

**ORANGE COUNTY  
DISTRICT ATTORNEY**

**NEWS RELEASE**

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**FOR IMMEDIATE RELEASE**

Case # 30-2016-00880665-CU-BT-CJC

Date: December 8, 2017

**OCDA OBTAINS \$7.8 MILLION SETTLEMENT AND ADMISSION OF LIABILITY  
IN LAWSUIT AGAINST TWO COMPANIES WHO UNLAWFULLY SOLD FETAL  
TISSUE AND CELLS FOR PROFIT**

**\*Both companies ordered to cease business in California**

SANTA ANA, Calif. – Orange County District Attorney (OCDA) Tony Rackauckas obtained a \$7.8 million settlement and an admission of liability in a civil lawsuit against two sister companies for their role in the unlawful sale of fetal tissue and stem cells for profit. As part of the settlement, DV Biologics, LLC, and DaVinci Biosciences, LLC, must permanently close and cease all business operations in the State of California within 60 and 120 days, respectively, pay a settlement amount of \$7,785,000 through the donation of assets and biological materials to a non-profit academic and scientific teaching institution affiliated with a major U.S. medical school, and pay \$195,000 in civil penalties. The settlement was filed today in the Orange County Superior Court.

"This settlement seized all profits from DV Biologics and DaVinci Biosciences, which they acquired by viewing body parts as a commodity and illegally selling fetal tissues for valuable consideration. These companies will never be able to operate again in Orange County or the State of California," stated District Attorney Rackauckas.

**Background**

DaVinci Biosciences was incorporated in Delaware in November 2007, and DV Biologics was incorporated in March 2009, with their principal place of business in Orange County, including Costa Mesa and in June 2015, in Yorba Linda. DaVinci Biosciences was jointly owned and operated by the same individuals who also owned and

operated DV Biologics. The two companies shared office space, management, and employees. The California Franchise Tax Board forfeited DaVinci Biosciences, and DV Biologics' powers, rights, and privileges in July 2015 and November 2014, respectively, and both companies continued to operate illegally until December 2016.

In September 2015, the OCDA opened an investigation into DaVinci Biosciences and DV Biologics after a complaint was submitted by the Center for Medical Progress regarding the illegal sale of aborted fetal tissue by both companies.

Based on the evidence uncovered in its investigation, the OCDA filed a Complaint for Violations for unlawful, unfair, and fraudulent business practices in the Superior Court of the State of California in Orange County on Oct. 12, 2016.

### **Defendants' Unlawful and Unfair Business Practices**

- In early 2009, DaVinci Biosciences expanded its business to include a revenue-driven unit by selling products derived from the cells and tissues they were already collecting, processing, storing and using for research purposes. A few months later, DV Biologics launched its first marketing campaign to start producing sales.
- The defendants hired an outside marketing consultant to develop marketing materials, including a catalog posted on the company's website in January 2010, and sent them to various sales leads. The two companies advertised prices in a range as low as \$40 a vial for the "total RNA" cells from several fetal tissue sources to as high as \$1,100 a vial for specific cells derived from fetal brain tissue. They priced the products in a middle range from \$300 to \$375 a vial for fetal lung derived products, \$300 to \$450 a vial for fetal kidney derived products, \$500 to \$700 a vial for fetal heart derived products, and \$250 to \$700 a vial for fetal liver derived products.
- Between 2009 and 2011, the defendants nearly tripled sales revenues. The defendants unlawfully sold fetal-derived products to pharmaceutical companies and academic institutions around the world through a network of distributors. By the end of 2011, the defendants unlawfully sold fetal-derived tissues and cells worldwide to countries including Japan, China, Singapore, Korea, Germany, Switzerland, Spain, Australia, Netherlands, Canada, and the United Kingdom.
- By 2012, the defendants had over 500 products in inventory "with some 13,900 units available," for sale – an inventory the defendants "valued at much greater than \$4.4 million dollars."
- The companies also regularly offered "sales" pricing promotions, including, for example, a "25% off" summer sale and "25% off" fall promotion in 2013. Sales staff was given wide flexibility in using discounts in order to close a sale, because they all knew they still ended up "on top."
- In both 2013 and 2014, the companies grossed in excess of \$400,000 in revenue, which was double the gross revenue earned in 2012. From August 2012 to October 2015, the defendants unlawfully sold approximately 500 fetal tissue "products" for valuable consideration and reached over \$550,000 in gross revenues.
- In July 2014, the companies discussed the pricing of prenatal renal fibroblasts via email, explaining they were currently selling the "product" for \$350/vial, and suggesting they raise the price to \$375 per vial, stating, "1000% gross does not seem unreasonable based on infrastructure and lack of competition." In that email exchange, they further stated, "If the market can handle a higher price then we will go with [that] since we will be giving discounts to the distributors." After this discussion, the 2015 list price for prenatal renal fibroblasts was set at \$450 per vial.

### **The Law Regarding Sales of Fetal Tissue and Cells**

Under California law:

- **HSC §125320** (a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter, (b) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.

- **Business and Professions Code § 17200** – unlawful, unfair, and fraudulent business practices.

Under Federal law:

- **42 USC § 289g-2(a) Purchase of tissue:** it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

The term “valuable consideration” does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

- **42 USC § 289g-1(g) “Human fetal tissue” defined:** for purposes of this section, the term “human fetal tissue” means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

### **Legislative History and Case Law:**

Legislative history and case law recognizes that “stem cell research, including the use of embryonic stem cells for medical research, raises significant ethical and policy concerns, and, while not unique, the ethical and policy considerations associated with stem cell research must be carefully considered.” (Stats 2002, ch. 789 [S.B. No. 253] sec. 1 (g)-(h).)

There is a “societal belief” based thereon that “rejects commercialization of human organs and tissues and tolerates only an altruistic system of voluntary donation.” (*Id.*) Thus, any such “commerce is generally seen as revolting.” (*Flynn v. Holder* (9th Cir. 2012) 684 F.3d 852, 861 [quoting Congressional legislative history regarding organ donations and noting the widely held belief that: “Human Organs should not be treated like fenders in an auto junkyard”; “Human body parts should not be viewed as commodities”].) “People tend to have an instinctive revulsion at denial of bodily integrity, particularly removal of flesh from a human being for use by another and most particularly ‘commodification’ of such conduct, which is the sale of one’s bodily tissues.” (*Id.*)

The OCDA Bureau of Investigations investigated this case.

Prosecutor: Deputy District Attorney Kelly Ernby, Consumer Protection Unit.

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