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Experts Concerned As Phase I Studies Reach Deeper Into Community Practice

By Paul Goldberg

Second story in a two-part series examining changes in conduct of industry-sponsored phase I studies.

Recently, Gail Eckhardt, a medical oncologist at the University of Colorado, got a call from a community doctor who often refers late-stage cancer patients to her studies.

"This person was basically calling me to say, 'My hospital really wants us to start doing phase I trials, and I am just calling you to find out how to do phase I trials,'" Eckhardt recalled.

Learning about phase I would take more than a telephone conversation, no matter how long and how meandering. A patient has to understand that he

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In the Courts:

NY Federal Court Rules Against Myriad, Finding Patents On Genes Unlawful

A New York federal court ruled that patents on genes associated with hereditary breast and ovarian cancer are invalid.

The March 30 ruling affects patents held by Myriad Genetics (Nasdaq: MYGN) and the University of Utah Research Foundation and marks the first time a court has found patents on genes unlawful.

The ruling in the case filed by the American Civil Liberties Union and the Public Patent Foundation could have far-reaching implications as approximately 2,000 human genes are now covered by patents. Public Patent Foundation is a not-for-profit organization affiliated with Benjamin N. Cardozo School of Law. Judge Robert Sweet, of the Federal District Court for the Southern District of New York, ruled that some claims covering isolated DNA sequences in seven of the 23 patents covering Myriad's BRACAnalysis are invalid.

"The ruling is a victory for the free flow of ideas in scientific research," Chris Hansen, a staff attorney with the ACLU First Amendment Working Group, said in a statement. "The human genome, like the structure of blood, air or water, was discovered, not created. There is an endless amount of information on genes that begs for further discovery, and gene patents put up unacceptable barriers to the free exchange of ideas."

Myriad said it will appeal the decision to the Court of Appeals for the Federal Circuit.

"While we are disappointed that Judge Sweet did not follow prior judicial

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Lure Of Revenues, Pharma Control, Drives Multi-Site Trials

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is unlikely to benefit from the treatment, and that harms from that treatment are unknown. In fact, not enough medical training programs teach young physicians to conduct such studies, Eckhardt said.

Until a decade ago, industry-sponsored phase I studies were conducted exclusively by academic programs, even as phase II and phase III trials spread out to multiple institutions and contract research organizations.

Now, this picture has changed. A review of a government database of clinical trials by The Cancer Letter shows that single-site studies account for a quarter of all phase I cancer research done in the U.S., and for-profits are now used in more than half of all multi-site studies (The Cancer Letter, March 26).

Large for-profit practices have been run by experienced phase I investigators who left the administrative burdens and academic politics of universities and came up with a way to turn early phase clinical research into a money-making proposition.

Now, phase I research appears to be spreading further into the community as for-profits set up referral networks and franchise arrangements, sending out the message that phase I can be profitable.

"Some hospitals are getting wind of the competition, and grasping the fact that these studies can definitely bring in some income," Eckhardt said. "If people who are inexperienced start opening phase I sites because of financial motivations, that would be a concern."

As phase I research splinters and moves deeper into private practices, experienced academics and former academics working at for-profits lose control of the studies and only the pharmaceutical company scientists located thousands of miles from the clinic are privy to all the data. Critics of this new state of affairs point out that sponsors have incentives to push drugs through phase I, because a product that moves to phase II can push up the stock price or translate into venture capital funding. An error made in phase I can remain invisible until phase III.

"It makes some people in the companies feel good, but it doesn't get them to the right answer," said Mark Ratain, the Leon O. Jacobson Professor of Medicine and associate director for clinical sciences at the University of Chicago Cancer Research Center. "I think if you look at the falling success rates in oncology, you have to start asking why. Is part of it that there is less input from experienced investigators? Phase III failure often comes back to phase I mistakes."

The new economic underpinnings in phase I shape the scientific questions that are being asked and the manner in which they are asked.

"My reason for being here at the University of Chicago is to do research," Ratain said. "I also see patients. I also teach. If I were in private practice, my primary reason to be there would not be to do research and publish papers. The interests of a private phase I group are much better aligned with the pharmaceutical industry. Maybe that's why this partnership is blossoming."

Also, Ratain reserves the right to say no. He declines offers to take part in multi-site studies, and he follows his clinical judgment even when it contradicts instructions of pharmaceutical sponsors.

"Is it acceptable to have your responsibility to your patients to be taken over entirely by a company?" Ratain said. "I am not willing to do that. If a company says, 'Do this,' and I don't feel it's appropriate, I will just say, 'No, I won't do that.'

"I have recently told companies that I am unwilling to escalate until I have both additional data on patients currently being treated as well as potentially more patients treated at the current or lower dose levels."

The diffusion of phase I research is at least partially driven by the increasing number of biomarker studies. In the past, such translational studies, which can involve moving inventions from bench to bedside and

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back to bench, could be performed only at academic institutions.

Now, a sizable segment of such studies has moved to less sophisticated settings, where specimens are packaged and sent off to an outside lab.

"Biomarker studies and pharmacokinetics used to be routinely run at academic centers," Eckhardt said. "As the industry became more worried about standardization and regulation, more and more of the assays and PKs are being outsourced to independent contractors."

In many cases, this happens because drug companies want to see uniform test results from the same lab as they decide whether to keep a drug candidate going.

"I don't know what we can do about that," Eckhardt said. "That to me is a result of the fact that some of these drugs are going to need to be approved with a CLIA-certified biomarker, and many, many academic labs are not certified."

Conflicts Heat Up

Phase I research has always created the potential for conflicts, particularly because patients don't always understand that the studies are not intended to benefit them personally.

Investigators, on the other hand, stand to benefit either as they advanced their academic careers or, in the case of for-profits, financially. The makers of the drugs stand to benefit, too.

"There are lots of reasons to be concerned about patients and the undue pressures that might come," said Chris Daugherty, an oncologist at the University of Chicago whose interests involve ethics of clinical trials. "What's difficult to sort out is the motivations for why a doctor, a clinic, an institution would pursue clinical research. And if the motivations are nothing but pure, that is establishing what the future care of cancer patients ought to be, then you could trust the system. But the concerns come when there may be motivations beyond that."

What would ordinarily happen to patients who had exhausted all options but who remain well enough to take further treatment? Data suggest that many of them would continue to receive treatment that could not be expected to produce any benefit, Daugherty said.

"There is plenty of evidence to say that if there is no clinical trial available, the physician might still pursue chemotherapy, and with that chemotherapy comes revenue," Daugherty said. "One of the criticisms that have been launched against all oncologists is that we continue chemotherapy longer than we should. Fourth-line therapy for non-small cell lung cancer, most people would agree that in almost all cases that's probably not an appropriate use of chemotherapy. There is pretty good evidence that there is no benefit to doing it, but physicians still do it. The question is why?"

The pressure on patients is not new. "It's always been hard to help advanced cancer patients who have the diagnosis that they are not going to survive understand that when they enroll in these early phase trials that the likelihood of benefit is really small for them," Daugherty said. "But what patients understand, and believe and hear at the end of the day is very difficult to know sometimes."

Inappropriate pressure can come from academic physicians, too.

"I would have a hard time thumping my fist on the table and saying the motivations of those who do trials at places other than academic medical centers are anything but pure," Daugherty said. "Those in academic medical centers have other motivations as well. They have interests that go beyond the care of the patients. The investigators are not out to forward their own careers? Of course, they are. I have heard physician investigators say, 'If I put one more patient on this trial, I will be the first author.'"

Financial motivations can enter the picture as well, as academic centers increase their competitiveness with for-profits, speeding up scientific and Institutional Review Board scrutiny of protocols.

"Can you say that academic medical centers aren't out to improve their revenue streams; in this day and age? Of course, they are."

As phase I research moves deeper into private practice, inappropriate pressure could be exacerbated, said Jordan Berlin, clinical director of gastrointestinal oncology and head of phase I research at Vanderbilt-Ingram Cancer Center.

"I am most concerned about completely inexperienced investigators doing phase I research," Berlin said. "These are new drugs with completely unknown side effects, and inexperience at recognizing a side effect as due to a new drug could make a difference on dose that could prove dangerous.

"Moreover, the most important aspect of opening a phase I trial is the ability to provide informed consent. That is not exclusive to academic centers, but doing a good job of obtaining a truly informed consent takes experience and true understanding of the nature of phase I. Patients who go into phase I often have a certain desperation, and one has to break through that to get them the information and be sure they understand what

they are signing up for. That is not an easy task."

Exodus From Academia

The first major for-profit to get involved in phase I research was Sarah Cannon Research Institute of Nashville, which started enrolling patients in such studies in 1997 and now has 53 open phase I studies in oncology. Sarah Cannon officials didn't respond to requests for interviews.

The newest big player is South Texas Accelerated Research, or START, a group whose web address can be taken as an indicator of considerable ambition: www.startthecure.com.

Anthony Tolcher, START's founder, is the former director of clinical research at the University of Texas Cancer Therapy & Research Center's Institute for Drug Development. Three years ago, Tolcher and 65 other former CTRC employees set up a for-profit at a large practice located two blocks East of their former business address.

"We were at the CTRC, and we were being charged an overhead just to be at the pleasure of CTRC and UT of $200,000 a month," said Tolcher. "So much in many academic institutions is lost to overhead, which doesn't benefit the investigator. One of the more chronic complaints among academic investigators is they don't have resources or have enough of the research staff to do the job properly. People are not given the tools to succeed."

Few cancer centers understand the value of phase I, Tolcher said. "Having a strong phase I program is very important to any cancer center, but most cancer centers don't understand that, because they are driven by thinking that it very much revolves around getting an NIH R01 grant and doesn't think about the long-term benefits of working with industry," he said.

Lee Rosen, an oncologist who led about 20 staff members out of the University of California, Los Angeles in 2002, similarly seems to have no regrets about leaving academia.

"The difficulty about being in any university is that you don't have control over the entire parts of the program," Rosen said. "For example, the laboratory was a separate department, and if they wanted to charge me X, Y or Z, or if they wanted to say 'No,' I couldn't control that.

"And the same with radiology, and the same even with the infusion room. When mistakes would be made and I would try to say something, I would bump up against bureaucracy," Rosen said.

The IRB approvals were slow, and the contracting department required personal attention.

"There was a contracting officer, an older guy, and we just knew that if we kind of went and talked with him personally, we would get the contract through much faster," Rosen said. "Who needs to deal with that kind of stuff? And then the university, administered out of Berkeley, would have these very rigid rules about intellectual property that really had nothing to do with phase I trials. It really reminded me of what it must have been like to live in the Soviet Union."

According to its website, START currently runs 45 studies, but Tolcher said the actual number is higher, because some studies are not publicly announced. Federal rules require only that phase II and phase III studies be announced on the www.clinicaltrials.gov database. Phase I studies, which don't address the efficacy question, are exempt from this requirement.

Generally, Rosen's Premier Oncology of Santa Monica can get a trial started within three weeks, he said. START can get going within about a month. Academic centers generally need two to four months to complete scientific review and IRB review. "We can oftentimes move much faster than sponsors," Rosen said. "What delays us oftentimes is FDA, because FDA won't answer in less than 30 days, and sponsor bureaucracy—getting either drugs, electronic or paper database information out here. So the small companies love us, because they are lean and they can move quickly."

Rosen said that putting a patient on two cycles of an experimental therapy over two months can bring in $7,000 to $10,000. However, if tests have to be run, the gross can reach as high as $20,000 to $30,000. Other insiders say that per-patient revenues can reach $50,000.

No one has done side-by-side comparisons of what drug companies pay, but Tolcher and Rosen say they are not competing with academic centers on price points.

"We believe it can be done a lot faster, because most academic organizations are incredibly slow and bureaucratic, and I don't think we are any cheaper than a university," Tolcher said. "We may be a little more expensive, but we do a much better job."

Neither Premier nor START conduct investigator-initiated biomarker studies. "It's usually sent out," Rosen said. "We have a clinical lab that processes specimens, but we wouldn't be doing our own biomarker analysis. To recreate that for the size we are would be incredibly expensive. And there is no reason to do it."

Companies are paying for well-conducted phase I trials, not biomarker studies, Tolcher said.

"If you are a good phase I center, you may not be the

best at doing gene sequencing or expression analysis," he said. "So most people say, 'Let's go to the expert in gene sequencing and expression analysis.' It's the idea that some people have that one-stop shopping that there are people who should be able to do biomarkers.

"Nonsense."

"A Contradiction of Terms"

Academic oncologists have a range of responses to for-profit centers.

All are quick to point out that the leading existing for-profits are operated by former academics, who remain as competent as they were before they moved across the street.

However, many academics admit to being frustrated by not being able to open trials and accrue as rapidly as for-profits. Worse, having the name of a non-academic oncologist appear on a paper above the name of an academic's can be painful. The order in which names appear on publications is determined by the number of patients accrued.

Also, academics say that review procedures at their institutions are becoming faster.

"The biggest problem is that not enough patients go on phase I studies under any circumstances," said Francis Giles, director of IDD, which runs about 60 active phase I studies. "There are too many people dying of cancer with no hope, where it's never even mentioned. They fade into oblivion without anybody saying, 'Look, I can't promise you a miracle, but I can offer you the fact that we are not giving up on you, and every day somewhere some advance is being made.'

"The economic background of where they go on might have nuances, but from my personal perspective, the more people are out there talking to patients who have very advanced disease about a phase I option the better," Giles said.

That said, "for-profit" and "phase I" is an inherent contradiction in terms, Giles said. "I think it's inherently, absolutely a passing phase."

"Phase I is far, far, far more than just establishing a maximum tolerated dose and walking away," Giles said. "There is a lot of work in developing pharmacogenomic markers, specialized imaging. And the cost of moving from phase I to phase II is so enormous that anybody who has a drug worth caring about wants an enormous amount of information from the phase I, and quite often needs the level of academic collaboration that's just as important as putting the patient on.

"The actual fiscal part of doing phase I on a respectable level now is so enormous in terms of background IRB and keeping all the regulatory authorities happy, the concept of charging companies sufficient per patient to make phase I profitable, to me is inherently ridiculous.

"Those of us who run such enormous units are reliant on support from many other sources—such as peer reviewed grants, philanthropy—that make it possible for us to do them," Giles said.

Some organizations are capable of performing some phase I work outside academia, but that doesn't constitute a genuine phase I organization, Giles said.

Genuine phase I programs depend on high-level collaborations, Giles said.

"I have calls back-to-back for the next few hours, all of them are about one drug," he said. "Among the people I have to talk to are biostatisticians, crystallographers, chemists, and they are all in different parts of the world, For those three or four hours which I am on the phone calls, somebody is paying my salary, some infrastructure has to support it.

"The whole idea of being able to cherry-pick phase Is and make a profit from them per se is a little like an airline choosing a couple of routes.

"Can an airline go out there, take the five busiest routes out of many hundreds that are possible? Is it sustainable to do that? I see new airlines pop up every few years and vanish without a trace two or three years later, or maybe change their name when something goes wrong. To use an airline analogy, I am sure there are faster ways of turning around the plane, but would you want to be in one that is turned around the fastest?"

Shortcuts in review are a problem.

"There are always shortcuts," Giles said. "But in the end, over the years, you will have these thousands of patient faces in front of you, and you either kept you contract with them individually or you didn't.

"It's that simple."

Bruce Chabner, clinical director of the Massachusetts General Hospital MGH Cancer Center, doesn't see a major role for for-profits.

"The major role is going to be played by institutions that can do tumor profiling, and I don't think a lot of the for-profits can do that," he said. "I would like to think that the smart companies are going to be doing trials with academic centers that can do profiling and select the right patients, because they get an immediate answer as to whether the drug works or not. Here, we do molecular profiling routinely, but there are very few institutions that can. I don't know any for-profits that can do that at the moment."

The Harvard institutions run about 40 phase I trials,

with initiation time of about 90 days. "I don't think we match regional hospitals that don't have scientific review and basically do a relatively cursory review of the trial," Chabner said. "They are mainly concerned about safety, and the scientific aspects of it are not going to hold them up."

A for-profit, too, can probably move things along faster, Chabner acknowledged.

"You get what you pay for in this situation," he said. "If you do a trial with a top academic center and you get a lot of input into how it's designed and the translational research that goes with it, it may make your drug for you. You will see things that will clarify how you can do it, in what patient population, and you will get a real break from that. If you do it in a for-profit center that just puts people on trial for money, you will get less of a return for your buck. It's a matter of strategies."

Not every trial needs Harvard, Chabner said.

"We try to work with companies that want to do interesting things. I think there is selection bias," he said. "We don't just test everything that comes along. The fifth platinum analog probably would not interest too many people. But a unique inhibitor of a molecular target would very much interest people."

Making money on a trial is not always a goal. "The more input we have into designing a trial, the more it's investigator-initiated, the less money we make," he said. "The more we putter around in the lab, the less we make. That's the fun of it. We want to do it the right way."

Competing With For-Profits

START's Tolcher said it's possible to make money on phase I—or at least survive without subsidies—even in an academic institution.

"If you had a great organization and if you ran it as a great organization, you are likely to be able to at least break even," he said. "People who always fail always blame the circumstances. It's a common excuse in the academic circles to say that we need funding or a bailout. That's because there is not the tight management that you need."

Specialization in phase I is key, Tolcher said. "There are some people I know at the Farber who do phase I, but that's almost a side interest of theirs," he said. "They have labs, and for them it is not the whole reason for being. I am not a lung cancer guy dabbling in phase I. I am a phase I guy."

"That's a difference in terms of commitment to see the study through. I am in the clinic three to four days a week. I an not in a situation where I have one day in the clinic, and the rest of the time is for academic pursuits."

Many academic investigators view for-profits as formidable competition.

"I have a trial, which was three academic centers and one for-profit," said Vanderbilt phase I researcher Berlin. "And the for-profit put on the most patients, because they opened before anybody else could.

The arithmetic is simple: while a for-profit can get going within a month, an academic institution can join the study within three months at best. This means that by the time the Vanderbilt site opens, a for-profit can go through two dose escalation cycles.

Premier's Rosen tells a similar story. "We can have a study with our Arizona site and UC San Francisco, and we fill the first two cohorts before UCSF is open," he said. "It infuriates them, but they understand because they are all friends."

This doesn't always happen, said the University of Colorado's Eckhardt. "Yes, they are a little faster, but it don't think there is a huge difference," she said. "I wouldn't say it's always a community site that starts out. Sometimes it's another academic site. Sometimes it's us. To me that hasn't become a consistent issue."

Competition for accrual can test collegiality, in part because academic centers have to predict accruals as part of their budgeting. If accrual targets aren't met, the academic program will lose money. "Most academic centers lose money in their clinical trials office, anywhere from a few hundred thousand a year to a couple of million dollars a year," said Berlin.

Phone calls where the sponsor notifies the sites that a new patient is needed can be tense.

"Companies like to enroll trials competitively, which isn't right, because this creates the atmosphere where people load up the patients," Berlin said. "Somebody will fall through at one site and they will say, 'We no longer have a third person for that level. We need a third person,'" Berlin said. "And then they will go through the list. They will say, 'Vanderbilt, do you have a person?' And if I don't have a pair of initials with a diagnosis sitting there, somebody else is going to get the slot. For us, the fewer slots we get, in addition to a lost opportunity for a patient, the greater the potential that we will lose money for the year, because we build some of the fixed costs into the per-patient costs."

Insiders said that in some cases, academics and for-profit sites prepare for these events by giving patients multiple protocols to read, then formally consenting them once a slot becomes available. In those situations, few patients could be expected to make an informed

decision on the potential downside of experimental agents, sources acknowledge.

Competition for credit in publications is a problem, too, especially when a for-profit enrolls more patients than an academic center.

"They get more slots because they start faster," Berlin said. "Our start times, like others, are improving all the time, but we have more bureaucracy and will not be able to compete with them in opening times completely."

Indeed, recently, Daniel Von Hoff, of the Scottsdale Clinical Research Institute, which operates in conjunction with patients with Translational Genomics Research Institute, appeared as the lead author on a New England Journal of Medicine study of the hedgehog inhibitor. Von Hoff could not be reached for comment.

Multi-Site Trials: The Real Enemy?

Few investigators seem to like multi-site studies, and many say that they decline to take part in any phase I trial that involves more than three sites.

"I lobby for one, I will accept two when the other site is good, and when there is three, it has to be because I am really excited about the drug," said Premier's Rosen. "If I am really excited about the drug, then we will do it, but really being dragged kicking and screaming."

Eckhardt doesn't like multi-site trials either.

"There appears to be a perception in the pharmaceutical industry that the more sites you have, the more efficient your trial is," she said. "Many of us in academics generally try to dispel that myth, because generally what happens if you have too many sites on a phase I study, it's less efficient, because there is less communication among the sites and there is a lot of time involved in getting all those sites up and running.

"It's almost like there was a period when we thought we could convince people not to do multi-site phase I, but they are here to stay. So, many of us have had to deal with formulating criteria that we require to participate in a multi-site phase I."

Eckhardt's criteria: "The maximum number of sites I want to see is two. If a sponsor wants to go to three sites, in general that is reasonable if you think you are going to have tissue-based biopsy studies, which are harder to enroll patients to, and if you have three motivated sites doing that it probably is more advantageous.

"The other mandate we have is there has to be excellent communication. There needs to be a team that is set up at the sponsor site that will spearhead having regular teleconferences, and in our view it is a good idea to have sites that have worked well together in the past. So we generally say that we don't like it when the sponsor cherry-picks the sites that may be their favorites, but not necessarily sites that are used to working together."

Ratain said the industry will not get the message until investigators start voting with their feet. "Experienced academic investigators with adequate patient populations should refuse to participate in multi-site phase I studies," he said. "If that drives more studies towards non-academic sites, that will be industry's loss."

Since many companies view multi-site trials as insurance against investigators who lose interest, there will likely be a market for phase I sites that don't object to taking orders. And with centralized control, many players think that they would be able to keep trials moving on schedule.

"It's interesting that in the private world that practices see phase I as a component that they now need to add to be competitive with other practices or with academics," said Eckhardt. "It's going to be an interesting component as to how it's going to play out."

In the Courts:

Federal Court Rules Myriad Gene Patents Are Unlawful

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precedent or Congress's intent that the Patent Act be broadly construed and applied, we are very confident that the Court of Appeals for the Federal Circuit will reverse this decision and uphold the patent claims being challenged in this litigation," Peter Meldrum, president and CEO of Myriad Genetics, said in a statement. "More importantly, we do not believe that the final outcome of this litigation will have a material impact on Myriad's operations due to the patent protection afforded Myriad by its remaining patents."

The ACLU suit claimed that the challenged patents are illegal and restrict both scientific research and patients' access to medical care, and that patents on human genes violate the First Amendment and patent law because genes are "products of nature."

In addition to Myriad, the suit named U.S. Patent and Trademark Office. However, the court granted the USPTO request that it be released as a defendant in the lawsuit. The court found that it was unnecessary to reach the First Amendment claims against the USPTO because it had already ruled in favor of the plaintiffs.

The lawsuit, Association for Molecular Pathology,

et al. v. U.S. Patent and Trademark Office, et al., was filed on May 12 in the U.S. District Court for the Southern District of New York on behalf of breast cancer and women's health groups, individual women, geneticists and scientific associations representing approximately 150,000 researchers, pathologists and laboratory professionals.

The court recognized the far-reaching impact of the case on medical research and public health. The opinion stated, "…the resolution of the issues presented to this Court deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their investors, and those seeking to advance public health."

The specific patents the ACLU had challenged are on the BRCA1 and BRCA2 genes. Mutations along the BRCA1 and 2 genes are responsible for most cases of hereditary breast and ovarian cancers. The patents granted to Myriad give the company the exclusive right to perform diagnostic tests on the BRCA1 and BRCA2 genes and to prevent any researcher from even looking at the genes without first getting permission from Myriad. Myriad's monopoly on the BRCA genes makes it impossible for women to access alternate tests or get a comprehensive second opinion about their results and allows Myriad to charge a high rate for their tests.

The American Medical Association, the March of Dimes and the American Society for Human Genetics, filed friend-of-the-court briefs in support of the challenge to the patents on the BRCA genes.

According to Myriad, a woman who tests positive with the BRACAnalysis test has, on average, an 82 percent risk of developing breast cancer during her lifetime and a 44 percent risk of developing ovarian cancer.

The decision is available at: www.aclu.org/free-speech-technology-and-liberty-womens-rights/association-molecular-pathology-et-al-v-uspto-et-al

Professional Societies:

ASCO Honors Eli Glatstein, Daniel Von Hoff, Nine Others

The first physician-scientist to combine radiation oncology with medical oncology—forever impacting the effect and importance of radiation oncology in treating people living with cancer—is among the notable awardees who will be honored by the American Society of Clinical Oncology at its 2010 annual meeting in Chicago in June.

This year's ASCO Special Awards include:

Distinguished Achievement Award: Eli Glatstein, professor, vice chair, and clinical director of the Department of Radiation Oncology at the University of Pennsylvania School of Medicine. Throughout his career, Glatstein's research has made a significant impact on the way a number of cancers are diagnosed and treated, particularly Hodgkin's disease. In the early 1970s, Glatstein was the first to combine radiation oncology with medical oncology, which has had a deep and lasting impact on the effect and importance of radiation oncology in cancer care. In addition to his numerous breakthroughs in research, Glatstein has also committed his career to teaching and training medical students. Twenty-one of his former trainees, fellows, or junior faculty have gone on to become chairs of academic radiation oncology departments.

David A. Karnofsky Memorial Award: Daniel Von Hoff, for his outstanding achievements in cancer research and for his impact on the treatment of patients with cancer. Von Hoff is an internationally recognized physician-scientist who has contributed to the development of numerous anticancer agents, including paclitaxel, docetaxel, irinotecan and gemcitabine. He currently serves as physician-in-chief for the Translational Genomics Institute in Phoenix, chief scientific officer of Scottsdale Healthcare and US Oncology, and clinical professor of medicine at The University of Arizona College of Medicine.

Science of Oncology Award: Frank McCormick, director of the University of California San Francisco Helen Diller Family Comprehensive Cancer Center and professor in the Department of Microbiology and Immunology. McCormick is a pioneering molecular biologist and cancer researcher, whose contributions include the development of sorafenib, a small-molecule tyrosine protein kinase inhibitor used for the treatment of kidney cancer and advanced liver cancer. The Science of Oncology Award is in recognition of this advance and Dr. McCormick's other outstanding contributions to translational research in cancer.

ASCO-American Cancer Society Award: Joseph Simone, for his contributions to the prevention and management of cancer and for his leadership in the field of oncology. Simone served as physician-in-chief of the Memorial Sloan-Kettering Cancer Center and director of the University of Florida Shands Cancer Center, but spent the majority of his career at St. Jude Children's Research Hospital, where he served as director from 1983 to 1992. In his years there, he played a leadership role in the development of curative treatments for

childhood leukemia and lymphoma. Simone was also the founding medical director and chairman of the National Comprehensive Cancer Network and was instrumental in the creation of the ASCO's Quality Oncology Practice Initiative (QOPI). He serves as senior advisor to the Shands Cancer Center and as president of Simone Consulting. Simone is also clinical director emeritus of the Huntsman Cancer Institute and professor emeritus of pediatrics and medicine at the University of Utah School of Medicine.

Gianni Bonadonna Breast Cancer Award: Nancy Davidson, for her distinguished record of accomplishments in advancing the field of breast cancer research. Davidson has published key findings on the role of hormones, particularly estrogen, on gene expression and cell growth in breast cancer. She also guided several important national clinical trials of potential new therapies, including chemoendocrine therapy for premenopausal breast cancer and antiangiogenesis therapy for advanced disease. Davidson is director of the University of Pittsburgh Cancer Institute and professor of medicine in pharmacology and chemical biology and served as director of the Johns Hopkins Kimmel Cancer Center's Breast Cancer Program. She was also president of ASCO in 2007-2008. This award will be presented at the 2010 Breast Cancer Symposium, Sept. 30-Oct. 2 in the Washington, DC, area.

B. J. Kennedy Award and Lecture for Scientific Excellence in Geriatric Oncology: Harvey Jay Cohen, director of the Center for the Study of Aging and Human Development and Walter Kempner Professor of Medicine at Duke University Medical Center. Cohen has written more than 300 articles and book chapters on topics in geriatrics and hematology/oncology, with special emphasis on aspects of cancer and immunologic disorders in the elderly. He is also past president of the American Geriatrics Society, the Gerontologic Society of America, and the International Society of Geriatric Oncology.

Pediatric Oncology Award and Lecture: Sharon Murphy, for her outstanding contributions to pediatric oncology. Murphy has devoted the past 35 years to improving cure rates for childhood cancer, particularly childhood lymphomas and leukemias. She has authored more than 220 original articles, reviews, and book chapters, and has served as the inaugural director of the Greehey Children's Cancer Research Institute and professor of pediatrics at The University of Texas Health Science Center at San Antonio. Murphy currently is a scholar-in-residence at the Institute of Medicine.

Partners in Progress Award: Ellen Sigal, for her dedicated efforts to raise public awareness about cancer. Sigal is chairman and founder of Friends of Cancer Research, a nonprofit organization. For more than 12 years, Friends of Cancer Research has pioneered innovative public–private partnerships, organized critical policy forums, educated the public, and brought together key communities to develop collaborative strategies in cancer research. Sigal also holds leadership positions with a broad range of cancer advocacy and public policy organizations and academic health centers.

Special Recognition Award: Patrick Loehrer Sr., for his outstanding contributions to clinical oncology and cancer research and for his dedicated service to the oncology community. He serves as associate dean for cancer research and H. H. Gregg Professor of Oncology at the Indiana University School of Medicine and director of the Indiana University Melvin and Bren Simon Cancer Center. Loehrer is an internationally recognized researcher and specialist in thymoma, genitourinary cancers, and gastrointestinal cancers.

ASCO Statesman Award: Laurence Baker, University of Michigan Comprehensive Cancer Center/Southwest Oncology Group; Edward Balaban, University of Pittsburgh Medical Center; C. D. Blanke, BC Cancer Agency and University of British Columbia; Howard Burris III, Sarah Cannon Research Institute; John Cox, Texas Oncology; Robert Dreicer, Cleveland Clinic: Stephen Edge, Roswell Park Cancer Institute: Alexander Eggermont, Erasmus University Medical Center; Charles Haskell, University of California, Los Angeles; Maha Hussain, University of Michigan Comprehensive Cancer Center; Mark Kris, Memorial Sloan-Kettering Cancer Center; Theodore Lawrence, University of Michigan Comprehensive Cancer Center; Gary Lyman, Duke Comprehensive Cancer Center; Gregory Masters, Helen F. Graham Cancer Center; Therese Mulvey, Commonwealth Hematology Oncology; Olufunmilayo Olopade, University of Chicago Comprehensive Cancer Center; Bruce Peterson, University of Minnesota Medical School; William Purcell, Billings Clinic Cancer Center; Derek Raghavan, Cleveland Clinic; Gregory Reaman, Children's Oncology Group; Mack Roach III, University of California-San Francisco Helen Diller Family Comprehensive Cancer Center; Bruce Roth, Vanderbilt Ingram Cancer Center; Mace Rothenberg, Pfizer Oncology; Charles Schiffer, Wayne State University; Branimir Sikic, Stanford University; Margaret Tempero, University of California, San Francisco; Linda Vahdat, Weill Cornell Medical College; Antonio Wolff, Johns Hopkins Kimmel Cancer Center.