

Having Patients Pays Off

El Segundo firm assists drug and medical device companies in lining up clinical test participants.

By DEBORAH CROWE Staff reporter

THE fate of a potential blockbuster drug or medical device can hinge on submitted clinical study data. And that takes lots of suffering patients willing to be guinea pigs.

Yet, for many years, recruiting clinical trial participants was a low-key, generally inefficient process. Medical companies often relied on a network of doctors, known as investigators, with whom they had worked in the past and could be trusted to bring in enough qualified patients.

**This Week:
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Ten years ago, Frank and Linda Kilpatrick, with a background in advertising and public relations, decided to launch an El Segundo consultancy to bring a little Madison Avenue to the task.

Today, **Healthcare Communications Group** is among the oldest and best known firms in the country offering patient recruitment services — with the stakes higher than ever.

Recruiting the right mix of patients can save a drug company nearly \$1 billion and a decade of effort on a drug that doesn't pan out. That's critical for products with often limited patent protection. Moreover, regulators have upped their scrutiny of experimental therapies in the wake of several high-profile disasters, such as **Merck & Co. Inc.**'s arthritis drug Vioxx, which was recalled in 2004 after it was linked to thousands of heart attacks.

"Our role is to help companies bring their products to market more quickly, efficiently and safely," said President Frank Kilpatrick, whose company's client list has included such heavyweights as Thousand Oaks biotech giant **Amgen Inc.** and **Pfizer Inc.** in New York.

The difficulties of putting together clinical studies are documented.

Clinical study industry tracker CenterWatch estimates that nearly 50 percent of trial delays result from patient enrollment problems, and 86 percent of all U.S. clinical studies fail to recruit the required number of subjects on time. For specialty or blockbuster drugs, delays completing a study can translate to \$288 million in potential annual lost revenue.

Drawing on the Kilpatricks' advertising and marketing background, HCG has developed an expertise in how to draw in potential patients. For an experimental Alzheimer's drug, it might place a spot on a morning radio talk show in Philadelphia, or it might work through a medical association. For a diabetes study, the best method might be tapping a patient advocacy group.

With just 5 percent of the U.S. population willing to participate in a clinical trial, it's also increasingly meant looking outside the country for trial participants. HCG, which has another U.S. office in Philadelphia, has opened offices in London and Singapore, and is considering expanding into India and China.

Ken Getz, who founded and later sold CenterWatch, said the kind of direct-to-consumer advertising that is the forte of HCG has become less effective in recent years as the drug industry used more and more advertising to attract patients.

Horror stories about clinical trial problems haven't helped. But there is still a place for a well-run firm that can get patient populations to drug companies.

"That means companies like HCG that are



Global Reach: Healthcare Communications' Dr. Kate Zhong and President Frank Kilpatrick at firm's El Segundo office.

very flexible and nimble, and use a variety of techniques, have an advantage over companies that rely on one method to recruit enough patients who meet a study's criteria," said Getz, now a senior fellow at Tuft University's Center for the Study of Drug Development in Boston.

Strategic alliances

Indeed, the field of clinical trial recruitment has become more competitive over the years, with even PR giant **Fleishman-Hillard** opening its own clinical trials division. More often, HCG competes with specialty firms like suburban Philadelphia **Acurian Inc.**, which touts a national database of patients willing to participate in studies.

There wasn't that level of competition when the Kilpatricks decided to start their agency in 1998. Their ad agency occasionally took on clients who were conducting clinical trials, and they felt that there was an untapped market to provide their services to more drug and device makers.

"Sometimes clinicians developing a study undervalue the logistical challenges of participating in a clinical trial, and potential partici-

Healthcare Communications Group

HEADQUARTERS: El Segundo

FOUNDED: 1998

CORE BUSINESS: Helping drug makers attract clinical trial participants

EMPLOYEES: About 40

GOALS: To expand its overseas operations, possibly in India and China

DRIVING FORCE: Desire of drug makers to conduct clinical trials accurately and efficiently to get products to market quickly

pants might not receive a clear picture about the benefits and risks of participating in a trial," Frank Kilpatrick said.

The Kilpatricks launched the company with their own money and to date haven't sought outside investors. Frank Kilpatrick said they may eventually look to strategic alliances or some other type of partnership to better grow operations overseas.

So far, the company has built up its business fairly well on its own. It has 40 employees and revenues are in the millions; the company declined to release figures publicly.

HCG continues to grow its expertise in a variety of therapeutic areas, including Alzheimer's disease, insomnia, epilepsy and chronic pain. In diabetes alone, the company has assisted in more than 100 studies.

"We have a very in-depth medical advisory board, because you have to understand the disease and the patient population before you can launch a media campaign," said Dr. Kate Zhong, the company's chief scientific adviser.

Suzanne Steinberg, a Pfizer psychologist who oversees clinical trials for the New York-based drug company, said she can attest to HCG's expertise. Over the past eight years, she's worked with the company on recruitment campaigns for studies of everything from obesity to dementia.

"What's great about them is that they're willing to reinvent themselves and they're very customer focused," Steinberg said. "They'll research and get up to speed on a therapeutic area so they can talk intelligently with our people."

Brave Decision

Re: The Profile article in the April 20 issue headlined "Having Patients Pays Off."

We want to commend the Business Journal's efforts to present the challenges that the clinical research industry faces in recruiting and retaining patients. But we are disappointed that the article referred to study volunteers using the derogatory, ill-suited and insensitive term "guinea pig."

The millions of people who volunteer for clinical trials each year have made the profound and brave decision to participate in experimental studies for which there will likely be no direct benefit. Clinical trials do offer volunteers access to medical care and new investigational treatments. But participation in clinical research ultimately benefits other people and makes possible the advancement of medical knowledge. Although it is commonly believed that volunteers participate for pay – as your article insinuates – the

vast majority of clinical trials do not provide any monetary compensation for volunteers.

A guinea pig has no choice in an experiment; it has no ability to reason. A human volunteer chooses, after much deliberation, to give the gift of participation despite its risks.

Around the world, people are living longer, healthier lives because people they never met volunteered for clinical trials and gave this gift. We urge you and your staff to refrain from using the expression "guinea pig" and replace it with a more respectful and appreciative term such as "medical hero."

Ken Getz, chairman

Diane Simmons, president and chief executive

Center for Information and Study on Clinical Research

Participation

Dedham, Mass.