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## Guidant vs. Aspen: "Just Say No" (to confidentiality restrictions)

A trial wending its way through the legal system in Minneapolis in May 2006 could have a major impact on hospital purchasing, group purchasing organizations (GPOs), and services that hospitals may have for negotiating prices with vendors. Guidant, a manufacturer of defibrillators and pacemakers, sued Aspen Healthcare Metrics in August 2004 for four things, including Aspen's "tortious interference with Guidant's contracts" and "misappropriating Guidant's trade secrets." What exactly did Aspen do to get sued? They helped hospitals get better prices from Guidant for their defibrillators. If Guidant prevails in this lawsuit, and other vendors adopt their approach, this could affect a lot of companies that advise hospitals.

After an 18-month period in which each side deposed the other, and millions of dollars in legal fees were spent, the judge assigned to the case, Judge Donovan Frank, issued a Partial Summary Judgment in February of 2006 in St. Paul Minnesota in favor of Guidant. Although Aspen argued that they were acting as an agent of the hospital, the judge found that Aspen was

not and agent, and hence was subject to the tortious interference claims. Therefore, he essentially agreed that Aspen had "induced hospitals to violate the confidentiality provisions of their contracts with Guidant." A jury trial in May is supposed to determine the damages that Aspen must pay Guidant. Guidant's revenues in 2005 were about 1,000 greater than Aspens.

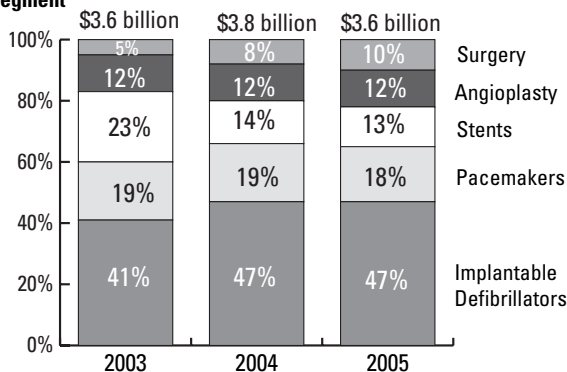
This case has not attracted much attention even though the implications are significant. Although this is currently limited to one company and one jurisdiction, if Guidant continues to pursue its legal rights throughout the country, it could make it difficult for any consultant, group purchasing organization, or publication to report on, compare, or provide assistance to hospitals to negotiate better prices. Significantly, Guidant began to include the following language (see page 4) in their invoices beginning in March 2005: "This invoice is provided solely for the purpose of payment. Acceptance of this invoice...reflects agreement to treat this invoice and all information contained in this invoice as confidential,...and not release to any third party without written consent." Huh? That means that technically, the hospital would have to get permission to send an invoice from Guidant to a payer, physician, or patient.

The reason that Guidant did this is pretty obvious. While Guidant can protect the communications they have with the hospital under the cloak of confidentiality, once they start invoicing the hospital, that is more difficult to do. So rather than getting a copy of a Guidant contract with the hospital, a consultant working for the hospital would be able to simply review the invoices that Guidant has sent and determine the average price the hospital has paid by looking at that source of data. So Guidant did the best that they could to keep that information out of the hands of consultants, referred to as "leeches" in one of the court documents by a Guidant executives.

Guidant may have a difficult time keeping a lid on their pricing information for a couple of reasons. Number one, Guidant may

### Profile of Guidant 2003-2005 sales

Percent of sales  
by segment

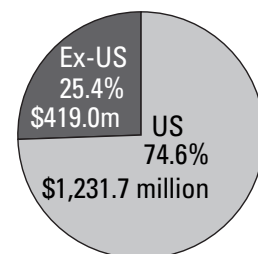


Source: 2005 Guidant 10-k

### Guidant 2005 defibrillator sales, by country of sale

**Guidant  
2005 Defibrillator  
revenues**

**US defibrillator revenues :  
\$1.231 billion**



Source: 2005 Guidant 10-k

have become a victim of its own success. In 2005, they posted world-wide revenues of \$3.6 billion, which was divided into segments of defibrillators, pacemakers, stents, angioplasty, and surgery. Although pacemakers are relatively well-known in the general public, they are a relatively small amount of Guidant's revenues (18% in 2005) compared with the higher priced defibrillators which accounted for 47% of their 2005 revenues. With a weight measured in grams and the size of a silver dollar, a box containing defibrillators and leads that can easily be transported in the trunk of a car can have a value of millions of dollars. Many in the orthopedic industry, who routinely must schlep trays of implants and devices that weigh hundreds of pounds, would be envious of a business with a small number of products, high price, and a light weight.

Second, the number of specific devices that they are trying to keep the prices secret on is quite small, relative to orthopedics. A search of Guidant's web site reported 5 Cardiac Resynchro-

nization Therapy (CRT) product lines, 4 defibrillator product lines, and about 20 parts which account for almost as much revenue as the entire US trauma industry. It is much harder to keep prices secret when there are so few of them to begin with. For example, Synthes alone has over 15,000 parts in its price list.

Third, there are a number of precedents supporting Aspen's contention that the prices of defibrillators are not trade secrets. *Orthopedic Network News* surveyed the Guidant web site, performed a web search, contacted some other sources, and performed a survey of some US hospitals that have purchased Guidant defibrillators in the last 2 years. The result of this research yielded the Western Australia prices for defibrillators and pacemakers, the French ministry of health's "tariffs" for implantable medical devices, including defibrillators, the prices paid by the State University of New York (SUNY) system, and a survey of Guidant defibrillator prices for 19 hospitals. (See footnotes below for URLs for the SUNY, French, and Australian

### Guidant's Defibrillators, prices

Product line <sup>1</sup>	Type <sup>2</sup>	Part implants	US <sup>3</sup> implants	Ex-US <sup>3</sup> implants	Approval Date (US) <sup>3</sup>	French Price <sup>4</sup>	Australian Price <sup>5</sup>	SUNY price <sup>6</sup>	Sample ONN US Price <sup>7</sup>
Contact Renewal 4 <sup>8</sup>	CRT-D	H190/H197 <sup>9</sup>	none	na	na	\$20,218	na	na	na
Contact Renewal 3 HE	CRT-D	H177/H179 <sup>9</sup>	19,000	none	June 2003	na	na	na	\$30,688
Contact Renewal 3	CRT-D	H170/H175 <sup>9</sup>	27,000	none	June 2003	na	na	na	\$27,643
Contact Renewal	CRT-D	H135	10,000	none	Dec. 2002	na	na	\$35,195	na
Contact Renewal TR	CRT-P	H120/H125 <sup>9</sup>	4,000	none	na	na	na	na	\$12,500
Vitality 2	VR EL	T177	2,000	2,000	March 2004	\$15,317	na	na	\$21,000
	DR EL	T167	3,000	1,000	March 2004	\$17,767	na	na	\$21,000
	VR	T175	7,000	3,000	March 2004	\$14,704	na	na	\$21,940
	DR	T165	9,000	4,000	March 2004	\$17,155	na	na	\$23,067
Vitality AVT	DR	A155	12,000	none	October 2003	na		na	\$22,054
	DR	A135	7,000	1,000			\$34,725	\$34,510	
Vitality DS	VR	T135	13,000	none	July 2003	\$14,704	na	na	\$21,295
	VR	T125	14,000	1,000	July 2003		na	na	\$22,609
	DR	T127	3,000	none	July 2003		na	na	\$19,000
Ventak Prizm 2	VR	1860	25,000	12,000	August 2000	\$14,704	\$11,057	\$31,760	\$19,500
	DR	1861	43,000	8,000	August 2000	\$17,155	\$14,742	\$33,260	na

Notes: <sup>1</sup> Product names, lines and part numbers from Guidant's web site, [www.guidant.com](http://www.guidant.com).

<sup>2</sup> CRT-D Cardiac resynchronization device (defibrillator), CRT-P Cardiac resynchronization device (pacemaker), DR: Dual chamber, VR: Single chamber, EL: Extended life.

<sup>3</sup> Estimates of implanted devices in US, outside the US (ex-US), and US approval date are from Guidant's publication: "Product Performance Report, 2006 Q1 Edition"

<sup>4</sup> French prices: Securite Sociale L'Assurance Maladie, Liste de Produit et des Prestations. Prices are translated from Euros at the exchange rate of 1 Euro = \$1.22

See web site: [http://www.codage.ext.cnamts.fr/codif/tips/chapitre/index\\_chap.php?p\\_ref\\_menu\\_code=1&p\\_site=AMELI](http://www.codage.ext.cnamts.fr/codif/tips/chapitre/index_chap.php?p_ref_menu_code=1&p_site=AMELI)

<sup>5</sup> Australian prices: From Department of Health, Government of Western Australia, Buyers Guide, Contract No: HSWA 065/2003 for the supply of Implantable Pacemakers, Defibrillators, Leads & Associated Equipment.. Contract period: 1st March 2003 to 28th February 2006. Prices are translated at the exchange rate of 1 Australian do Complete buyer's guide accessible at: [http://www.healthsupply.health.wa.gov.au/contracts/pdfs/HSC\\_065\\_2003.pdf](http://www.healthsupply.health.wa.gov.au/contracts/pdfs/HSC_065_2003.pdf)

<sup>6</sup> From "State of New York Executive Department, Office of General Services, Supplemental Contract Award Notification, for period April 1, 2003 through March 31, 2005." Available at [www.ogs.state.ny.us/purchase/spg/pdfdocs/1260102612sa.pdf](http://www.ogs.state.ny.us/purchase/spg/pdfdocs/1260102612sa.pdf). H135 Contak Renewal includes EasyTrak lead and lead delivery system. Other prices are systems with 2 leads and Endurance RX lead.

<sup>7</sup> US prices obtained from a selection of 19 hospitals that purchased Guidant defibrillators between 2005 and 2006. May not be reflective of national averages, an individual hospital's experience, or the experience of a larger group of hospitals.

<sup>8</sup> Contak Renewal 4 not available in US; presumably somewhat more "modern" CRT-D device than the Contak Renewal 3. Note in Guidant's Performance report (see citation footnote #3) indicates: "Contak Renewal 4 RF HE, Contak Renewal 4 RF, Contak Renewal 3 RF HE, Contak Renewal 3 RF, Contak Renewal 4 AVT HE, Contak Renewal 4 AVT, Contak Renewal 4 HE, Contak Renewal 4, Contak Renewal 3 AVT HE, Contak Renewal 3 AVT, and Contak Renewal 2 do not have sufficient US implant experience and therefore do not meet inclusion criteria for reporting cumulative survival."

<sup>9</sup> Two part numbers (eg. H177/H179) designate different types of programming the lead connectors. The first one (H177) designates that the defibrillator was programmed with international standard, IS-1. The second part (H179) designates defibrillator programmed with Guidant's proprietary LV-1 standard.

prices.) In the case of the Australians and the French, one could argue that the prices these entities pay would not necessarily apply to US hospitals. Furthermore, many of the devices available in the US are not available overseas. However, in at least one case, the French have access to the Contak Renewal 4 bi-ventricular defibrillator (H190/H197) for a price of 16,500 euros (about \$20,218 US) while US hospitals have the somewhat older Contak Renewal 3 (H170/H179) with a surveyed price of over \$30,000. In addition, there are other public sources of information on Guidant prices, including records from many US hospitals which are subject to Freedom of Information Requests (FOI), the Veteran's Administration contracts, services such as ECRI, IMS, and others that report average prices of devices.

By publicly pursuing Aspen, which is owned by the larger MedAssets group purchasing organization, Guidant may have called undue attention to this practice. For example, just because Guidant unilaterally changed the wording on the invoices they send to hospitals, this may not result in an obligation on the part of the hospital to keep the pricing information confidential.

Second, as hospital administrators become aware of these restrictions that Guidant is trying to place on their information, they become irritated to the point of outrage. Hospitals typically have regulators up the wazoo who want access to all kinds of records, including patient records, invoices, financing, and contracts. Medicare, for one, has a stipulation that requires hospitals to fork over anything that they ask for. For Guidant to assume that they have a protected position in the galaxy of hospital information is naive at best. And their attempt to make this confidential smacks of "trying to hide something."

However, hospitals and their allies appear to be waking up. In March, 2006, Newt Gingrich, former Speaker of the House of Congress, testified in front of a House Committee about how a legislative initiative was necessary to keep transparency of pricing in the industry. Although he didn't mention Guidant by name, his comments regarding "prices as trade secrets" was a clear reference to the Guidant vs. Aspen lawsuit.

**Guidant invoice, 2006**

**GUIDANT**

**INVOICE:**   
**INVOICE DATE:**   
**CUSTOMER:**   
**DELIVERY:**   
**PAYMENT TERMS:** 30 days net

This invoice is provided solely for the purpose of payment. Acceptance of this invoice and all information contained in this invoice by the recipient and its employees reflects agreement to treat this invoice and all information contained in this invoice as confidential, use only for the purpose of payment, and not release to any third party without written consent.


**Propensity to Litigation?**

Sometimes it is possible to characterize a company or an industry as more prone to litigation than others. For example, there are relatively few lawsuits for intellectual property/patent infringement in joint replacement and trauma, but there have been quite a few in the spine industry. In Guidant's 2005 10-K, they list 7 pages of outstanding and resolved litigation, including class-action and individual lawsuits on behalf of patients with recalled defibrillators, class-action lawsuits for shareholders, lawsuits involving stents, and lawsuits involving former employees. However, the ongoing litigation with Aspen did not merit mention in their 10-K.

It is unlikely that Guidant would sue a hospital for violating a confidentiality clause—good business dictates that you don't sue your customers. However, they have sued Aspen and may sue similar companies that provide this type of comparative service. By sheer legal intimidation, they may try to keep services from sharing price information, since they are better served if hospitals are in the dark on how much they and their competitors are paying. If Guidant is successful, it is possible that other device companies, emboldened by Guidant's success, will follow suit and declare their prices as trade secrets too.

Neither Aspen nor Guidant appear to have any intention on backing down in this lawsuit, and it is possible that this will be appealed all the way to the Supreme Court. What is ironic is that events often overtake the legal system. In the Federal Register published April 25, 2006, the DRG rates proposed for reimbursing hospitals for defibrillators were reduced as much as 23%. Although the rates may change before the final rule is published in August, it is possible that the prices that Guidant is trying to keep secret in this lawsuit will be rendered moot by the events of the day.

Most hospitals want the flexibility to decide when, where, and how to use their information, including the prices that they pay for devices. Driving down the cost of devices is at odds with the shareholders which own the companies that manufacture them, but then the broader issue is who are the shareholders? The investment companies and executives who own stock in the company, the broader society who benefits from these devices, or the taxpayers who ultimately pay for them?

I personally know people who have defibrillators implanted who would not be alive today if they didn't have one. The decision of which device is best for a patient will depend on a variety of factors including the patient condition and physician's judgement. The injection of litigation into the decision process will simply poison the discussions, and relegate these devices to commodities, where the price becomes the only topic that is discussed.  *Guidant's response to this article is posted on [www.OrthopedicNetworkNews.com](http://www.OrthopedicNetworkNews.com). Legal filings, judgments, and Guidant prices mentioned in this editorial available at [www.orthopedicnetworknews.com/litigation/guidant.htm](http://www.orthopedicnetworknews.com/litigation/guidant.htm)*