

U-T Business

IN DEPTH C3

PERSONAL TOUCH IN WAR ON CANCER

San Diego's Clarity uses genetic testing to create individualized treatments for patients with recurring ovarian tumors

"THEY WERE MY LAST HOPE."

Jan Amato, ovarian cancer survivor, got aid from the Clarity Foundation, which helps select the best treatment. JOHN GASTALDO • U-T

BRADLEY J. FIKES • U-T

After two remissions from ovarian cancer, Jan Amato was diagnosed for the third time in 2011. Because ovarian cancer grows more resistant with each round of treatment, it was doubtful whether she would have a third remission.

For her third round of treatment,

Amato received chemotherapy. But after four months, another tumor had formed — the cancer was still spreading. Her physician, Dr. Bridgette Duggan, said the treatment had failed, and nothing else was likely to work. Because of her previous treatment, Amato didn't qualify for any clinical trials of experimental drugs.

At that bleak point, the Clarity

Foundation, which brings personalized medicine to ovarian cancer, entered the picture. Clarity helps relapsed ovarian cancer patients by giving doctors the latest information on the most effective drugs for each patient.

Both Amato and Duggan knew of the San Diego-based foundation — Duggan from her work as a doctor, Amato from an article in

the April 2011 issue of O, the Oprah Magazine.

"They were my last hope," Amato said.

With Amato's permission and Duggan's encouragement, Clarity ordered tests from clinical laboratories that generated a genetic profile on Amato's tumor, called a tumor blueprint. This blueprint was

SEE CLARITY • C2

IN DEPTH

TODAY'S FOCUS: Biotech & Health Care

CLEARITY • Genetic profiling of tumor helps doctors target treatment

FROM C1
correlated with Clearity's database of ovarian cancer patients.

Clearity's somewhat unorthodox recommendation was to use the drug Pemetrexed, usually indicated for treating lung cancer and mesothelioma.

"Within three treatments, I was clear of tumor and any evidence that it ever existed," said Amato, 59, a financial planner and Chula Vista resident.

'Off-label' uses

The tests Clearity orders measure a number of molecular markers, which can be matched to which mutations are "driving" the patient's particular cancer. Then the patient's physician can choose a treatment that matches the cancer profile.

Insurance usually pays for the tests. If not, and the patient can't afford them, Clearity will pay. With each patient Clearity helps, another tumor profile is entered into its database of hundreds of ovarian cancer tumors. Clearity also constantly updates the database with the results of new research.

As with Amato, the suggested drugs might not even be indicated for ovarian cancer. Doctors have the authority to approve such "off-label" uses, using their medical judgment. But information on the genetic causes of cancers piles up faster than doctors can assimilate. They are too busy treating patients to keep up with the research, a full-time job in its own right.

Drug companies, a major source of information for doctors, would like to promote off-label use of their products, but it's illegal to do so, even if the information is accurate. The reason is that drug companies, with their interest in selling more drugs, are too prone to providing biased information.

Clearity, as a not-for-profit, operates solely in the interest of ovarian cancer patients, said Laura Shawver, a biotech executive who founded Clearity in 2008 after her own experience with ovarian cancer.



Hillary Theakston, executive director of the Clearity Foundation, is a biotech veteran. She previously worked at Diversa and ResMed. HOWARD LIPIN • U-T

"The numbers are against us, and there's not enough of us, and we don't make a lot of noise, and therefore we don't get a lot of attention for a very difficult problem," Shawver said. "I did not realize what a difficult problem it was, even though I've been in cancer research and

cancer drug development for a number of years."

After her diagnosis, Shawver assumed that her tumor would be genetically profiled to find the best treatment.

"That's what I was doing in the laboratory as we were developing the drug Sutent (for kidney cancer),"

Shawver said. "We would collect tumors from people involved in our clinical trials, and we would analyze them in the lab. I wanted that done for my tumor."

"I found that Dr. Laura Shawver the scientist could do that pretty readily, but Laura Shawver the patient couldn't get it done to save

Clearity Foundation

Established: 2008

Headquarters: San Diego

Purpose: Provide ovarian cancer patients with tumor profiling to guide therapy

Founder: Laura Shawver

Executive director: Hillary Theakston

Patients assisted in 2012: 110

Total contributions in 2012: \$740,000

Total expenses in 2012: \$595,000

Contact: clarityfoundation.org or (858) 657-0282

my life."

As is usual with a first-time diagnosis, Shawver responded to the conventional therapy and went into remission. Then she decided that since genetic profiling of ovarian cancers didn't exist, it had to be created.

Biotech support

With donations from her biotech friends and other supporters, including other ovarian cancer patients, Shawver formed the Clearity Foundation to provide those services.

The biotech community

continues to form the core of Clearity's supporters. Peter Johnson, co-founder of San Diego-based Agouron Pharmaceuticals, is one of the most generous. Last year, he donated a matching gift of \$30,000.

For 2012, Clearity reported receiving \$565,000 in donations, and provided tumor profiles for 110 ovarian cancer patients.

Change of attitude

Hillary Theakston, Clearity's executive director, is another biotech veteran, having formerly worked at Diversa and ResMed. Theakston said she had considered going into non-profit work a bit later in her life, but couldn't refuse Shawver's request to work for Clearity.

Theakston said San Diego, with its large biotech community, is a good headquarters for Clearity, although the organization helps ovarian cancer patients across the country.

"I think it's gratifying for people in the industry to see technology that they're deeply familiar with actually being applied to help patients today," Theakston said.

"You hear about crizotinib (for non-small-cell lung cancer), which was developed by the Pfizer team right here in San Diego," Theakston said. "And biomarkers are routinely used in determining the best course of treatment in breast cancer. We're just lagging in those smaller indications that are more difficult to treat. Ovarian cancers are very heterogeneous, and rather than looking at a handful of biomarkers, you're looking

Discover the **MOSSY** Difference



45 MPG.
THE ALL-NEW BMW 328i DIESEL
Drive One Today.



2013 BMW 328i Sedan Includes Moonroof

Lease for **\$349 Month** + Tax
36 Months
ONLY \$1995 Total out of pocket

MSRP of \$36,225. \$500 Loyalty Cash included in payment. All advertised prices exclude government fees and taxes, any dealer document processing charge, any electronic filing charge and any emission testing charge. Not all lessees qualify through BMW Financial Services. Residency restrictions apply. 20 cents per mile in excess of 30,000. Expires 8/19/13.

5 to choose from

2013 BMW 528i Sedan 5 to choose from

Premium Package - Navigation and Backup Camera

A slow killer

Shawver, who was diagnosed in 2006, said she was "shocked" at the lack of progress in treatments.

Ovarian cancer is rare, accounting for 3 percent of cancers in women, according to the American Cancer Society. But it is disproportionately deadly. It's the 10th most common cancer among women, and the fifth-leading cause of cancer-related deaths among women.

In 2013, the society estimates that 22,240 new cases of ovarian cancer will be diagnosed, and 14,030 women will die of it in the United States. Moreover, the mortality rate from ovarian cancer is about the same as it was 40 years ago.

Ovarian cancer is a slow killer. About 80 percent of newly diagnosed women respond well to a standard chemotherapy treatment and go into remission. However, in most of them, the cancer returns. With each recurrence, the time of remission shortens, and the mortality rate increases.

Amato's experience, until receiving help from Clarity, is typical of the course of ovarian cancer. She was diagnosed for the first time in 2001, the second time in 2008 and again in July 2011.

Duggan, Amato's doctor, said she was treated the second time with surgery and a two-drug combo of carboplatin and paclitaxel, sold under the brand name Taxol. The combo is the standard for first-time ovarian cancer patients; it was used the second time because of Amato's long remission time, and she had not had chemotherapy before.

"She did fairly well with that; we gave her some radiation also," Duggan said. "That treatment left her in remission for approximately nine months."

Shawver said ovarian cancer's rarity helps account for the dismal statis-

Lease for
\$499 Month
36 Months ONLY + Tax
*1995 Total out of pocket

MSRP of \$55,395. \$1000 Loyalty Cash included in payment. All advertised prices exclude government fees and taxes, any dealer document processing charge, any electronic filing charge and any emission testing charge. Not all lessees qualify through BMW Financial Services. Residency restrictions apply. 20 cents per mile in excess of 30,000. Expires 8/19/13.



MOSSY BMW of Vista



(888) 846-0673
Mossy.com
1715 Hacienda Drive, Vista, CA 92081

Mossy
BMW of Vista



INSURANCE • State slow to provide training for agents

FROM C1

in selling policies in the new venue. Federal health reform requires most Americans to buy insurance on Jan. 1, 2014, if they aren't already covered.

Licensed insurance agents can sell exchange-listed plans only if they have been certified by Covered California, and getting certified requires passing a test after eight hours of in-person and four hours of online instruction.

Training is necessary because the new exchange offers the subsidized rates to some uninsured Californians, and small businesses, based on their economic status. Plans offered from a dozen different private insurance companies also are listed at different tiers corresponding to precious metals from bronze to platinum.

Kara Voelker, a group insurance broker with Teague Financial Insurance Services in La Mesa, said she believes brokers have an important role in helping Californians make sense of the options.

"An agent's value comes in explaining the differences between the many different options that are available. Our goal is to have the breadth and depth of the marketplace for our clients," Voelker said.

While insurance agents seem eager to learn about how the new exchange works, getting certified by the state is not yet possible despite the fact that the exchange is set to open on Oct. 1.

Craig Gussin, co-owner of Auerbach & Gussin Insurance and Financial Services and a board member of the San Diego Association of Health Underwriters, said most in the industry expected

"Our goal is to have the breadth and depth of the marketplace for our clients."

Kara Voelker • Teague Financial Insurance Services in La Mesa

that the training would come in the late spring or early summer to give agents plenty of time to study. The fact that preregistration is just starting, he said, has gotten agents and brokers talking.

"It's probably the biggest buzz out there right now. We want to sell Covered California, and we can't do it unless we're certified. Agents have been asking me for months 'when can we get certified,'" Gussin said.

Voelker said she, too, is hearing some concern from agents.

"The biggest buzz around this is the lateness. People are becoming concerned that it's not going to be complete when the exchange opens on Oct. 1," Voelker said.

There is no doubt that California's training is lagging behind other states. The U.S. Department of Health and Human Services opened its online training for brokers in the 27 states with federally operated exchanges on Aug. 1.

Given that California was the first state in the nation to receive approval from the government, it is not clear why

agent training is not starting until September.

No information was available on why training is not starting until September or on when it was originally planned to start.

Larry Hicks, a spokesman for Covered California, said the state hopes to train more than 10,000 insurance agents and added that the work is expected to be complete when the exchange opens on the first day of October.

In addition to agents, the state is also training 20,000 certified enrollment counselors who will work with community-based organizations across the state to help Californians understand their options when trying to decide which plan to buy.

"We're using many channels to reach our target demographic, which is the more than 5 million Californians eligible to buy insurance through our exchange," Hicks said.

He said insurance agents will have their own Internet portal into the exchange, allowing them direct access for the clients they represent. Agents, he added, will continue to earn commissions on the plans they sell according to their existing agreements with insurance companies.

Covered California released a narrow set of rate information for its individual marketplace in May with seven companies offering a total of nine plans in San Diego County. On Aug. 1, the exchange also released information on small-business plans.

paul.sisson@utsandiego.com
(619) 293-1850

at dozens."

Clarity has recently added Foundation Medicine's genetic sequencing service to its assembly of tests, which screens for more than 200 oncogenes, genes that when mutated can lead to cancer, Theakston said.

Physician adoption shift

Doctors are taking notice of what Clarity offers, Theakston said.

"When Laura started, 100 percent of patients either identified us through research, learned through a chat room, heard from a support group, or an acquaintance who was familiar with us," she said. "Now we think that greater than 30 percent of patients are being referred by their physicians. So just in the brief time that Clarity's been around, we've seen a shift with physician adoption and comfort with profiling."

Duggan said Amato's third remission has lasted more than a year, compared with nine months for the second remission. Usually remissions get shorter in ovarian cancer. Making the result even more remarkable, Amato had previously received radiation, which usually impairs the effectiveness of drugs by damaging the blood circulation to tumors. The drug has more difficulty reaching its target.

Amato said that in addition to Clarity's assistance, she's been helped by a combative attitude toward cancer, both by Duggan, whom she called "a warrior of a doctor," and personally.

"I've seen people passively approach cancer, and I say no, you're going to be a fatality if you do that," Amato said. "The information's out there, and always ask questions. If I had given up right then and there, you wouldn't be talking to me now."

bradley.fikes@utsandiego.com
(619) 293-1020
Twitter: @sandiegoscience