

Local support and research firms thrive off Big Pharma

Stricter drug testing may prove a bonanza.

By Thomas Ginsberg

INQUIRER STAFF WRITER

Oddly enough in the globalized drug industry, outsourcing companies are holding their own in a place hardly cheap and definitely not exotic: the Philadelphia suburbs.

"Many companies are started by people who leave the big companies here, then go back and get them as clients," said Jonathan Seltzer, founder of Applied Clinical Intelligence L.L.C., a small pharmaceutical research firm off City Avenue in Bala Cynwyd.

In the shadow of the area's well-known pharmaceutical behemoths, scores of support and research firms, unseen by the public and even by local policymakers, live off Big Pharma's fortunes and, sometimes, misfortunes.

Some outsourcing companies - from drug testers in the suburbs to advertising firms in Center City, collectively employing several thousand people - have been growing faster than host companies themselves.

In particular, clinical research organizations, or CROs, which conduct and monitor drug trials on behalf of manufacturers, have seen their revenues rise at least 15 percent a year as a group, says the Washington-based trade group Association of Clinical Research Organizations. That's triple the drug industry average.

While growing fastest overseas, most of the world's biggest CROs keep offices around Philadelphia, and several have headquarters here. Add to them many small ones, like Seltzer's, whose 25-person firm monitors trials on behalf of CROs and manufacturers, including McNeil Consumer & Specialty Pharmaceuticals, Neuromed Pharmaceuticals Inc. and Merck & Co. Inc.

The CRO business soon may grow even faster. The U.S. Food and Drug Administration plans to step up safety reviews of products on the market, and Congress may require drugmakers to submit more safety data.

That could be a bonanza for contractors that do the actual studies, especially bigger CROs. Currently, there is no automatic FDA requirement for the so-called Phase IV, or post-marketing, studies. The change is partly a response to Merck's 2004 recall of the pain-reliever Vioxx, whose cardiovascular risks were confirmed only after it had gone to market in 1999.

"That is going to stimulate a lot of safety work in the CRO industry," said John W. Hubbard, U.S. president of Icon Clinical P.L.C., an Ireland-based clinical-research company that has its U.S. headquarters in North Wales, Montgomery County.

CROs are not the only local firms benefiting from the outsourcing trend. Across Philadelphia, there are drug-sales consultants, advertising agencies, corporate deal-makers, data-crunchers, bloggers, and even professional "human guinea pigs" for trials - all focused on the drug business.

While employing a small fraction of the region's estimated 30,000 drug-industry workers, the firms broaden and gird the regional economy by providing well-paying, high-skilled jobs in mostly small businesses.

"We're starting to woo people to Philadelphia," said Larry Mickelberg, vice president of Medical Broadcasting Co., an interactive ad agency that intends to grow from 200 employees to 250 this year. "It's alluring to people in media and entertainment to work in an altruistic calling like health care, and we're at the epicenter."

The firms are too numerous to list completely. But a snapshot shows their scope and ambitions.

Marketing and sales

Norm Smith, founder of Viewpoint Consulting Inc., of Langhorne, helps drugmakers figure out how to position and price their products. He is a former marketer at Merck and Johnson & Johnson, whose clients include J&J subsidiary Janssen Pharmaceutica, north of Trenton.

"I can go there for lunch," Smith said. "If you're doing back-office work, you could put it in Bangladesh. But if you do market research, you need it here. "

A slew of companies work in drug sales, including consultants TargetRx Inc., of Horsham, and ImpactRx Inc., of Mount Laurel. Supply Marketing Inc., King of Prussia, is responsible for the logo-embazoned clipboards and exam-table paper seen in doctors' offices. Verispan L.L.C., of Yardley, is a major supplier of sales data. And one of the country's leading bloggers on drug marketing, John Mack, is based in Newtown, Bucks County.

Next to the Plymouth Meeting Mall sits IMS Health Inc., a leading information analysis and consulting firm employing about 7,000 worldwide. Its 1,700-person Montgomery County facility is the source of data on which industry loyalists and critics both depend, including this tidbit: Americans spent \$190 billion on prescription drugs in the last year, more than Europe, Latin America and Japan combined.

Near Rittenhouse Square in Philadelphia, Medical Broadcasting Co. is trying to shepherd the industry into Internet marketing. It created, among other things, a breast-cancer-awareness campaign at www.GetBCFacts.com, on behalf of AstraZeneca P.L.C., whose U.S. base is near Wilmington.

Linda Holliday, a cofounder with David Kramer, said disease-education Web sites sponsored by manufacturers whose names are barely mentioned may be key to product credibility, hence sales. "If we can shorten the path of somebody considering taking a cholesterol [drug] from two years to six months, it would be good for everybody - the client and the patient," she said.

Clinical Trials

Perhaps contrary to popular belief, pharmaceutical giants do not test all their own drugs. Contractors conduct an estimated 25 percent to 30 percent of the roughly 23,000 clinical trials worldwide each year, according to John Kreger, an equity analyst at William Blair & Co. of Chicago.

Kreger cited safety concerns as one major change now making outsourcing companies, including CROs, one of the fastest-growing sectors of the industry.

"It's hard to imagine any Big Pharma company saying their core competence is doing Phase IV studies," he said.

Among the global, publicly traded CROs in the region are Icon Clinical, North Wales; Covance Inc., Princeton; MDS Pharma Services, King of Prussia; Pharmaceutical Product Development Inc., Blue Bell; Pharmaceutical Research Associates Inc., Horsham; eResearchTechnology Inc., Philadelphia; and Encorium Inc. (formerly Covalent), Wayne.

Most of those CROs, although not all, saw a big increase in their share prices over the last year. Those gains outstripped the 1 percent for the Dow Jones U.S. Healthcare Services sector and 5 percent for the Dow Jones Pharmaceutical-Biotech index.

"The safety push definitely has been good for the CRO business," said Tami Klerr, a vice president of North Carolina-based PPD Inc., rated one of the top CROs in an industry poll by William Blair & Co.

The 9,100-employee PPD has about 200 workers in Montgomery County. Its 16-country trial of Flumist, a nasal flu vaccine made by MedImmune Inc. and produced partially in Philadelphia, formed the basis for FDA approval earlier this month of a refrigerated version of the usually frozen vaccine.

Demand for cost-effective trials has led drugmakers to look for subjects in Asia, Africa and Eastern Europe, where CROs are growing fastest.

"You need a foot in both places," said Lawrence R. Hoffman, executive vice president of Encorium, which merged with a Finnish CRO last year.

But that also creates concerns about trial quality and exploitation of subjects, as fictionally portrayed in the movie *The Constant Gardener*. CROs insist they are part of the antidote, not the problem.

"We don't have a vested interest in the product. We call it as we see it," said Hubbard, of Icon, also a top-rated CRO, which expects to expand its North Wales office this year to 1,060 employees, from 830.

Swimming alongside the big CROs are small locals like Seltzer's Applied Clinical Intelligence, JeanMarie Markham's Clinlogix L.L.C. in North Wales, and Diversified Recruitment for Clinical Trials, a Norristown firm run by Thelma Pruitt Jacks that tries to increase participation of minority groups in trials.

Middlemen

When Pfizer, of New York, unveiled its new inhalable insulin, Exubera, last year, Robert Moran in Blue Bell was cheering. His Plexus Ventures L.L.C. had brought Pfizer together with the drug's original developer, California-based Nektar Therapeutics, 11 years ago.

"We bring parties together like a broker," said Moran, a former GlaxoSmithKline P.L.C. executive. Like many people in ancillary companies, his eight employees and partners came from Big Pharma.

"How many careers end happily in these big companies?" he asked. "So many times, they're looking for early retirements and [face] layoffs. "

With such a labor pool, Philadelphia is also a prime spot for trade groups and nonprofit efforts. The Drug Information Association, about one-fifth of whose 18,000 individual members come from support firms and CROs, is based in Horsham.

The fledgling Pharmaceutical Safety Institute, started and funded by the biggest CRO, Quintiles Transnational Corp., is based in Newtown.

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