

***Regional Dialogue on  
the San Diego-Baja California  
Biomedical Products Industry***

**Briefing Paper Prepared for  
*Crossborder Innovation & Competitiveness Initiative***

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## Introduction to the Crossborder Dialogue on Innovation & Competitiveness

The crossborder region, encompassing Baja California and San Diego County, represents nearly six million people whose economic livelihood, physical environment, personal health, and social well-being are inextricably linked. Legally separated by an international border, this crossborder region can be viewed as one major metropole in which trade, commerce, health, recreation, and social life are increasingly intertwined.



Source: Adapted from SDSU's San Diego-Tijuana International Area Planning Atlas

While the San Diego-Baja California region holds enormous economic and social promise, there remain lingering challenges in developing mutually beneficial economic development goals and policies, building trust and cooperation amongst the public- and private-sector, as well as fostering the required number and skills of a qualified workforce on either side of our shared border.

This series of *Crossborder Dialogues on Innovation and Competitiveness* is an attempt to begin to address these issues, focusing on a small number of regional industry clusters; as well as to better understand how synergies between San Diego and Baja California can improve these clusters' value chains. The *Dialogues* themselves are a collaborative effort intended to build crossborder capacity, led by UCSD Extension's San Diego Dialogue, Tijuana-based CENTRIS, and Ensenada-based CICESE

### Improving Innovation & Competitiveness Through Crossborder Collaboration

This effort is based upon the premise that the San Diego-Baja California region can become more globally competitive in key science and technology sectors by leveraging opportunities across our border. Such opportunities potentially exist both in terms of crossborder research partnerships, and by connecting San Diego and Baja California in high value-added economic clusters that link regional R&D capabilities to manufacturing and service industries in our region. The future of both the San Diego and Baja California economies (and, thus, our jobs, our incomes, and ability to better the quality of life in our community) depends on remaining competitive and on continuous innovation in a globalized and increasingly skilled world.

The present crossborder regional dialogue will focus on the **biomedical products industry**.

#### Missed Opportunities for Crossborder Economic Linkages?

Several recent studies have concluded that San Diego's economy could be strengthened with better linkages between manufacturing and service sectors across the border.

The 2001 "*Clusters of Innovation Initiative*" Series produced by Harvard economist Michael Porter for the Council on Competitiveness observed that "*San Diego is not thinking hard enough about its proximity to Mexico...*", and that "*better linkages with Mexico could spur the growth of a number of industries and clusters in San Diego.*"

In a similar vein, a report by the Pacific Council on International Policy entitled "*San Diego, Baja California and Globalization: Coming From Behind*", noted: "...the commercial linkages between Baja California and San Diego remain less developed than is generally understood. San Diego could gain much more from Baja's global networks."

## Trends in The Biomedical Products Cluster

### What is the Biomedical Products Cluster?

While definitions of the biomedical products cluster may vary by region (and across borders), the San Diego Association of Governments (SANDAG) - one of the leading entities promoting the development of regional employment clusters - provides this general description:

*“The... Biomedical Products cluster produces instruments, medical devices, equipment and other apparatus primarily for consumption by the medical field. Examples of this cluster’s products include X-ray machines, surgical knives, and contact lenses. Biomedical products have a wide range of uses such as delivering pharmaceuticals, monitoring patients, providing therapy, and serving as artificial human organs. The Biomedical Products cluster is knowledge intensive, requiring advanced research and development”.*<sup>1</sup>

As both the concept of industrial clusters develops, and as even the definitions used to classify business activities evolves (such as from traditional U.S. Standard Industrial Classification [SIC] or Mexico’s CMAP codes to the North American Industry Classification System [NAICS]), some argument about which specific companies fall into the biomedical products cluster will likely continue. However, for the purposes of this briefing, SANDAG’s cluster definitions were used when possible, including forthcoming NAICS-based definitions. These include:

2002 6-Digit NAICS	2002 6-Digit NAICS Title
333314	Optical Instrument and Lens Manufacturing
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing
334517	Irradiation Apparatus Manufacturing
339111	Laboratory Apparatus and Furniture Manufacturing
339112	Surgical and Medical Instrument Manufacturing
339113	Surgical Appliance and Supplies Manufacturing
339114	Dental Equipment and Supplies Manufacturing
339115	Ophthalmic Goods Manufacturing
339116	Dental Laboratories

In addition, some analysis is based upon classifications used by the U.S. Food and Drug Administration (FDA), which oversees the registration of medical device manufacturers both in the U.S. and abroad (for those companies that sell their products into the U.S. marketplace).

### Major Crossborder Trends

While the United States continues to be both the world’s largest manufacturer and user of medical device products, there is an increasing tendency to move production or assembly of many biomedical device products to non-U.S. locations. According to FDA data, there were nearly 9,000 registered foreign medical device manufacturers in 2003, a 14.5% increase over the previous year. Over one-third of these manufacturers are located in Taiwan, China, and Germany.

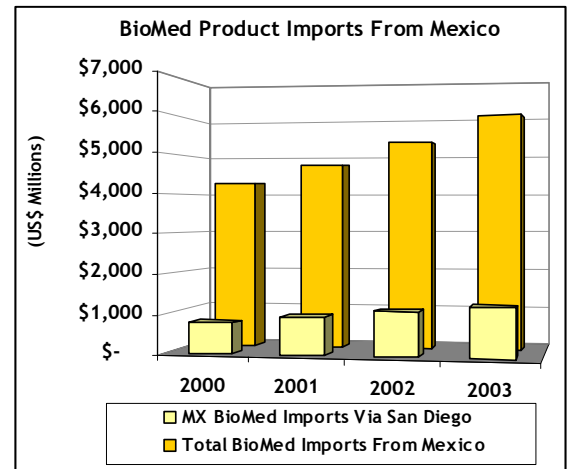
<sup>1</sup> “Science and Technology: The Key to Creating Prosperity”, SANDAG, April 2004.

Over the last decade, however, Mexico has been one of the leading locations for non-U.S. medical device manufacturing and assembly, with more than 208 FDA-registered medical device manufacturing facilities currently operating in the country (an increase of 12.4% over 2002 figures). As seen in the map at right, one of the highest concentrations of such companies is in neighboring Baja California.

FDA Registered Medical Device Manufacturers in Mexico (2003)



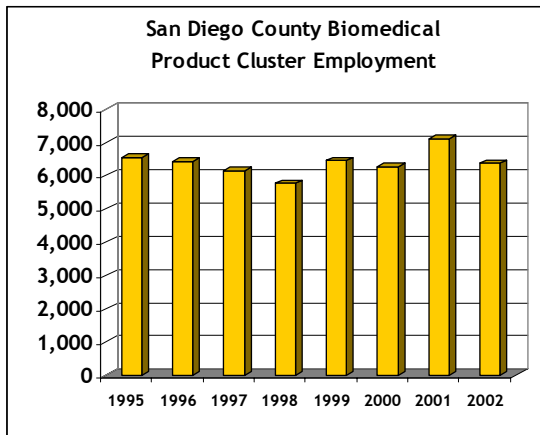
Trade data further confirms the status of Mexico as an important partner in crossborder medical device manufacturing. Using the U.S. Department of Commerce classification of “medical devices” as those primarily within NAICS classifications of 33911 and 33451, Mexico is actually the leading exporter of such products to the U.S., having surpassed Japan in 2001. As seen at right, U.S. imports of these products from Mexico were valued at more than \$6 billion in 2003, approximately 20% of which (\$1.2 billion) came through the San Diego Customs District.



source: USITC, NAICS 33911 & 33451

However, Despite this apparent strong trade relationship of medical devices between the U.S. and Mexico, imports from several other countries - notably, Ireland, Switzerland and China - are growing at a faster rate. FDA registration of non-U.S. manufacturers are also increasing at faster rates for other countries such as China and Korea, among others.

### Biomedical Product Companies in the San Diego-Baja California Region

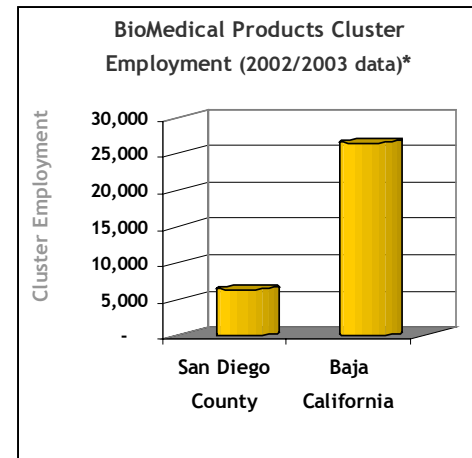


While often combined with the larger biotechnology and pharmaceuticals cluster<sup>2</sup> in discussions about regional economic development, *biomedical products* have been identified by the San Diego Association of Governments as one of the San Diego region’s 15-most important employment clusters. In part, this is due to the positive economic impact that biomedical products and other clusters bring to the region’s employment base. However, as can be seen at left, the biomedical products cluster has had little employment growth between 1995-2002 (the last year comparable data was available). One possible reason cited by SANDAG for this apparent stagnation was expansion of these firms outside of San Diego County (in Riverside and Mexico).

<sup>2</sup> “Science and Technology: The Key to Creating Prosperity”, SANDAG, April 2004 (p. 22).

In fact, as can be seen at right, a comparison of the number of employees working for biomedical products companies on both sides of our border provides additional evidence of the strength of the cluster in Baja California - and perhaps an opportunity for collaboration.

According to Tijuana-based ProduCen (a technology industry promotion research center sponsored in part by the State Government of Baja California), there were approximately 60 companies in Baja California's biomedical products cluster, employing nearly 26,500 individuals in 2003. This contrasts with San Diego County's cluster of approximately 130 firms that employed around 6,400 individuals.



Also of note is the existing inter-relationship that Baja California's biomedical product companies already have with the United States. Of the 60 firms identified as in the cluster by ProduCen, slightly more than 40 have U.S. parent companies. Of these, nearly one-third (thirteen) have either a San Diego headquarters or a related subsidiary in San Diego County. These San Diego-related crossborder biomedical product firms include Alaris Medical Systems, Breg, Continental Laboratory Products, DJ Orthopedics, and Sunrise Medical, among others.

## Opportunities and Challenges for Retaining Regional Competitiveness

Given the already-existing linkages that San Diego's biomedical product companies already have with Baja California-based manufacturers and assembly firms; the relatively poor growth of San Diego's employment in this cluster; and the apparent strength of this cluster in Baja California, a latent opportunity to foster additional growth in the biomedical products cluster may exist. Several challenges, however, may make this goal difficult. Some of these challenges include:

- **Workforce-Related Competitive Weaknesses in Both San Diego and Baja California**

As noted by various sources, the San Diego-Baja California biomedical products cluster faces competition from not just domestic U.S. or Mexico-based businesses, but also companies in Europe and Asia. To remain competitive, the San Diego-Baja California region must be able to attract and develop a workforce sufficiently skilled to continue moving towards higher value-added activities within clusters such as biomedical products. A sufficiently skilled workforce must be able to undertake activities involving research and development, product design, world-class manufacturing, and the commercialization of those products - not to mention the fact that such activities may also include crossborder interaction amongst universities and firms on either side of the border.

- **High Cost Business Environment**

In addition to relatively high labor costs, the San Diego-Baja California region also may have other intrinsic disadvantages for biomedical product R&D firms, manufacturers and assemblers. Real estate costs tend to be high on either side of the border (compared to other locations in each country); as are general business net taxation rates (again, compared to other global locations). As an example: one technology manufacturing

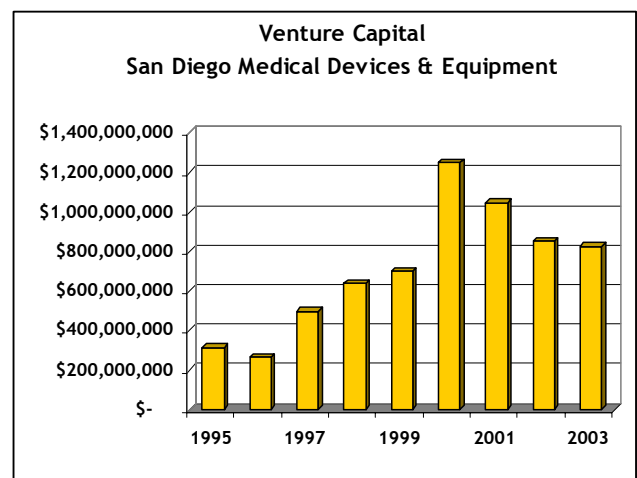
executive recently noted that the only way they were able to keep their company's Mexican operations competitive against Asian firms was to use global accounting rules to have an Asia-based subsidiary "contract" production in Mexico, to allow for shifting the tax burden away from Mexico to another country.

- **Low Levels of Manufacturing Flexibility**

In a November 2000 report issued by San Diego Dialogue, "*The Global Engagement of San Diego/Baja California*", it was noted that, "Tijuana and San Diego both lack a broad base in critical areas such as contract manufacturing...". For biomedical products, this is still primarily the case, with the exception of a handful of such companies now in both San Diego and Tijuana. The relatively low number of more flexible, contract manufacturers that can aggressively compete against those from other global regions still leaves the San Diego-Baja California region at a disadvantage.

- **Insufficient Financing for Baja California Firms**

Although there are a few cases of Mexico-grown biomedical products companies in Baja California (such as Augen Opticos), financing of biomedical product entrepreneurs in Mexico is challenging at best. San Diego firms, on the other hand, have a strong history of being positioned in venture capital circles for seed, early, and expansion stage financing (as seen in the PricewaterhouseCoopers survey data at right). No such venture funding has been identified for Baja California firms.



Source: PricewaterhouseCoopers MoneyTree Survey

- **Shifting of Local Control**

While not necessarily a negative, the increasing number of mergers and buyouts in the biomedical products industry (particularly among larger San Diego-based firms) might potentially result in less interest by non-regional parent companies for fostering growth of this cluster in the San Diego-Baja California region. This might particularly be the case for parent companies that are looking for more immediate ways to reduce costs or that consolidate operations to gain economies of scale. Should the capabilities of the San Diego-Baja California region be stronger in the area of integrating research and development with manufacturing, less pressure might be placed on parent companies to consider leaving the region.

- **Lack of Common Cluster Definitions and Collaboration Amongst Economic Development Entities & Trade Groups**

While perhaps not a challenge that affects the day-to-day operations of biomedical product companies, a more profound weakness for this sector's growth may be the lack of a consistent definition of which activities actually make up the biomedical products cluster on both sides of the San Diego-Baja California border, as well as how regional

economic development entities and trade groups might more effectively collaborate to promote policies that would support a stronger crossborder regional growth of this cluster.

## Conclusion

Ample evidence suggests that the biomedical products cluster has great potential to both continue growth in Baja California, as well as achieve much stronger growth in San Diego County - should additional linkages be developed across the San Diego-Baja California border. Despite some potential challenges, it appears that many of the largest such companies in San Diego County may have reached their size in part because of the competitive advantages gained by developing a portion of their manufacturing or assembly operations in Baja California.

In addition, it is also clear that attempting to improve the cluster's value chain in the region will require not only more crossborder business-to-business linkages, but also increased university-to-university and university-business collaborations - within the region and across the San Diego-Baja California border.

## Appendices

### Appendix I: Sources of Additional Information

- California Healthcare Institute ([www.chi.org](http://www.chi.org))
- CENTRIS-CDT ([www.centris-cdt.org.mx](http://www.centris-cdt.org.mx))
- Innovation Mexico Journal ([www.innovationmexico.com](http://www.innovationmexico.com))
- Medical Device Manufacturers Association ([www.medicaldevices.org](http://www.medicaldevices.org))
- ProduCen ([www.producen.org](http://www.producen.org))
- San Diego Association of Governments ([www.sandag.org](http://www.sandag.org))
- U.S. Department of Commerce Medical Equipment Division ([www.ita.doc.gov/td/mdequip/](http://www.ita.doc.gov/td/mdequip/))
- U.S. FDA/Office of International Programs ([www.fda.gov/oia/homepage.htm](http://www.fda.gov/oia/homepage.htm))

### Appendix II: Directory of Selected San Diego-Baja California Companies in Cluster

Mexico Company	Baja CA City	U.S. Company	SD County City	Website
Breg de Mexico, SA de CV	Mexicali	Breg ( <i>Orthofix</i> )	Vista	<a href="http://www.breg.com">www.breg.com</a>
Coastline de Mexico, SA de CV	Tijuana	Coastline International	San Diego	<a href="http://www.coastlineintl.com">www.coastlineintl.com</a>
Continental Laboratory Pds, S de RL de CV	Tijuana	Continental Laboratory Pds	San Diego	<a href="http://www.clpdirect.com">www.clpdirect.com</a>
DJ Orthopedics de Mexico, SA de CV	Tijuana	DJ Orthopedics	Vista	<a href="http://www.djortho.com">www.djortho.com</a>
Labomex MBP, S de RL de CV	Tijuana	Molecular Bioproducts	San Diego	<a href="http://www.arttips.com">www.arttips.com</a>
Lancer Orthodontics de Mexico, SA de RL de CV	Mexicali	Lancer Orthodontics, (Biomerica subsidiary)	San Marcos	<a href="http://www.lancerortho.com">www.lancerortho.com</a>
Manufactura Integrada del Pacifico, S de RL	Tijuana	Pacific Integrated Mfg, Inc	Bonita	
NPA de Mexico, SA de CV	Tijuana	Nypro	Chula Vista	<a href="http://www.nypro.com">www.nypro.com</a>
Pacific Device of Mexico, SA de CV	Tijuana	Avail Medical Products	San Diego	<a href="http://www.availmed.com">www.availmed.com</a>

Mexico Company	Baja CA City	U.S. Company	SD County City	Website
Sig Armolite de Mexico, SA de CV	Tijuana	Signet Armorlite	San Marcos	<a href="http://www.signetarmorlite.com">www.signetarmorlite.com</a>
Sistemas Medicos Alaris, SA de CV	Tijuana	Alaris Medical Systems	San Diego	<a href="http://www.alarismed.com">www.alarismed.com</a>
Sunrise Medical Tecnologias, SA de CV	Tijuana	Sunrise Medical	Carlsbad	<a href="http://www.sunrisemedical.com">www.sunrisemedical.com</a>

Appendix III: FDA Foreign Registered BioMedical Product Manufacturers

FDA Registered Foreign Medical Device Manufacturing Establishments			
Country	2002	2003	% change
Taiwan	1042	1152	10.6%
China	752	1028	36.7%
Germany	882	941	6.7%
Canada	562	611	8.7%
United Kingdom	478	530	10.9%
Japan	463	519	12.1%
Republic of Korea	362	457	26.2%
Italy	377	430	14.1%
Pakistan	288	343	19.1%
Hong Kong	279	324	16.1%
France	254	291	14.6%
Malaysia	224	234	4.5%
<b>Mexico</b>	<b>185</b>	<b>208</b>	<b>12.4%</b>
Israel	173	188	8.7%
India	158	179	13.3%
Switzerland	155	170	9.7%
Sweden	142	163	14.8%
Thailand	95	109	14.7%
Australia	86	104	20.9%
Netherlands	88	97	10.2%
Ireland	83	85	2.4%

source: Food and Drug Administration, 2004