

Editorial: This drug war would hurt Colorado

Rocky Mountain News

February 15, 2009

Colorado boasts a dynamic bioscience industry. Scores of companies in this state conduct research and development involving medical devices, diagnostic equipment and cutting-edge pharmaceuticals, as well as produce a variety of such products.

And in metro Denver, the bioscience park associated with the Fitzsimons redevelopment offers spectacular potential for industry growth.

So why single out an industry for burdensome regulations that will mark Colorado as seemingly hostile to bioscience companies? It makes little sense, but that's nevertheless what Senate Bill 166 proposes to do.

The bill, sponsored by Sen. Morgan Carroll, D-Aurora, asserts that "the lack of transparency on behalf of pharmaceutical manufacturers regarding the costs of advertising and marketing activities related to the sale of prescription drugs contributes to the high cost of prescription drugs and health care services and the lack of access to adequate prescription drugs and health-care services." This loaded contention is arguable at best. Companies are in competition, after all, and need to get the word out on their products. Marketing can educate professionals and the public about their options.

Meanwhile, to the extent marketing does accelerate sales, it helps companies pay for the research that leads to breakthroughs in the first place.

But even if you believe that bioscience marketing is problematic in a way that advertising for other products is not, SB 166 appears interested to a surprising degree in imposing pointless compliance costs on the industry, enlarging the state bureaucracy and giving politicians leverage to attack companies for their business practices. SB 166 would require companies to file annual reports with the state Board of Pharmacy that would include an astonishing array of data related to "expenses, direct or indirect, associated with the marketing of prescription drugs, biological products, and medical devices in this state." That means, among other things, expenses for TV, radio, newspapers and magazines and direct mail, and even "a reasonable estimate of the value of expenses associated with advertising purchases for a regional or national market" including Colorado.

And that's not all. Companies would have to report the value of their support for continuing education programs and the production costs of patient education materials, as well as expenses related to charitable grants (!) and product

samples. Even market-research costs must be dutifully aggregated and reported.

And as part of the annual filing, companies would have to report executive salaries, stock options and bonuses, lobbying expenses and charitable contributions - yes, charitable contributions.

In effect, SB 166 demands a wealth of data revealing company business practices, some of which typically have been confidential. And for what purpose? Marketing itself isn't outlawed by the bill, although it does impose a highly restrictive ban on gifts or subsidies from bioscience companies to health-care practitioners.

Presumably the data will be used by anti-marketing politicians and activists as a club against bioscience firms in the ongoing campaign to blame this allegedly greedy industry for health-care inflation.

Is this what legislative leaders meant when they promised in January to focus on economic development and jobs - that they would pass a law saddling one of the most dynamic sectors of the Colorado economy with a blizzard of busywork? Let's hope not. But if they intend to keep their earlier promise, they need to kill this Senate bill.



BUSINESS, LABOR, & TECHNOLOGY COMMITTEE

February 18, 2009

The Biotechnology Industry Organization (BIO) respectfully submits the following comments in opposition to Senate Bill 166 -- the *Prescription Drug Ethics Act*.

BIO is a national trade organization, based in Washington, D.C., representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. In Colorado we work closely with the Colorado Bioscience Association (CBSA), an organization that represents more than 420 biotechnology companies, universities, academic institutions and others dedicated to advancing cutting edge research.

BIO and CBSA member companies serve a vital role in helping to educate physicians about breakthrough medicines -- and we believe this communication is in the best interest of public health. Healthcare providers and, most importantly, patients benefit from the free flow of truthful, non-misleading scientific information regarding biologic products that can only occur in interactions between biotechnology company representatives and healthcare providers.

The gift ban provision threatens research and treatment for patients in Colorado.

As currently drafted, the definition of "gift" may prohibit companies from providing physicians with research grants, education grants, and funding for educational seminars and continuing medical education (CME) conferences. Specifically, this prohibition on research and education grants could negatively impact the ability of Colorado researchers to discover new cures by curtailing investigator-sponsored clinical trials. A ban on access to fundamental educational opportunities will ultimately result in a health care system that does not serve the best interest of patients. Physicians must be able to benefit from all of the accessible information necessary for informed clinical decision-making.

There are consistent national standards for sales and marketing set forth under federal law and industry guidelines, and BIO believes that additional state regulation is unnecessary. Industry sales and marketing practices are strictly regulated and subject to significant penalties under the Federal Anti-Kickback Laws, False Claims Act, and other federal statutes, and BIO supports strict adherence to these laws. This umbrella of federal laws broadly encompasses biotechnology manufacturers' activities and is actively enforced by the Department of Health and Human Services (HHS). Additionally, the HHS Office of Inspector General's (OIG) Compliance Program Guidance (CPG)¹ provides guidance on how companies can establish compliance programs to help to assure that contact between physicians and manufacturers are appropriate and minimize the risks of fraud and abuse.

¹ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).



The prescription drug privacy provision will negatively impact small biotechnology companies. Although this legislation is aimed at consumer protection and provider privacy interests, enactment of this bill will have the unintended consequences of negatively impacting access to new innovative therapies and efforts to research and develop biologic medicines. Small biotechnology companies generally do not have the same resources as large pharmaceutical companies to reach out to physicians. Small biotech companies target their education and outreach activities to physicians who prescribe their products and to physicians whose practices are concentrated in specific analogous specialties (such as oncology or neurology). This targeted education and outreach activity permits small biotech companies to expand access to and use of specialized medications developed for the treatment of chronic and intractable diseases. These biologic therapies are often the only available treatment in their therapeutic class.

Research and development of biologic medicines is dependent on access to health information. Access to health information, including prescriber-identified data, facilitates high quality research on appropriate treatments using biotechnology therapies. For small biotech companies, access to this information enhances efforts to research and develop new drugs and biologics. Drug development for biologic products is highly specialized. Unlike pill products, biotech products require specialized manufacturing facilities that are often times individually constructed for an individual product. Companies rely on pharmaceutical market studies, often including prescriber-identifiable data, to develop manufacturing capabilities that will meet consumer demand.

Additionally, biotech companies use prescriber-identifiable data to facilitate enrollment in clinical trials. By targeting physicians who have patients in the targeted area of drug development, manufacturers can identify potential research sites and eligible patient populations for participation in trials.

Patient privacy rights are not at issue in this debate. The confidentiality of patient-identifiable prescription data is protected under federal law pursuant to the Health Insurance Portability and Accountability Act of 1996² (HIPAA). *Nothing in these state legislative vehicles enhances or further protects patient privacy.*

BIO supports the American Medical Association (AMA) opt-out program. The American Medical Association (AMA) has instituted a Physician Data Restriction Program (PDRP)³ to prevent access to physician prescribing information for those physicians who do not want their information shared. Nationwide implementation of the PDRP negates the need for a state-by-state patchwork of legislation to protect the privacy interests of physicians.

² Public Law 104-191. 45 CFR Parts 160 and 164.

³ <http://www.ama-assn.org/ama/no-index/about-ama/12054.shtml>

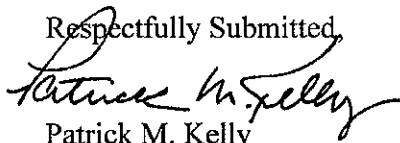
BIO hopes that Colorado lawmakers will not decide to limit communication between physicians and the manufacturers of innovative medicines. We stand ready to work with the state on procedures and safeguards to ensure that ethical principles are not compromised. We believe that carefully crafted policies can accomplish this goal without eliminating important information resources for physicians, ultimately benefitting patients in Colorado.

Senate Bill 166 will only serve to impede the state's efforts to grow its life sciences industries. This legislation is reactionary and would only serve to harm the state's reputation as a center of excellence for technology development – a reputation that has attracted, grown, and retained so many outstanding research organizations. BIO applauds the commitment Colorado has shown to new technologies and research. Senate Bill 166 could significantly undermine the state's leadership position in the life sciences.

We appreciate the Committee's consideration of our concerns and respectfully request that you oppose Senate Bill 166.

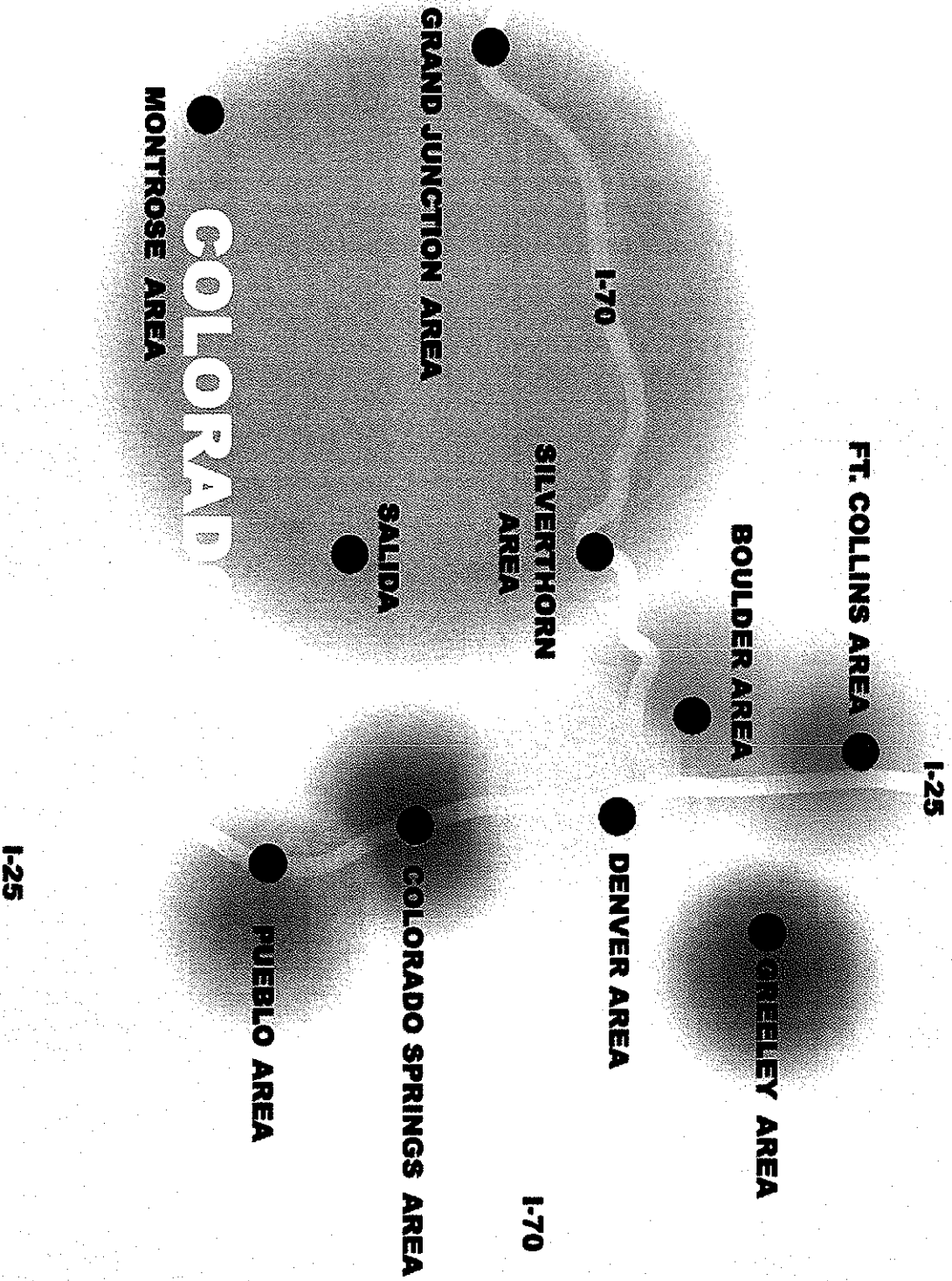
Thank you for your consideration of these comments. We would welcome the opportunity to further discuss these issues. Please feel free to contact me at (202) 962-9200 or pkelly@bio.org if you should have any questions or concerns regarding this matter.

Respectfully Submitted,

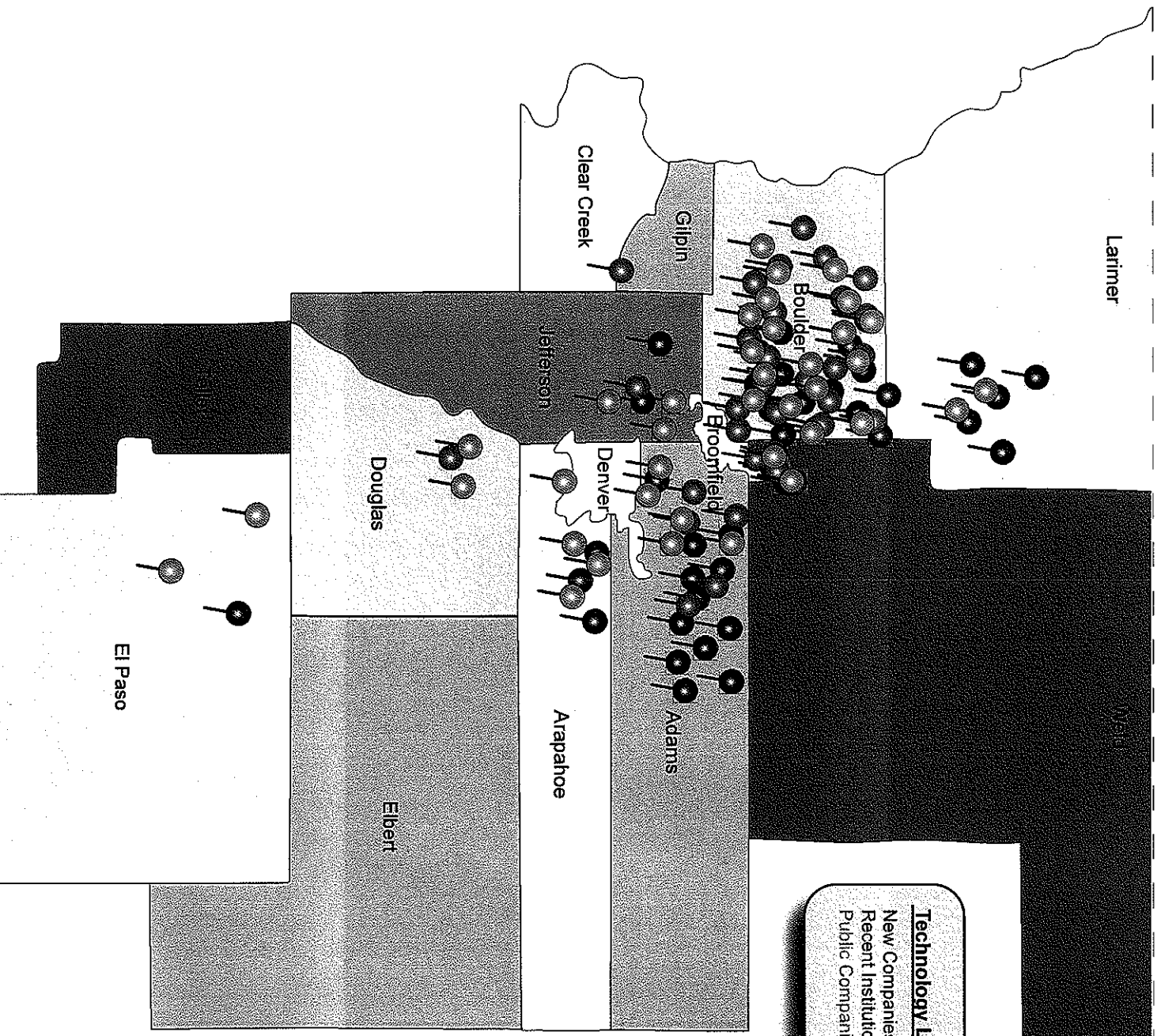


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Colorado BioScience Clusters



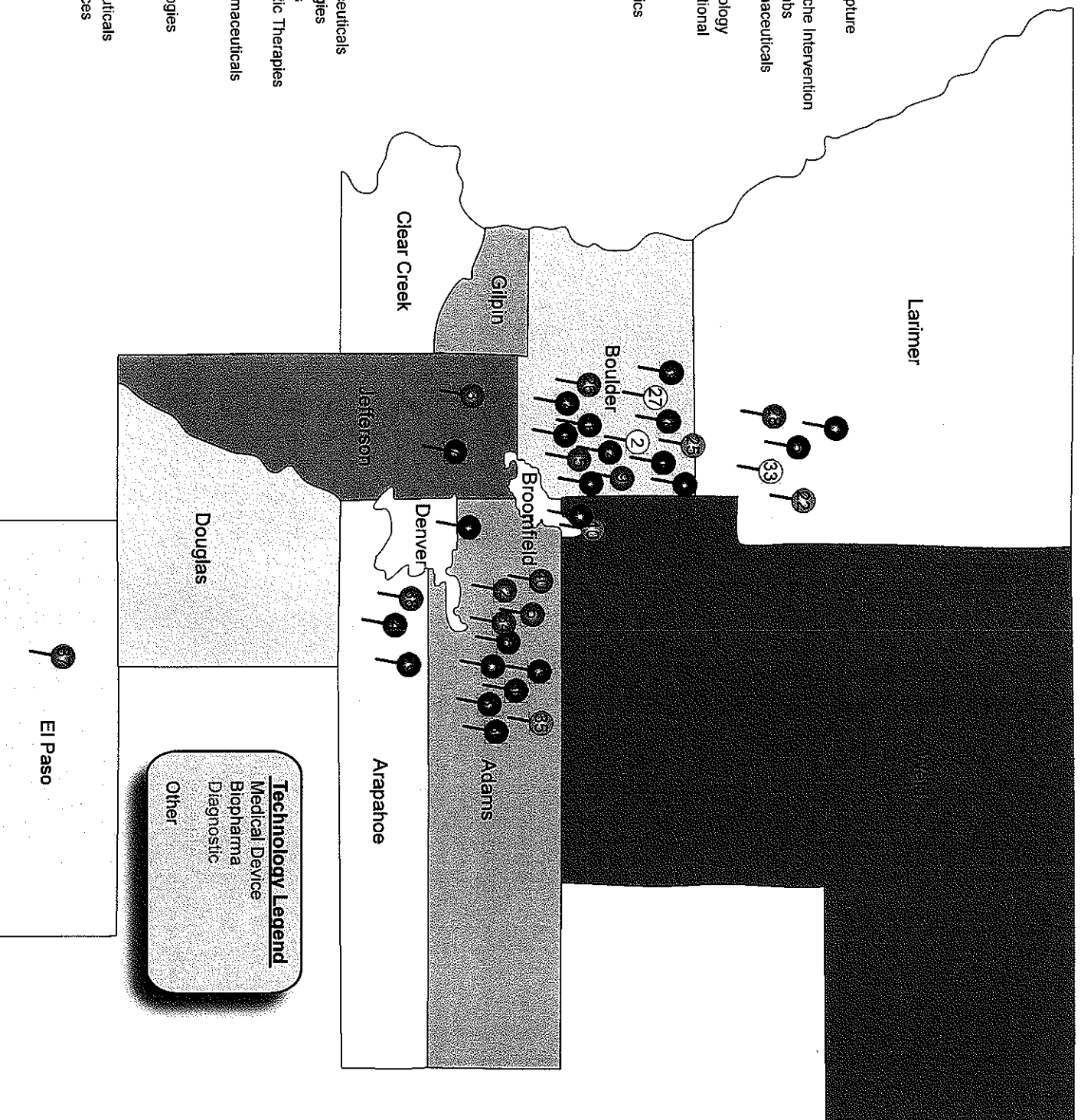
San Miguel County
Telluride, CO



Technology Legend
New Companies since 2006/07
Recent Institutional Financing
Public Companies

New Companies Formed | 2007 to Present

- 1 3Q Matrix
- 2 AZBE Carbon Capture
- 3 Accuthera
- 4 Advanced Headache Intervention
- 5 Advanced Microlabs
- 6 Apoptologic Pharmaceuticals
- 7 ArcScan Inc.
- 8 Beacon Biotechnology
- 9 BioAMPS International
- 10 Biodesix
- 11 BlueSun
- 12 Caveo Therapeutics
- 13 Chemizon
- 14 Clarimedix
- 15 CycleGen
- 16 EndoShape
- 17 FireFly Medical
- 18 Fluonic
- 19 HepQuant
- 20 Hiberna
- 21 Illumasonix
- 22 KomalidTID
- 23 Lanx
- 24 Locomotion
- 25 mBio Diagnostics
- 26 Miragen Pharmaceuticals
- 27 OpX Biotechnologies
- 28 Peak Biosciences
- 29 pico-tesla Magnetic Therapies
- 30 Precision Biopsy
- 31 Sierra Neuropharmaceuticals
- 32 Snocasis Medical
- 33 Solix Biofuels
- 34 Talga Biotechnologies
- 35 Tissue Genetics
- 36 ValveXchange
- 37 V-Clip Pharmaceuticals
- 38 Ventrus Biosciences
- 39 Viturned
- 40 Mycologics

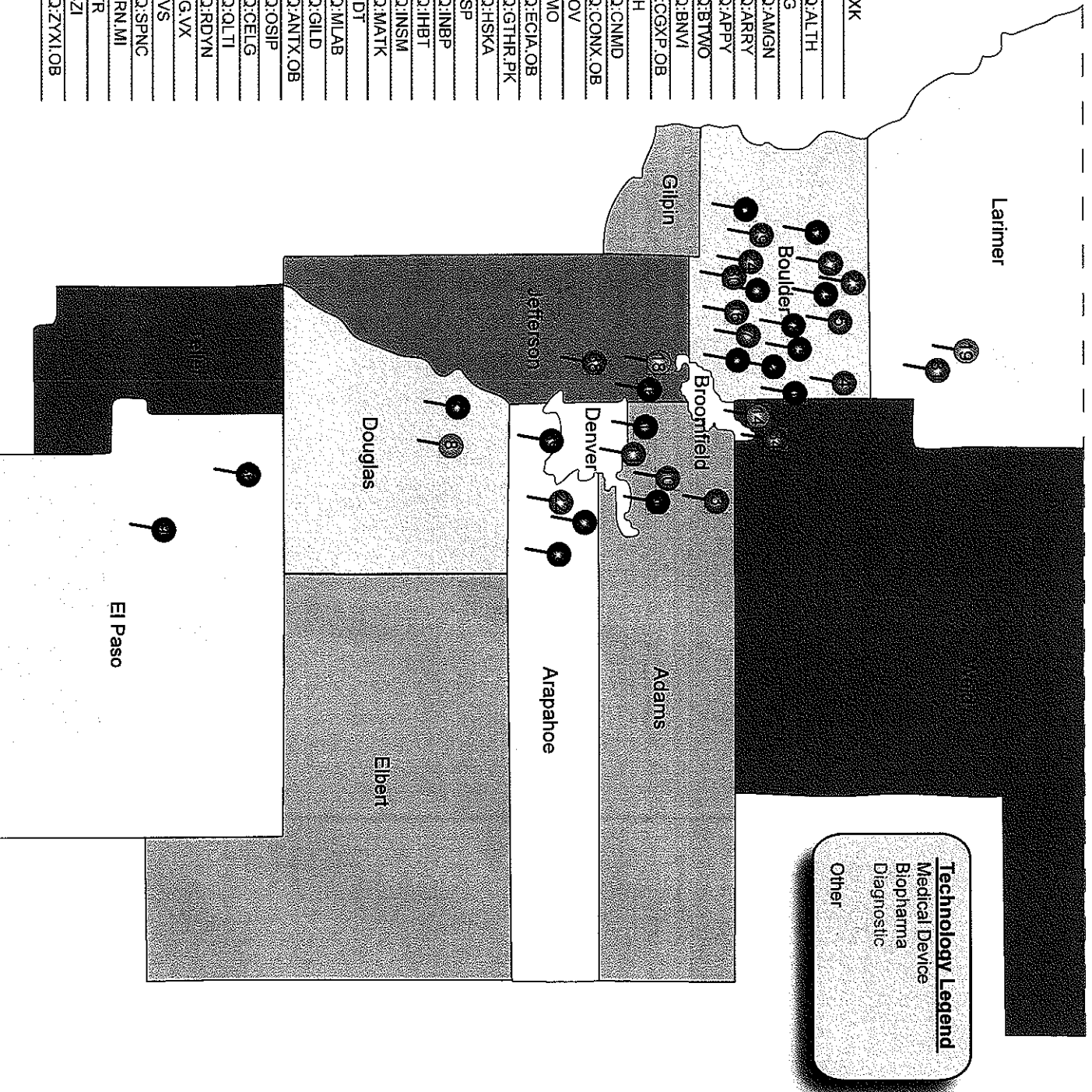


Technology Legend

- Medical Device
- Biopharma
- Diagnostic
- Other

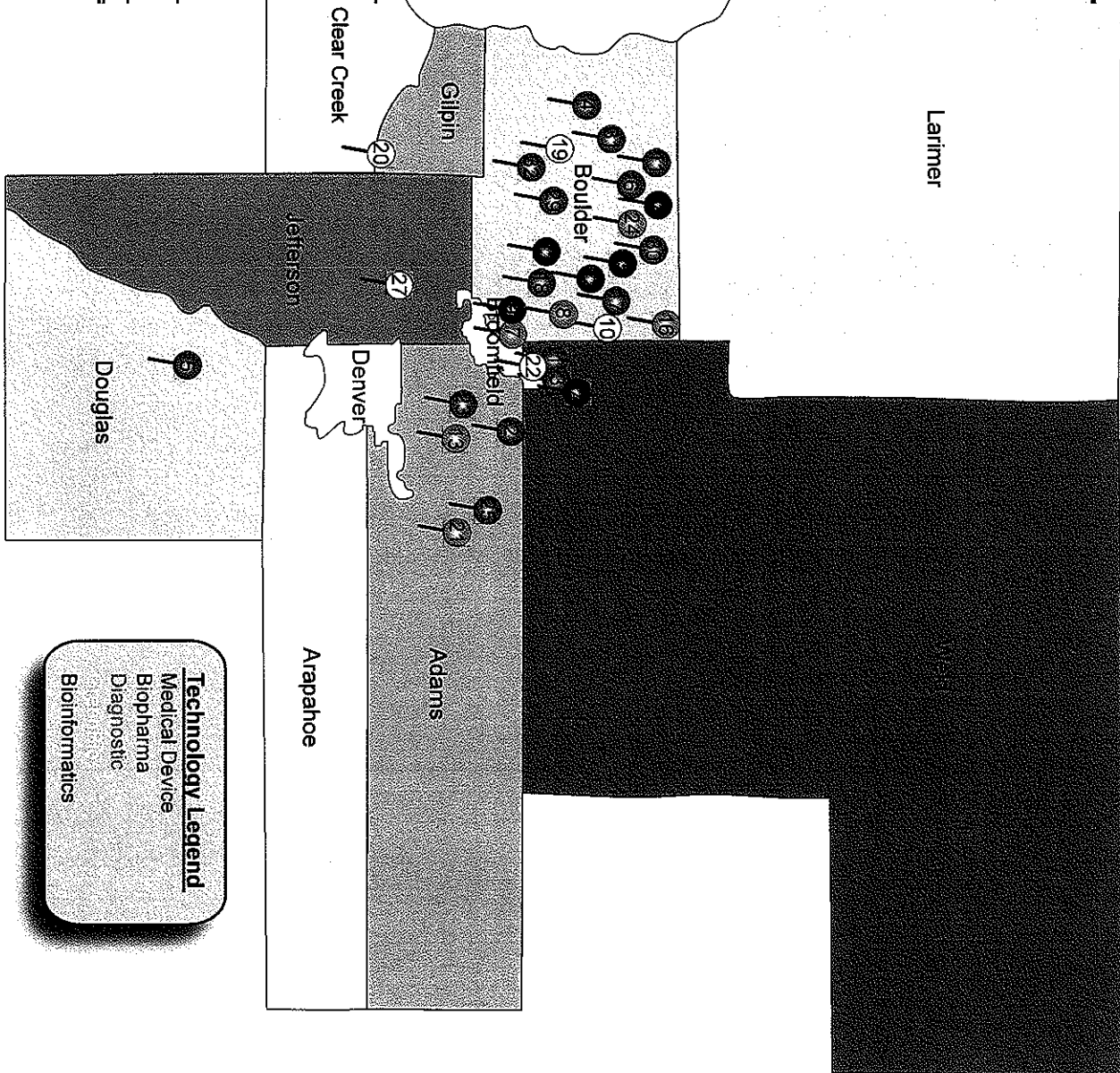
Colorado-Based & Related Public Companies

1	Accel8 Technology	AMEX:AXK
2	Agilent Technologies	NYSE:A
3	Allios Therapeutics	NASDAQ:ALTH
4	Alpharma Animal Health King Pharma	NYSE:KIG
5	Amgen	NASDAQ:AMGN
7	Array Biopharma	NASDAQ:ARRY
8	AspenBio Pharma	NASDAQ:APPY
9	B2 Health	NASDAQ:B2WO
10	Bionovo	NASDAQ:BNVI
11	Ceragenix Pharmaceuticals	OTC:BB:CGXP:OB
12	Cochlear Americas	ASX:COH
13	Commed	NASDAQ:CNMD
14	Corgenix Medical	NASDAQ:CONX:OB
15	Covidien	NYSE:COV
16	Dharmacon Thermo Fischer Scientific	NYSE:TMO
17	Encision	NASDAQ:ECIA:OB
18	GenetEra	NASDAQ:GTHR:PK
19	Heska	NASDAQ:HSKA
20	Hospira	NYSE:HSP
21	InB:Pxix / Hauser CRO Integrated BioPharma	NASDAQ:INBP
22	Inhibition Therapeutics	NASDAQ:IHBT
23	Insmrd	NASDAQ:INSM
24	Marek Biosciences	NASDAQ:MATK
25	Medtronic	NYSE:MDT
26	Mesa Labs	NASDAQ:MLAB
27	Myogen Gilead	NASDAQ:GILD
28	OrthonNexx	NASDAQ:ANTX:OB
29	OSI Pharmaceuticals	NASDAQ:OSIP
30	Pharmion Celgene	NASDAQ:CELG
31	QLT	NASDAQ:QLTI
32	Replidyne CardioVascular Systems	NASDAQ:RDYN
33	Roche Colorado	VTX:ROG.VX
34	Sandoz	NYSE:NVS
36	Spectranetics	NASDAQ:SPNC
38	The Sornn Group	MTAX:SRN.MI
39	Vitrolife	SEK:VITR
40	Xcel8 Holdings	AMEX:BZI
41	Zyrex	NASDAQ:ZYX1:OB



Institutional Financings | 2007 to Present

COMPANY	ROUND/EVENT	VALUE (\$M)
1 Accera	Series C	\$ 35.00
2 Allos Therapeutics	Secondary	\$ 65.20
3 ARCA biopharma	Series B	\$ 50.50
4 Array Biopharma	Debt + Warrants	\$ 18.00
5 Aspen Biopharma	Secondary	\$ 80.00
6 BaroFold	Series A	\$ 18.20
7 Biodesix	Series B	\$ 12.00
8 BioOptix	Series B	Undisclosed
9 CeratPedics	Series A financing	Undisclosed
10 Evolutionary Genomics	Series A	\$ 12.30
11 Globelmmune	Series C	\$ 5.00
12 iBalance Medical	Series A	\$ 44.20
13 Illumasonix	Series A	\$ 13.50
14 Lanx	Series A	Undisclosed
15 MID-IT	Series A	\$ 25.00
16 Microphage	Series B	\$ 11.00
17 Miragen	Series A	\$ 11.00
18 N30 Pharma	Series A	\$ 8.00
19 OPX Biotechnologies	Series A	Undisclosed
20 OberonFMR	Series A	\$ 3.60
21 Precision Biopsy	Series A	\$ 1.00
22 Range Fuels	Series B	Undisclosed
23 Sierra Neuropharma	Series A	\$ 130.00
24 Somalogic	Series D	\$ 21.50
25 Taligen Therapeutics	Series B	\$ 35.00
26 Theratogs	Series A	\$ 65.00
27 Luca Technologies	Series C	\$ 1.10
		\$ 76.90
Sub-total Capital Raises		\$ 739.10
28 Dharmacon	Acquired	\$ 80.00
29 Sirna	Acquired	\$ 1,100.00
30 Pharmion	Acquired	\$ 2,900.00
31 Myogen	Acquired	\$ 2,500.00
32 Rkkinetix	Acquired	\$ 115.00
Sub-total Exits		\$ 5,515.00
TOTAL Capital Infused to Colorado		\$ 6,254.10



Technology Legend

- Medical Device
- Biopharma
- Diagnostic
- Bioinformatics