & Drug Division, OGC, HHS
Email: Kelsey.Schaefer@fda.hhs.gov
Phone: 301-796-3666

ITEM FOURTEEN

(b) (6), (b) (7)(C) (USADC)

From: Schaefer, Kelsey <Kelsey.Schaefer@fda.hhs.gov>
Sent: Thursday, September 20, 2012 4:06 PM
To: (b) (6), (b) (7)(C) (USADC); (b) (7)(F) ; Lash, Matthew J. (CIV); (b) (6), (b) (7)(C) (USADC)
Subject: RE: Abiomed Call
Attachments: CIRCULATIONAHA.112.098194.full.pdf

Kelsey A. Schaefer
Associate Chief Counsel for Enforcement
Food & Drug Division, OGC, HHS
Email: Kelsey.Schaefer@fda.hhs.gov
Phone: 301-796-3666

From: (b) (6), (b) (7) (USADC) [mailto (b) (6), (b) (7)(C)
Sent: Thursday, September 20, 2012 4:00 PM
To: (b) (7)(F) Lash, Matthew J. (CIV); Schaefer, Kelsey; (b) (6), (b) (7) (USADC)
Subject: RE: Abiomed Call

http://phx.corporate-ir.net/phoenix.zhtml?c=95629&p=irol-newsArticle&ID=1730993&highlight=

From (b) (7)(F)
Sent: Thursday, September 20, 2012 3:36 PM
To: Lash, Matthew J. (CIV); Schaefer, Kelsey; (b) (6) (USADC); (b) (6), (b) (7)(C) (USADC)
Subject: Re: Abiomed Call

Dueling numbers. Which should I dial in to??

From: Lash, Matthew J. [mailto:Matthew.J.Lash@usdoj.gov]
Sent: Thursday, September 20, 2012 03:35 PM
To: Schaefer, Kelsey; (b) (6) (USADC) <(b) (6), (b) (7)(C) ; (b) (6), (b) (7)(C) USADC)
(b) (6), (b) (7)(C) >; (b) (7)(F)
Subject: Re: Abiomed Call

Thanks Kelsey! Let's use this

From: Schaefer, Kelsey [mailto:Kelsey.Schaefer@fda.hhs.gov]
Sent: Thursday, September 20, 2012 03:33 PM
To: Lash, Matthew J.; (b) (6), (b) (7) (USADC); (b) (6), (b) (7)(C) (USADC); (b) (7)(F)
(b) (7)(F)
Subject: RE: Abiomed Call

Sure:

1-877-917-8505
Participant: (b) (6)

Kelsey A. Schaefer
Associate Chief Counsel for Enforcement
Food & Drug Division, OGC, HHS
Email: Kelsey.Schaefer@fda.hhs.gov
Phone: 301-796-3666

From: Lash, Matthew J. [mailto:Matthew.J.Lash@usdoj.gov]
Sent: Thursday, September 20, 2012 3:32 PM
To: Schaefer, Kelsey; (b) (6), (b) (7)(C) (USADC); (b) (6), (b) (7)(C) (USADC); (b) (7)(F)
Subject: Re: Abiomed Call

The DOJs antiquated system at work. Do you have a dial in we can use?

From: Schaefer, Kelsey [mailto:Kelsey.Schaefer@fda.hhs.gov]
Sent: Thursday, September 20, 2012 03:30 PM
To: (b) (6), (b) (7)(C) (USADC); Lash, Matthew J.; (b) (6), (b) (7)(C) (USADC); (b) (7)(F)
(b) (7)(F)
Subject: RE: Abiomed Call

Is this the call in number? Not working for me.
Call-in: 1-800-521-6079 or 202-353-0878

Passcode: (b) (6)

Kelsey A. Schaefer
Associate Chief Counsel for Enforcement
Food & Drug Division, OGC, HHS
Email: Kelsey.Schaefer@fda.hhs.gov
Phone: 301-796-3666

From: (b) (6), (b) (7)(C) (USADC) [mailto (b) (6), (b) (7)(C)
Sent: Thursday, September 20, 2012 3:22 PM
To: Lash, Matthew J. (CIV); Schaefer, Kelsey; (b) (6), (b) (7)(C) (USADC); (b) (7)(F)
Subject: RE: Abiomed Call

Here is a more recent version, with edits from (b) (6), (b) for the call

(b) (6), (b) (7)(C)
Assistant United States Attorney
District of Columbia
555 4th Street, NW
(b) (6), (b) (7)(C)
Washington, D.C. 20530
(b) (6), (b) (7)(C)
(b) (6), (b) (7)(C)

From: Lash, Matthew J. [mailto:Matthew.J.Lash@usdoj.gov]
Sent: Thursday, September 20, 2012 2:03 PM

To: (b) (6), (b) (7)(C) (USADC); Kelsey.Schaefer@fda.hhs.gov; (b) (6), (b) (7)(C) (USADC); (b) (7)(F)
Subject: Re: Abiomed Call

I like the additional changes. Thanks for circulating. Talk to you all at 3:30.

From: (b) (6), (b) (7)(C) (USADC)
Sent: Thursday, September 20, 2012 01:32 PM
To: Lash, Matthew J.; Schaefer, Kelsey <Kelsey.Schaefer@fda.hhs.gov>; (b) (6), (b) (7)(C) (USADC); (b) (7)(F)
(b) (7)(F)
Subject: RE: Abiomed Call

In anticipation of this afternoon's call, attached please find the revised subpoena attachment.

(b) (6), (b) (7)(C)
Assistant United States Attorney
District of Columbia
555 4th Street, NW
(b) (6), (b) (7)(C)
Washington, D.C. 20530
(b) (6), (b) (7)(C)

From: Lash, Matthew J. [mailto:Matthew.J.Lash@usdoj.gov]
Sent: Monday, September 17, 2012 3:48 PM
To: Schaefer, Kelsey; (b) (6), (b) (7)(C) (USADC); (b) (7)(F) ; (b) (6), (b) (7)(C) (USADC)
Subject: RE: Abiomed Call

Let's plan on 3:30 on Thursday unless there are any objections? I will get a call-in number and circulate a meeting planner.

Matt Lash

From: Schaefer, Kelsey [mailto:Kelsey.Schaefer@fda.hhs.gov]
Sent: Monday, September 17, 2012 2:50 PM
To: Lash, Matthew J.; (b) (6) (USADC); (b) (7)(F) (b) (6), (b) (7)(C) (USADC)
Subject: Re: Abiomed Call

Thanks all for the accommodation. I can do before 10 or after 2 on thursday.
Kelsey A. Schaefer
HHS/OGC/FDD

From: Lash, Matthew J. [mailto:Matthew.J.Lash@usdoj.gov]
Sent: Monday, September 17, 2012 02:46 PM
To: (b) (6), (b) (7)(C) (USADC); (b) (6), (b) (7)(C) ; (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) (USADC)
(b) (7)(F)
Cc: Schaefer, Kelsey
Subject: RE: Abiomed Call

Great. It looks like Thursday will work. (b) (7)(F) thanks for flexibility on travel. I will get times from Kelsey tomorrow and finalize with everyone.

Regards,

Matt Lash

From: Radway, Ted (USADC)
Sent: Monday, September 17, 2012 2:31 PM
To: (b) (7)(F) Lash, Matthew J.; (b) (6), (b) (7) (USADC)
Cc: Schaefer, Kelsey
Subject: RE: Abiomed Call

Thursday is the only one of those that works for me, but feel free to go ahead if Jim is available another time. Thanks

From: (b) (7)(F)
Sent: Monday, September 17, 2012 2:23 PM
To: Lash, Matthew J. (CIV); (b) (6), (b) (7) (USADC); (b) (6), (b) (7) (USADC)
Cc: Schaefer, Kelsey
Subject: RE: Abiomed Call

I'm on travel the rest of the week but can do a call. I'm available for a call Tuesday afternoon, Wednesday afternoon, all day Thursday, and Friday until 2.

From: Lash, Matthew J. [mailto:Matthew.J.Lash@usdoj.gov]
Sent: Monday, September 17, 2012 2:20 PM
To: (b) (6) (USADC); (b) (6), (b) (7) (USADC); (b) (7)(F)
Cc: Schaefer, Kelsey
Subject: Abiomed Call

All,

Can we push our Abiomed call to later this week? Kelsey had something unavoidable come up. I am around all week if there are dates that work for you all, I will coordinate. Thanks.

Matt Lash

Matt Lash
Trial Attorney
Department of Justice
Consumer Protection Branch
Ph: (202) 514-3764
Email: matthew.j.lash@usdoj.gov

ITEM FIFTEEN

[redacted] (USADC)

From: [redacted] (USADC)
Sent: Friday, September 28, 2012 3:37 PM
To: [redacted] (USADC)
Subject: FW: Abiomed

[redacted] – these are the folks that brought us the case. I haven't talked to them so haven't told them you're running the show. Monday is bad but the rest of the week is better. What works for you?

[redacted]

From: Pivnick, David J. [mailto:DPivnick@mcguirewoods.com]
Sent: Friday, September 28, 2012 11:44 AM
To: [redacted] (USADC)
Subject: Abiomed

[redacted]

Is there a time that you would be available for a brief call regarding Abiomed either later today or next week? Please let me know.

Thank you.

David J. Pivnick
McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
312.750.3585 (Direct Line)
312.698.4539 (Direct FAX)
dpivnick@mcguirewoods.com
http://www.mcguirewoods.com

(b) (6), (b) (7)(C) (USADC)

From: (b) (6), (b) (7)(C) (USADC)
Sent: Friday, September 28, 2012 5:48 PM
To: Pivnick, David J.; (b) (6), (b) (7) (USADC)
Subject: RE: Abiomed

David, how is 4 pm EST on Wednesday?

From: Pivnick, David J. [mailto:DPivnick@mcguirewoods.com]
Sent: Friday, September 28, 2012 5:26 PM
To: (b) (6), (b) (7) (USADC); (b) (6), (b) (7) (USADC)
Subject: RE: Abiomed

I am available on Wednesday afternoon after 1 p.m. Central and am generally available on Thursday.

Please let me know if there is a time that is best.

Sincerely,

David

From: (b) (6), (b) (7) (USADC) (b) (6), (b) (7)(C)
Sent: Friday, September 28, 2012 3:36 PM
To: Pivnick, David J.; (b) (6), (b) (7) (USADC)
Subject: RE: Abiomed

David –

(b) (6), (b) has taken over the reins on this case, though I'm still involved, so I've cc'ed him. All day Thursday and Wednesday afternoon are best. Do either of those work?

Thanks,
(b) (6), (b) (7)(C)

From: Pivnick, David J. [mailto:DPivnick@mcguirewoods.com]
Sent: Friday, September 28, 2012 11:44 AM
To: (b) (6), (b) (7) (USADC)
Subject: Abiomed

(b) (6),

Is there a time that you would be available for a brief call regarding Abiomed either later today or next week? Please let me know.

Thank you.

David J. Pivnick
McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
312.750.3585 (Direct Line)
312.698.4539 (Direct FAX)
dpivnick@mcguirewoods.com
http://www.mcguirewoods.com

(b) (6), (b) (7)(C) (USADC)

From: Pivnick, David J. <DPivnick@mcguirewoods.com>
Sent: Tuesday, October 2, 2012 9:49 AM
To: (b) (6), (b) (7)(C) (USADC)
Cc: (b) (6), (b) (7)(C) (USADC)
Subject: RE: Abiomed

Please call my office at 312-750-3585.

Thank you.

David

From: (b) (6), (b) (7) (USADC) [mailto (b) (6), (b) (7)(C)
Sent: Monday, October 01, 2012 4:53 PM
To: Pivnick, David J.
Cc: (b) (6), (b) (7) (USADC)
Subject: RE: Abiomed

We'll call you. Just send us the number. Thanks.

From: Pivnick, David J. [mailto:DPivnick@mcguirewoods.com]
Sent: Friday, September 28, 2012 7:23 PM
To: (b) (6), (b) (7) (USADC)
Cc: (b) (6), (b) (7) (USADC)
Subject: Re: Abiomed

That will work well. What number is best?

David

Sent from my iPhone

On Sep 28, 2012, at 6:17 PM, (b) (6), (b) (7)(C) (USADC)" (b) (6), (b) (7)(C) wrote:

> David, how is 4 pm EST on Wednesday?

From: Pivnick, David J. [mailto:DPivnick@mcguirewoods.com]
Sent: Friday, September 28, 2012 5:26 PM
To: (b) (6), (b) (7) (USADC); (b) (6), (b) (7) (USADC)
Subject: RE: Abiomed

I am available on Wednesday afternoon after 1 p.m. Central and am generally available on Thursday.

Please let me know if there is a time that is best.

Sincerely,

David

From: (b) (6), (b) (7) (USADC) [mailto:(b) (6), (b) (7)(C)
Sent: Friday, September 28, 2012 3:36 PM
To: Pivnick, David J.; (b) (6), (b) (7) (USADC)
Subject: RE: Abiomed

David –

(b) (6), (b) has taken over the reins on this case, though I'm still involved, so I've cc'ed him. All day Thursday and Wednesday afternoon are best. Do either of those work?

Thanks,

(b) (6), (b)

From: Pivnick, David J. [mailto:DPivnick@mcguirewoods.com]
Sent: Friday, September 28, 2012 11:44 AM
To: (b) (6), (b) (7) (USADC)
Subject: Abiomed

(b) (6), (b) (7)

Is there a time that you would be available for a brief call regarding Abiomed either later today or next week? Please let me know.

Thank you.

David J. Pivnick
McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
312.750.3585 (Direct Line)
312.698.4539 (Direct FAX)
dpivnick@mcguirewoods.com
http://www.mcguirewoods.com

ITEM SIXTEEN

(b) (6) (USADC)

From: (b) (6), (b) (7)(C) (USADC)
Sent: Monday, August 20, 2012 4:18 PM
To: (b) (6), (b) (7)(C) (USADC)
Subject: FW: Abiomed
Attachments: Active_28459933_1_FDA - Proof of Receipt.PDF

The referring attorney and one other document; formally from our office

-----Original Message-----
From: Rowan, J. Patrick [mailto:prowan@mcguirewoods.com]
Sent: Friday, February 03, 2012 3:43 PM
To: (b) (6), (b) (7) USADC)
Cc: Pivnick, David J.
Subject: Abiomed

(b) (6):

Thanks again to you and your colleagues for listening to our presentation yesterday. At one point, we were asked if we had corresponded with FDA and we said that we had. Enclosed is the letter that we sent to FDA in December, 2010. It references some attachments, which are not readily available to me. Obviously, the FDA will have them, but if you would like me to locate and forward a set, please let me know. We are happy to answer any questions you may have about this or other matters.

Pat

J. Patrick Rowan
McGuireWoods LLP
2001 K Street, NW
Suite 400
Washington, DC 20006-1040
202.857.1758 (Direct Line)
202.828.3304 (Direct FAX)
prowan@mcguirewoods.com

http://www.mcguirewoods.com

REFF-2016-02987

Release in Full

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Direct: 312.750.3585

McGUIREWOODS

dpivinck@mcguirewoods.com
Direct Fax: 312.698.4539

May 18, 2012

VIA EMAIL AND FEDERAL EXPRESS

(b) (6), (b) (7)
Assistant United States Attorney
Criminal Division
555 Fourth Street, NW
Washington, DC 20530
Email: (b) (6), (b) (7)(C)

Re: Update on Abiomed's Activities

Dear (b) (6),

We write to provide you with an update on Abiomed's activities subsequent to our meeting in February, as well as provide you with some additional materials that we obtained after that meeting. This letter attaches and provides a brief description of those materials. We believe that the materials reflect Abiomed's off-label promotion of the Impella and its emphasis on the reimbursements that are purportedly attainable through the use of the Impella®.

1. CGS Guidance on Coding

On May 10, 2012, CGS, which is the Medicare carrier for Kentucky and Ohio, issued guidance relating to the coding for the Impella®. This guidance noted that the CGS Administrators Medical Review Department has seen claims billed with code 33799 for the insertion of the Impella®. The CGS guidance noted that the Impella® "is not a ventricular assist device designed to provide transition to implant; it is designed to assist during revascularization procedures for a short term (6-8 hours)." In light of the intended short term use of the Impella®, CGS instructed providers to use CPT code 92970 in reporting the insertion of the Impella®. The CGS guidance then noted that "**Impella® procedures coded under any other CPT code will be denied as a billing error.**" The CGS guidance also noted that there was no separate reimbursement for the removal of the Impella® in light of its short-term nature.

2. Abiomed's May 2012 PowerPoint Presentation

This document reflects coding and reimbursement information that we understand was disseminated by Abiomed as well as a recent PowerPoint presentation we understand was given by Abiomed. The coding and reimbursement document provides information on the various codes that can be used with Impella® and the reimbursements associated with those codes, the

MCC's and CC's that are commonly used with the Impella® 2.5, and the CPT codes that can be used in connection with the insertion and removal of the Impella®.

The PowerPoint presentation includes a general description of the Impella® and its function. The presentation also includes a discussion of hospital reimbursements with the Impella®, including a slide that notes: "Payer mix: majority are Medicare. . . ." That same slide includes what appears to be information regarding the reimbursement for PCI procedures – which are procedures that are outside of Abiomed's FDA clearance for the Impella®. Similarly, there are other discussions of what appear to be off-label uses of the Impella®, including the discussion of prophylactic uses of the Impella. The PowerPoint also includes several slides that relate to the Protect II study, which appear to have originated at the 2011 TCT conference. These slides again provide data on the purported results of the Protect II, including at 90 days, despite the trial's primary endpoint being at 30 days. Abiomed is seemingly continuing to rely on this study for promotional purposes even though the study did not meet its 30 day primary endpoint and was terminated in or around December 2010. These points are not disclosed in the presentation. Further, the slides contain reimbursement information that appears to conflict with the recent guidance from CGS above (e.g., coding for removal of the Impella® and coding for a ventricular assist device (VAD) as opposed to the code for a short term percutaneous catheter).

3. Abiomed's May 2012 Financial Reports

On May 16, 2012, Abiomed announced its fourth quarter results for fiscal 2012, which included revenue of $37.3 million, which was a 31% increase over the fourth quarter of fiscal 2011. Abiomed also noted that it had achieved profitability for the fiscal year. Abiomed's numbers were largely driven by the Impella®. The Impella® had worldwide revenue of $106.9 million ($99.1 million in the U.S.) during fiscal 2012, which represented a 37% increase over the prior year. There was also a 44% increase in U.S. Impella® revenue during the fourth quarter of fiscal 2012 as compared to that period in fiscal 2011. The article also indicates that Abiomed expects substantial increases in revenues during fiscal year 2013.

Separately, it is notable that Abiomed's stock price has dramatically risen to over $23.00.

4. February 2012 Perfmail Digest

This is a copy of an email chain from an online forum discussing perfusion and the use of the Impella®. We found a few of the comments to be interesting, particularly the comments that were made by (b) (6), (b) (7) (b) (6), (b) (7) commented on the short-term use of the Impella®, but also discussed Abiomed's approach in promoting and selling the device. Specifically, [redacted] (b) (6), (b) stated that Abiomed's sales representative focused the presentation on billing and coding and emphasized the reimbursements that were available through the use of the Impella®. (b) (6), (b) (7) also noted that there was information provided about the opportunity to purchase 5 Impella® catheters and then obtain the controller for free. (b) (6), (b) (7) summarized by stating that "[t]he primary pitch is that if cardiology has the right patient mix and if it is coded correctly they will make $25-$35K per procedure." There are other emails in the chain that are also

notable in the manner in which they discuss the use of the Impella®. We have redacted the internal portions of the email chain that came after the email on March 1, 2012.

5. Abiomed Schedule of Events at the 2012 ACC Conference

Abiomed continued its comprehensive marketing of the Impella® at the American College of Cardiology 2012 Scientific Sessions, which were held in Chicago, Illinois from March 24-26, 2012. The schedule of events reflects that Abiomed had scheduled sessions related to patients treated with PCI and patients who were suffering from cardiogenic shock. There appears to have also been at least one session that was directly related to the PROTECT II Study.

6. Additional Materials Received from the FDA

After our meeting, we also received some additional materials from the FDA in response to previously submitted FOIA requests. We understand that you have likely already seen these materials, but we wanted to provide them to be sure.

Please do not hesitate to ask if you have any questions regarding these documents or if you require any additional information.

Sincerely,

David J. Pivnick

David J. Pivnick

cc: J. Patrick Rowan

---- Forwarded Message ----
From: Perfmail digest <perfmail@lists.perfusion.com>
To: perfmail digest recipients <perfmail@lists.perfusion.com>
Sent: Thursday, March 1, 2012 12:00 AM
Subject: perfmail digest: February 29, 2012

PERFMAIL Digest for Wednesday, February 29, 2012.

1 (b) (6)
2. Saint Thomas Solution
3. Re: IMPELLA perfusion coverage
4. Re: IMPELLA perfusion coverage
5. Re: IMPELLA perfusion coverage
6. Perfusion.com Jobs Search Results - Email Alert
7. Re: IMPELLA perfusion coverage

Subject: (b) (6) MD
From: <orders@perfusion.com>
Date: 28 Feb 2012 13:26:01 -0500

X-Message-Number: 1

****

Name: (b) (6)
Email: (b) (6)
Subject: (b) (6) MD

Message:

(b) (6) is heading to Albuquerque, NM and any information regarding (b) would be appreciated. (b) is coming from Jackson Memorial Hospital in Miami. We hope to make (b) transition smooth.

Subject: Saint Thomas Solution
From: (b) (6)
Date: Mon, 27 Feb 2012 15:16:34 -0000
X-Message-Number: 2

Hi, everybody!

I would like to know if someone has something about this type of cardioplegic solution. I'm helping in a work about this type of solution.
My personal e-mail is (b) (6)

Thank you all!

Have a great week!

(b) (6)
Cordis Perfusionist, Brazil.

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) net>
Date: Sun, 26 Feb 2012 11:19:02 -0600
X-Message-Number: 3

One needs to clarify between the Impella 2.5 which is sold to the cath =
lab/cardiologist and the 5.0 which is sold to surgeons. In either case =
the DFU states the same time frame (this is from the 5.0):
"The ImpellaR 5.0 Circulatory Support System is intended for circulatory =
support using an

extracorporeal bypass control unit, for periods up to 6 hours. It is =
also intended to be used

to provide circulatory support (for periods up to 6 hours) during =
procedures not requiring

cardiopulmonary bypass."

In my institution when the Abiomed sales person made the presentation to =
the cath lab, perfusion was only added as an after thought. The main =
focus was on the cardiologist and a small subgroup of patients who were =
not candidates for PCI. The focus was, "...put the catheter in, do your =
proceedure, remove the device and make 30K."=20

Before some of you go well he is just complaining again. OK, when have =
you ever been in a "technical presentation" where billing and coding =
personnel were addressed specifically and at length? Abiomed told our =
hospital to buy 5 and get the controller for free. Well each catheter is =
about $25K and the final agreement was for 3 catheters! The primary =
pitch is that if cardiology has the right patient mix and if it is coded =
correctly they will make $25-$35K per procedure. How do you say =
manufacturer driven product pitching to a market that is desperate to =
find ways to stay competitive and a specialty that loves invasive =
devices?

To address the issue of perfusion coverage, finally, there shouldn't be =
any. If you follow Abiolmed's logic there is no need for specialized =
care. Put in the catheter, hook it up to the controller, prime and away =
you go. Then pull it in an hour. The surgeons I work with told =
cardiology that if they had a problem too bad. They were not consulted =
and this was an elective procedure on a patient, by definition, who was =
not a surgical candidate. Repair of femoral artery perhaps but not a =
surgical intervention on an emergent basis.=20

I'm not Abiomed bashing. I think it is a good product and from what I =
hear they are developing a right sided device. For those of use who have =
seen a patient die of right sided failure it would be a very welcomed =
addition to our product mix. I do think that their "comprehensive =
training program" for the 2.5 is aimed at cardiology and nursing with no =
thought, at all, toward perfusion. Unless you are specifically told to =
provide coverage for the device let the nursing staff handle it, after =
all that is what the manufacturer says is safe after their "training".

By the way, we did 6 and perfusion was never called and after a cost =
analysis we won't do anymore. I know that a lot of people are using them =
regularly and are making great money but that's my story and I'm =
sticking to it.

Definitely my 2 cents worth,

(b) (6) [redacted]

----- Original Message -----=20
From: "Perfmail" <perfmail@lists.perfusion.com>
To: "Perfmail" <perfmail@lists.perfusion.com>
Sent: Sunday, February 26, 2012 8:19 AM
Subject: Re: IMPELLA perfusion coverage

Appropriate training for nursing staff should require your Perfusionists =
to NOT have to monitor Impella patients. Abiomed brings a comprehensive =
training program for all clinicians who will be caring for patients with =
Impellas. From Cath Lab to OR to ICU, all parties will be =
appropraitely trained so that it does not become a 24/7 Perfusion =
coverage type thing.
(b) (6)

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) .com>
Date: Sun, 26 Feb 2012 19:20:53 -0500
X-Message-Number: 4

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Content-Type: text/plain; charset=ISO-8859-1

(b) (6)

Your comment "*We will 'advise'---if we can remember after months of not even noticing the console in our office. I think we will wind up calling the cath lab and asking if anyone there remembers how to do it.*" bothers me a bit. It is our responsibility to be up to speed on each of the devices we are responsible for operating. We have a number of systems that we use on occasion, and considering the number of staff we have, a particular staff member may not see one of these systems for a number of months. It is our responsibility, through competency maintenance and personal efforts, to stay current on every system we employ. Having used the Impella, as I have, I would be surprised if you felt it was as simple to competently insert and operate as an IABP. I personally believe the direction companies who market these and other percutaneous systems are going is unwise. An apparent decrease in complexity does not change how the system interacts with the patient and the complications that may arise. Simply because a device is inserted percutaneously, the design is different, or the interface has changed doesn't change what the device does. IMO, those who deal with extracorporeal systems every day are the best prepared to manage these devices, perfusionists. AmSECT has published a position statement on this topic. One place to read it is here<http://pennperf.org/wp-content/uploads/2011/12/0021.pdf>

Respectfully,

(b) (6)

On Sun, Feb 26, 2012 at 1:13 PM, Perfmail
<perfmail@lists.perfusion.com>wrote:

> Okay, I've stopped laughing. Whew! What a gag.
> Impella: We have two sizes. The 2.5 was used by the cath lab, and no one
> even mentioned it to the perfusionists until after several had been
> inserted and they (cardiology) wanted the O.R. to have the 5.0 "just in
> case". After using it in the cath lab, it was usually withdrawn. At least
> one time the patient was sent to the intensive care unit, and at least one
> patient was sent out for further intervention. We have not heard about it
> in months.
>
> After a meeting of the heavy guns (and a few peons, like me), it was
> decided to equip the O.R. with 5.0 cannulae and one of the two consoles
> that cardiology had. It sits in my office, collecting dust. The cannula
> has faced expiration at least once and was exchanged. The O.R./purchasing
> complex has charge of it. The plan is that the perfusionist will be
> running the pump and will only be able to spare a small amount of attention
> to Impella insertion, which is a surgeon/PA/nurse task. We will
> 'advise'---if we can remember after months of not even noticing the console
> in our office. I think we will wind up calling the cath lab and asking if
> anyone there remembers how to do it.
>
> Certainly we do not have a mandate to babysit it in the unit. That task
> has already been laid on the nursing staff. We are perhaps 'resource
> persons' if they get into trouble, just as we are for the IABP. We did
> 24/7 in Unit coverage of that for 15-20 years, but for at least the past
> decade the ICU staff has handled it, and I have reached the point where,
> when I do my daily check, I tell the attending nurse that if there is a
> problem, "fix it and let me know how it went". They have been superb
> balloon sitters. Thank you very much, Datascope/Maquet for the training
> and in-servicings. BTW, we do 40 balloons / year +/-, decade in and decade
> out.
>
> In short, our experience with the Impella, as with the Angio-vac, mirrors
> that of many institutions: initial enthusiasm followed by total apathy. As
> with burn out---the first stage is enthusiasm.
>
> (b) (6) org

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) com
Date: Sun, 26 Feb 2012 20:52:31 -0500 (EST)
X-Message-Number: 5

This is a multi-part message in MIME format.
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Content-Transfer-Encoding: quoted-printable
Content-Type: text/plain; charset="us-ascii"

(b) (6)

I think you already know that we have already have 24/7 in-house coverage. =
With the Impella 2.5, we are there for the insertion. After the patient is =
transported to critical care, we are available for trouble-shooting. We hav=
e not yet inserted the 5.0 Impella, but will cover it the same way. Unlike =
many of the responses, we became involved with the Impella during one of th=
e early clinical trials.

(b) (6)
Riverside Hospital
Columbus, OH=20

-----Original Message-----
From: Perfmail <perfmail@lists.perfusion.com>
To: Perfmail <perfmail@lists.perfusion.com>
Sent: Sun, Feb 26, 2012 8:13 am
Subject: IMPELLA perfusion coverage

Could anyone share how perfusion coverage for IMPELLA catheters works=20
ost insertion at their institutions. I'm trying to match patient=20
afety with cost of 24/7 coverage.
(b) (6)

Subject: Perfusion.com Jobs Search Results - Email Alert
From: (b) (6) <services@perfusion.com>
Date: Tue, 28 Feb 2012 11:50:17 -0500
X-Message-Number: 6

Perfusion.com Jobs has found the following jobs for you:

Job Title, Organization, Location, Url

Perfusionist, Charleston Area Medical Center, Charleston
http://www.perfusion.com/jobs/jobdetails.aspx?id=3188

NEW FEATURE:

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to all new jobs posted that meet their exact specifications!

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All Job Links:

http://www.perfusion.com/jobs/jseeker/

This is an automated response. Please do NOT reply.

PDC Employment Services
http://www.perfusion.com/jobs
Toll Free: (866) 499-5672
jobs@perfusion.com

Subject: Re: IMPELLA perfusion coverage
From: (b) (6) (b) (6) .net>
Date: Sun, 26 Feb 2012 19:22:07 -0800 (PST)
X-Message-Number: 7

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Content-Type: text/plain; charset=iso-8859-1
Content-Transfer-Encoding: quoted-printable

=A0=A0 At one of our institutions our Perfusion team has taken charge of th=
e Impella.=A0 Mostly because there were too many Cath Lab personnel to
stay=
competent. We set it up and operate it in the Cath Lab. Usually the Impell=
a is put in as support for a high risk PCI, then removed at the end of the =
procedure. Some are put in emergently and the patient needs to be supported=
in the ICU. AbioMed has spectacular Reps and training programs. We hand th=
e Impella off to the ICU staff. If they aren't comfortable the Reps or our =
Perfusion staff will give them an in-service, etc. We are available to be c=
ontacted for trouble shooting, but the AbioMed Reps make that a very rare e=
vent. We bill it as any Ventricular Assist Device. It is very expensive, bu=
t the reimbursement to the hosp[ital is also very good.
=A0=A0 At our other institution the Cath Lab is completely autonamous from
=
the Perfusion Team and we only hear about use from the Reps at the other Ho=
spital. I think in most cases=A0 it comes down to the role of Perfusion in =
the Cath Lab before the Impella is put in practice.=20
(b) (6) CCP

--- On Sun, 2/26/12, Perfmail <perfmail@lists.perfusion.com> wrote:

From: Perfmail <perfmail@lists.perfusion.com>
Subject: Re: IMPELLA perfusion coverage
To: "Perfmail" <perfmail@lists.perfusion.com>
Date: Sunday, February 26, 2012, 10:29 AM

While I agree that perfusion bedside 24/7 monitoring is not needed for any

MCS/VAD system, Abiomed will train anyone to operate the Impella.

Now, I don't subscribe to this particular course.=A0 I believe perfusionist=
s
are the best equipped to provide optimal care for these patients and would highly recommend that your perfusion department be actively involved in any MCS system implanted at your institution.

(b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

APR 20 2010

(b) (6)
Sr. Vice-President, Global Product Operations
Abiomed, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Dear (b) (6):

The purpose of this letter is to acknowledge receipt of your April 7, 2010 correspondence addressed to (b) (6), (b) (7)(C) Your correspondence was in response to our March 29, 2010 letter addressing your proposed corrective actions to an Untitled Letter that was issued to you on January 28, 2010.

You took additional corrective actions to address the concerns we noted in our March 29, 2010 letter to you. These additional actions included:

- removing the brochure with the referenced charts and graphs from the website,
- providing screenshots to document the removal of the brochure and the press release from your website, and
- providing us with the standard operating procedure (SOP) and routing form for Customer or External Communication.

In reviewing your website, however, it was discovered that a copy of the brochure was still available under the heading of "Brochures" under the "Product" tab. You were notified of this oversight on April 16, 2010 via telephone call. You promised to remove that brochure by the end of the day. The removal of this brochure was documented, by you, via e-mail on April 16, 2010.

Your response appears adequate. No response to this letter is necessary.

The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website.

The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address: http://www.fda.gov/Training/CDRHLearn/ucm162015.htm.

Sincerely yours,

(b) (6), (b) (7)(C) [redacted]

Chief, Special Investigations Branch
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health

CC:

(b) (6) [redacted]

Chief Medical Officer
ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Indications for Use

510(k) Number (If known): K063723

Device Name: IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System

Indications for Use:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(b) (6) [redacted]

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063723

REFF-2016-02987
Additional Records

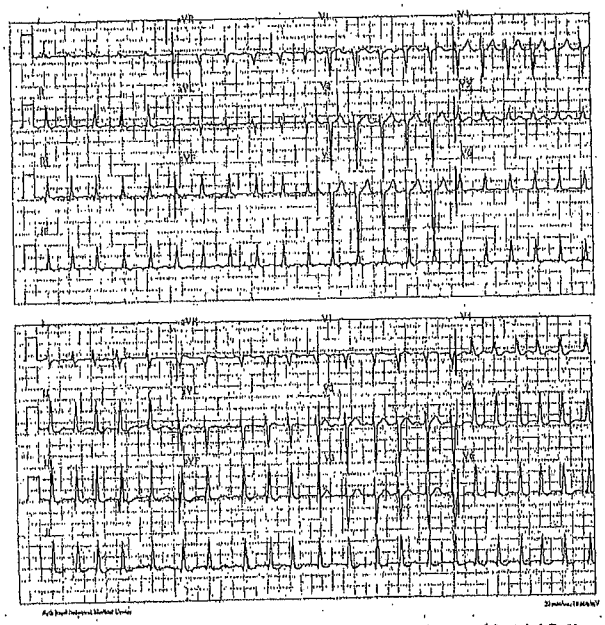


Figure 3. 12-lead electrocardiogram demonstrating rapid atrial flutter (top) and atrial fibrillation (bottom).

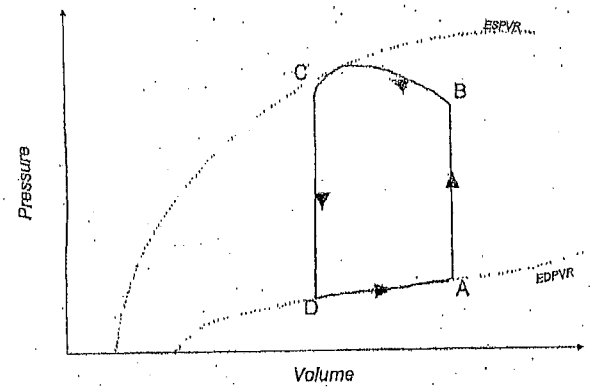


Figure 4. Schematic description of the pressure-volume loop. A. End diastole with mitral valve closure; B. Aortic valve opening; C. End systole with aortic valve closing; D. Mitral valve opening.

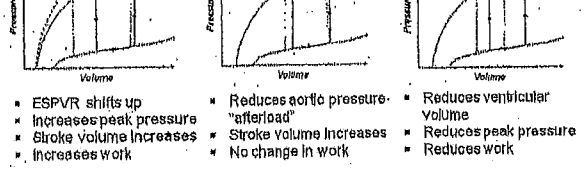


Figure 5. Effect of various therapies on the pressure-volume loop. IABP, intra-aortic balloon pump; ESPVR, end systolic pressure volume relationship; VAD, ventricular assist device.

Use of the Impella 2.5 circulatory support device may have had several complementary effects in this case.

on hospital day 14. At one month after discharge, the patient remains on hemodialysis, but is no longer oliguric, and functionally independent at NYHA Class 1.

Discussion

We describe a case of profound cardiogenic shock resulting from a non-ischemic cardiomyopathy, in which temporary percutaneous left ventricular support using the Abiomed Impella 2.5 resulted in clinical stabilization of the patient and myocardial recovery over the ensuing days. We believe that this innovative use of left ventricular support may have value in patients with sudden hemodynamic deterioration due to cardiac failure, including patients with myocarditis, postpartum cardiomyopathy, and in selected patients with acute on chronic left ventricular systolic dysfunction.

Use of the Impella 2.5 circulatory support device may have had several complementary effects in this case. First, blood pressure and cardiac output were improved with the use of the Abiomed device, reducing the need for ionotropic and pressor support during this critical time period. Experimental and clinical studies have shown that hemodynamic improvement is due to an increase in the cardiac output owing to the direct effects of the Impella device, albeit with a reduction in cardiac output due to instrinsic myocardial contractility, in effect, "resting" the myocardium during the time of hemodynamic collapse.[1-3] More importantly, percutaneous left ventricular assist devices reduced both the left ventricular end diastolic and end systolic pressures and volumes, reducing left ventricular oxygen demand.[2,3] Based on pressure volume simulation (Figure 4), there is a more profound leftward and downward shift with the use of the Impella percutaneous left ventricular assistance than with inotropes or with an intra-aortic balloon pump (Figure 5). Thirdly, maximum ventricular wall tension, T, occurs at end diastole and can be characterized using the Law of Laplace as:

$$T \propto \frac{(EDP \times EDV)}{w} \propto Microvascular\ Resistance$$

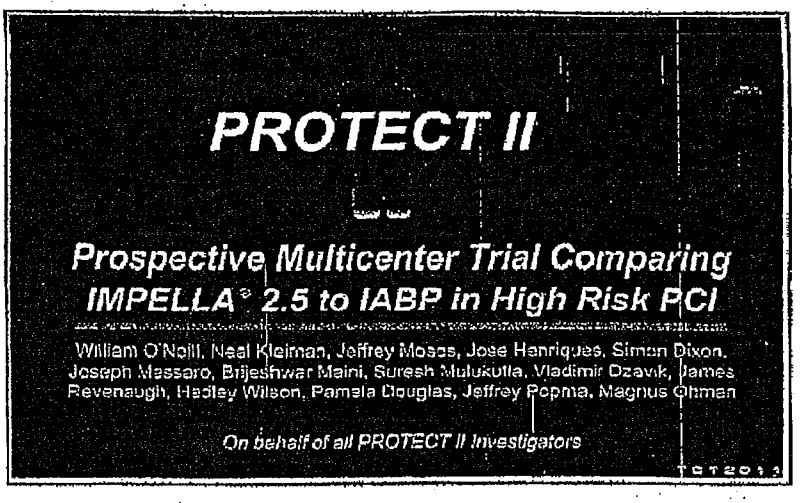
where *EDP* is the end diastolic pressure, *EDV* is the end diastolic volume and *w* is the ventricular wall thickness. By reducing the maximum wall tension and microvascular resistance, myocardial blood flow is improved.[4,7] Finally, the Impella provided temporary hemodynamic stabilization so that an ablation procedure for the refractory atrial arrhythmia could be performed.

We conclude from this case that the Impella 2.5 circulatory support device may be beneficial in patients with acute cardiogenic shock caused by non-ischemic cardiomyopathy. The improvement in left ventricular systolic function in this case may have occurred by unloading the left ventricle, improving cardiac output and myocardial blood flow, and halting the hemodynamic spiral associated with cardiogenic shock. ■

The authors can be contacted via Dr. David Leeman at dleeman@bidmc.harvard.edu

References

1. Burzotta F, Paloscia L, Trani C, et al. Feasibility and long-term safety of elective Impella-assisted high-risk percutaneous coronary intervention: a pilot two-centre study. *J Cardiovasc Med (Hagerstown)* Oct 2008;9(10):1004-1010.
2. Valgimigli M, Steendijk P, Sianos G, et al. Left ventricular unloading and concomitant total cardiac output increase by the use of percutaneous Impella Recover LP 2.5 assist device during high-risk coronary intervention. *Catheter Cardiovasc Interv* Jun 2005;65(2):263-267.
3. Dixon SR, Henriques JP, Mauri L, et al. A prospective feasibility trial investigating the use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (The PROTECT I Trial): initial U.S. experience. *JACC Cardiovasc Interv* Feb 2009;2(2):91-96.
4. Seyfarth M, Sibbing D, Bauer I, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. *J Am Coll Cardiol* Nov 4 2008;52(19):1584-1588.
5. Remmelink KD, Dekker AL, Van Ommen V, et al. Miniature intracardiac assist device provides more effective cardiac unloading and circulatory support during severe left heart failure than intraaortic balloon pumping. *Chest* Sep 2004;126(3):896-902.
6. Remmelink M, Sjauw KD, Henriques JP, et al. Effects of left ventricular unloading by Impella recover LP2.5 on coronary hemodynamics. *Catheter Cardiovasc Interv* Oct 1 2007;70(4):532-537.
7. Sauren LD, Accord RE, Hamzeh K, et al. Combined Impella and intra-aortic balloon pump support to improve both ventricular unloading and coronary blood flow for myocardial recovery: an experimental study. *Artif Organs* Nov 2007;31(11):839-842.



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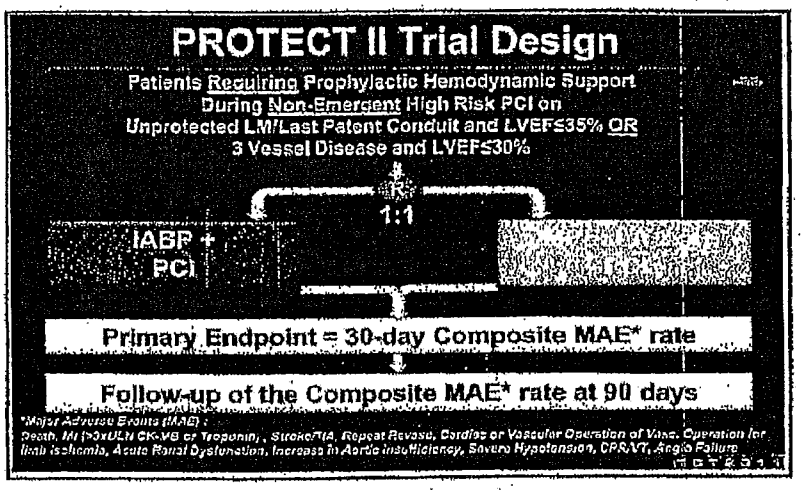

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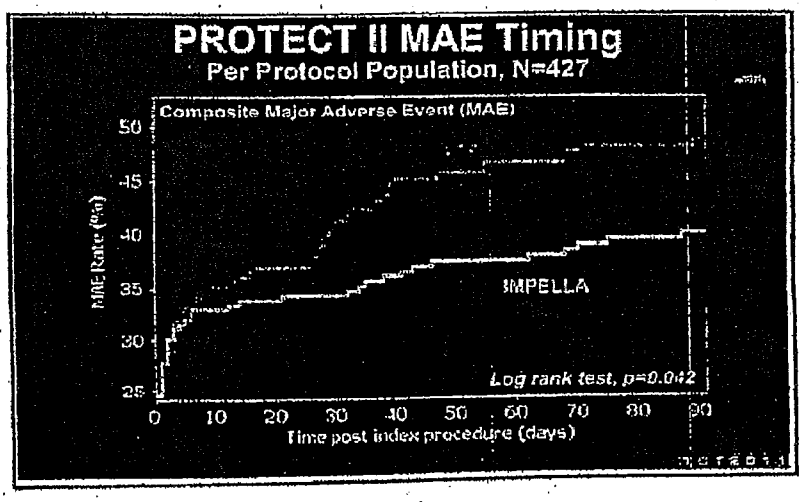

notes