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FDA Oncology Division Director Says Goal To Make Review Process "Predictable"

FDA needs to make its cancer drug review process more predictable by improving its communications with pharmaceutical companies, researchers and patient advocacy groups, according to Robert DeLap, director of the agency's Division of Oncologic Drug Products.

The division, which is responsible for the review of new anti-cancer drugs, plans to publish literature both in print and electronically regarding the agency's requirements for new drugs for specific cancers, DeLap said in a interview with ***The Cancer Letter****.*

The division also plans to hire five more medical officers this year

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Three Bomb Threats At NIH In One Week Result In Evacuations, Investigation

The NIH Division of Public Safety and Montgomery County, MD, police are investigating three bomb threats that caused evacuations of NIH employees on July 24 and July 29, officials said.

Officials said bomb threats at NIH are rare, though not unheard of. On the average, no more than two are reported in the course of a year. No explosive device has ever been found at NIH, sources said.

The first of the recent threats at NIH occurred following the crash of a TWA jet off Long Island, but prior to the explosion at the Atlanta Olympic Games, two events that appear to have triggered a rash of bomb threats around the country.

The threat was conveyed on July 24, when a caller to the detectives section at the Bethesda Station of the Montgomery County Police Department said a bomb would detonate at the NIH off-campus building, police said.

According to police, the caller, who had a foreign accent, referred to the federal raid on the Branch Davidian compound at Waco, Texas, and the bombing of a federal building in Oklahoma City.

The bomb threat resulted in the evacuation of the downtown Bethesda building, 7500 Wisconsin Avenue. The building, occupied exclusively by NIH houses various NIH components that appear to have no history of controversy.

The caller's decision to telephone the detectives rather than dial the emergency or non-emergency numbers point either to his naiveté or his sophistication. Calls to the detectives section are not routinely recorded, police said.

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Facing Increasing Workload, Oncology Div. To Add Staff

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to meet an increasing workload, he said.

DeLap was named director of the division last June. He served as acting director on a rotating basis with oncology team leader Robert Justice for more than a year. Justice was named deputy director of the division.

DeLap came to FDA in June 1990. He was an oncologist at the Lombardi Comprehensive Cancer Center at Georgetown University. Previously, he worked with the pharmaceutical companies Parke-Davis and Lederle Laboratories.

***The Cancer Letter** Editor Kirsten Goldberg spoke with DeLap in his Rockville, MD, office.*

CL: What has changed over the past year in the oncology division?

DELAP: We have had several final actions already this year [on New Drug Applications], and they keep coming in. A few years ago, the typical year for us was two, or perhaps three applications of one sort of another. Now, our more recent history is several applications approved each year. In fact, we've had six or eight NDA approval actions this year, and a couple of supplemental NDA applications approved already this year. That's an unusual level of activity for us, by historical standards.

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What's new is the level that we're going to be maintaining for the next few years, because we are seeing a lot of activity in the cancer research field. More companies are becoming interested in investing in this area of research. That's good for the public health. There is clearly a large need.

CL: Drug development is taking off because of advances in cancer research over the past five or 10 years?

DELAP: Certainly. There is just a tremendous difference in what's known today about the biology of cancer. What happens in the cell that makes it become a cancer cell. It's tremendously better understood today than it was five or 10 or 15 years ago. Obviously, there is still a lot to be learned. But we are at the point where we are getting away from the black box approach to drug development, where you're just trying out different drugs, and hope you get lucky in patients.

It's getting more to the point where people have models as to what they are trying to accomplish biochemically or pharmacologically, and then they find a drug that does that. It's getting more rational all the time.

Everyone's hope is that will translate to better, more effective, less toxic drugs. And I think we are seeing that. That's part of the basis for the interest was well. Companies see that drug development is getting to be less of a black box kind of a operation, and more of a scientific operation.

It's still unpredictable. Companies still have to invest a lot of money in research into compounds that just don't make it, because you can't predict, based on your pre-clinical studies, that drug X is going to prove to be a good drug for patients.

CL: In March the White House announced four "Cancer Drug Initiatives," some of which are supposed to speed drug approvals. What effect are these initiatives having on your work?

DELAP: The initiatives have helped a lot to focus some of our work, and help make our expectations and our work more explicit, and more understandable for the outside world.

I think a big problem that we have as a regulatory agency is that, by the regulations that govern us, a lot of what we do is private. We see a lot of proprietary data that comes to us from companies, that we simply cannot disclose, even if we wanted to. And so, we are something of a black box to people, oftentimes, as to why we do what we do.

The initiatives are helpful in that they make some things explicit, as to what we're looking for, and what kinds of actions we will take, based on what kind of data. The initiatives are also helpful in that they lead us in the direction of doing everything we can to make the best drugs available for people that need them, as quickly as possible.

If you look at the meat of the initiatives, in a sense, we're going to give accelerated approvals as soon as we think that there's a drug out there that people really need. For refractory situations, we will make the drug available on the marketplace, once we have the data that the drug produces responses in patients with refractory conditions. Follow-up studies would be done after the drug is approved.

Another initiative involves access. If there is a drug in another country that's been approved, that we think offers something of value to the American public, then, again, we will do what we can to get that drug available for American patients, even before we have a marketing application for it.

A third initiative says we will have patients on our advisory committees. Again, we think that also will help to direct us, and the whole process, in the direction of getting the drugs available for people that need them as quickly as possible, as long as we have evidence that the drugs do offer something of value.

The overall direction helps people to understand what we want, and what we are going to do. It makes the process more predictable for the outside world. I think that's very important for companies.

CL: Could you expand on that?

DELAP: As a person who worked for [pharmaceutical] companies in the past, I know that when you are planning your research, and you are planning how to spend a company's money doing research, it's very helpful to know what the outcome is going to be, and what your expectations can be about the outcome.

So, the more predictable it is that, if you do A, B, and C, and outcomes X, Y, and Z are achieved as a result of this, then, in a business sense, this is what you can expect to come back to the company.

That just makes it much more attractive. To the extent that people can predict what's going to happen as a result of their investments, they are much happier investing their money in that particular line of research.

CL: So the initiatives help make FDA more predictable?

DELAP: Exactly. Predicting how FDA's going to view your results, and what FDA is going to do based on those results.

We need to do more in that area. That's one of the things that we want to extend. We want to get more information out to the research community about exactly what we expect, in terms of study endpoints, regulatory approvals, and, in particular, kinds of cancer illnesses.

Companies spend a lot of money on monitoring and auditing studies, and they collect a lot of information in the course of the studies. And I think that, sometimes, they do things that we would not require that they do.

CL: Out of fear of FDA?

DELAP: They may feel that it's important, for their own purposes, to do some of these things. But if they are spending money based on their perception of what we want, and it's not the correct perception, then we have to correct that. So, we are interested in getting more information out.

CL: How do you plan to do that?

DELAP: FDA is getting more involved in electronic media. There is an FDA Web page (http://www.fda.gov). There is a Center for Drugs Web page. We are working on getting some information of our own up in those venues. My goal in this area is that we will put information about some of these things not only in the print media, but also in the electronic media, so people can simply look up and see what we're saying about the development of, say, drugs for breast cancer, or monitoring and auditing studies.

CL: The FDA Oncologic Drugs Advisory Committee in the past developed papers on their expectations for new drugs for particular kinds of cancer. Would you develop more of this kind of information? Some of these papers haven't received much attention.

DELAP: We would do more of that. There was a white paper published in the Journal of Clinical Oncology a few years ago, that I believe Joyce O'Shaughnessy [a senior investigator at NCI] was first author on, which provided a series of examples of different situations for new drugs, and what kinds of data might be obtained, and how it might be viewed in the regulatory sense, as to whether it would be enough to approve the drug or not. That paper has received a lot of attention over the years, and has been used quite widely.

I think you're correct that some of the white

papers that were generated by the ODAC reviews of standards in particular areas did not receive as much attention, although they have been, actually, fairly widely used. Again, a lot of it is not seen publicly, because a lot of it we discuss with companies when they meet with us,

I guess one of the things that makes me think this is really needed, is that we will see a few sponsors come in sequence, asking the same questions. What does the FDA expect, what does the FDA require, in terms of clinical studies, to get a drug approved for hormone-refractory prostate cancer? What is the FDA looking for, in terms of endpoints, in terms of numbers and kinds of studies?

It's a lot of work for companies to prepare their meeting packages: "This is where our drug is in development, and this is what we're proposing to do now, and have we read your mind properly?"

If we can do more to get our viewpoint out there so that companies and research sponsors can look at it before they develop their research plans and business plans, and come in and meet with us, it's going to make the process a lot easier.

I'm also hopeful that it will help to stimulate more work, simply because, to the extent that the whole process is more predictable, people are more interested in participating in the process.

In many therapeutic areas, expectations as to what is required to get a drug approved, over the years, have been well established. The problem we have in cancer is that, rather than being one therapeutic area, of course, it's hundreds of different therapeutic areas.

For example, a drug may work in adjuvant therapy. It may not work nearly as well, and it may not work at all, in advanced disease. There are certain kinds of drugs, some of the newer drugs that affect tumor angiogenesis, that might work in an adjuvant or early disease setting. But, once the tumor is established, and has its blood vessels already formed, there may not be much mileage in trying to block the formation of new blood vessels with that kind of drug. So, it's not even that you can divide by diseases. You have to almost divide by stage of disease.

To the extent that we can make at least our part of it as clear and explicit as possible, that takes away one part of the uncertainty of doing research in this area for sponsors.

CL: Tell me about your work with pharmaceutical companies before you came to FDA.

DELAP: I did my fellowship at Yale, with Joe Bertino—he was my mentor there. Bertino was working with a compound, trimetrexate, which I think they were calling JB-11, because Joe Bertino had done a lot of the early work on trimetrexate. I got involved, when I was working as a fellow, with the company that was developing the drug, Parke-Davis.

After I finished my fellowship, I took a job with Parke-Davis, to be in their clinical cancer drug development program. I spent a few years there.

CL: Working on trimetrexate?

DELAP: I was working on trimetrexate, and then on several other drugs Parke-Davis was developing for cancer indications. Subsequently, I took a job at Lederle Laboratories, in a similar role, but a slightly higher level. I spent a total of about seven years in those two jobs.

CL: So you saw this process from the other side. Were you involved in talking with FDA?

DELAP: Oh, yes. I was involved in coming in, meeting with FDA, with some of the same staff who are working here now.

CL: Does that experience give you a different perspective on your work within the agency?

DELAP: Well, I've walked in those shoes, so I can understand the different pressures and requirements that apply when you work for a company. Companies have to come up with something very tangible that helps people in this field. If you are doing cancer drug development, the only way you can survive as a company is by selling products. So you have to come up with products that help people, so that they can be sold. I don't care how good your marketing people are. If you have a drug that doesn't really help people, you're not going to sell very much of it.

The physicians in this country are too smart to use drugs that don't work, by and large. It's a matter of survival for companies. They have to come up with products. In fact, they have to come up with a continuing stream of new products, because, the way the patent laws work, they can only make money on a product for a certain number of years, until they lose their exclusivity, and then they've got to have a new product ready to take its place.

So there is a powerful incentive for companies to develop new products.

There is also the need to develop products in areas where some money can be made. Again, if you're working in a business, and you develop a wonderful new product for a disease that affects one person per year, then, obviously, you may cure

that person, and that person may be very grateful for what you've done, but your company will not survive. You're not going to be able to run a company off of the profits of selling a drug to one person per year.

And these are issues that potentially affect cancer drug development, because there are a lot of rare diseases in the spectrum of cancer. It's hard for companies to develop drugs for rare diseases. It's hard for companies to develop drugs that are used briefly for a disease.

If you've got a drug that you give one course of therapy to a patient, and the disease goes away and doesn't come back, that's going to be a lot less profitable than developing a drug that you may give it to the patient every day for years.

Companies like to develop drugs for common conditions that require chronic therapy. Those are obstacles for cancer drug development. They tend to be rare diseases, and, oftentimes, the drugs are used for fairly limited periods of time, and the patient moves on to get something different.

There's nothing inherently good or bad about what companies have to do to survive in the marketplace. These are the realities that the companies have to face as they are developing products. We can't fix a lot of these things at FDA.

But there are some things that we can try to fix, or deal with. We have been trying to make our part of it, at least, as predictable as possible.

CL: Would you say you view your role as helping companies bring their products to market?

DELAP: We have to respect the fact that there's a certain amount of money that people can spend on developing drugs. That's true in all areas, not just cancer, but especially in cancer, where you're trying to develop drugs for so many different diseases, and so many different stages of diseases, and the need is so great, there is a certain amount of money that can be spent, and you just can't see that money wasted.

Our role is to work with companies to make sure that they are doing things as efficiently as possible. They do the animal studies they need to do, but they don't spend a lot of money doing extra animal studies, just because they think we might like to see them, when, in fact, we don't need to see them.

And, similarly, in the clinical studies. They do the clinical studies they need to do, and we approve a drug for marketing as soon as we can. But we have to make sure they don't have inefficient or poorly designed clinical drug development programs, where they spend a lot more money than they need to spend.

We can't get away from the fact that we're a regulatory agency. We can't set aside our regulatory hat and adopt a promotional kind of hat. We are a regulatory agency, and I think we can be very careful about our regulatory policies, to make sure that we are not doing something that is not absolutely necessary to fulfill our regulatory role.

And, particularly, that we're not doing things that discourage research.

But, again, our responsibility is to make sure that drugs get out that are safe and effective for the treatment of the conditions that they're prescribed for. That's our fundamental role, that's our job.

CL: Often one will hear the view that FDA is blocking drug development. Do you see any need for major regulatory change? Do you see anything blocking drug development?

DELAP: Well, it's often difficult for me to sort those kinds of things out. It's much easier if you have specifics. Where someone says, "This is what the FDA is asking for, and we don't feel it's necessary, because it doesn't add to our knowledge about the drug, or it simply is asking for more information than should be required."

We are interested in discussing specifics. If there's a situation where somebody feels that we are putting up some kind of an obstacle to the development of their drug that is not warranted, we are interested in discussing that.

In general, I find it difficult to imagine that we could be much more aggressive about maintaining the minimum necessary standards for getting new drugs in the marketplace.

CL: You think you are doing that now?

DELAP: I think we are, in the recent history of the FDA. I'm not talking about five or 10 years ago. I wasn't around and I can't comment on that. But I would say, in the last few years, when I've been around, my observation is that we are being very aggressive about allowing drugs in the marketplace based on fairly early data—response rate data for patients with refractory illnesses. Again, the initiatives crystallize our position for us.

There is not a lot of further latitude for us to accept less data and still be reasonably assured that the drugs are adequately safe and have some effectiveness.

When we approve a typical cytotoxic drug, we

can accept that the drug is dangerous. We can accept that the sponsor is reporting some patient deaths related to the use of the drug. We have been able to accept that the drug produces some partial responses, but maybe not even complete responses, and the partial responses are limited in duration.

It's difficult for me to imagine that we would rationally support a much lesser standard than the kinds of standards that we're willing to accept.

It's impossible to be perfect as a regulatory agency, and whatever we do has risks and benefits for the American public. Right now, we're very much in the mode of accepting the fact that there are risks with these products. But we are saying, if there is a benefit, at least for some population of patients that we can identify, then we'll let the drug out there to be used.

I wish that the nature of the field, and of the drugs that we're dealing with, was such that we could afford to be more stringent in some of our requirements.

I would be delighted to be in that position, but we're not in that position. And, in a lot of these situations, there are patients out there for which there are no drugs. So we can't say, "We've already got a drug out there that works pretty well, and that's not very toxic, so you're going to have to meet that standard to get your new drug out there."

I think we will be at that point someday, but right now we're not, so we have to continue to accept these drugs that have serious toxicities and fairly modest effectiveness, until something better comes along.

CL: What do you see as the role of patients in helping FDA make these decisions?

DELAP: Patients have a lot of motivation to understand the illness that they're suffering from. Many times, patients have gone to the library and tried to understand as much as they can about their illness. Informed patients can be very helpful in giving that perspective of how people feel when they actually are faced with a situation.

There's a lot to be said for having a person who is actually dealing with the illness we're trying to treat tell us what they think about what we're doing.

It takes a special kind of individual. The most helpful thing for us is to have people that not only have the illness, but also have really done a lot of homework on what the illness is about, what the treatments are about, who has developed some informed understanding of their cancer, available treatments, and research.

We've seen a lot more interest among patients in getting informed and trying to make their own best informed decisions, rather than just taking what somebody says to them.

In any field, an informed consumer always comes out better than someone who just kind of goes into the showroom and takes what they're given. That applies to doctors as well as to anything else. I think that's a very good modern trend, and we're trying to take advantage of it.

CL: Do you see anything further than having patients involved with the FDA advisory committees? Are there other areas where patient activists can become involved with FDA?

DELAP: Well, we're still trying to get the first part right. It's a little complicated to get that patient involvement with advisory committees right. The advisory committees are not very large. They have 10 or 11 members. We can put some patients on those committees who can comment. But you are always getting one person, or maybe a couple of people, and you're not really sure that you're getting all the viewpoints that you want to get.

That's kind of a problem for us right now. We're still trying to figure out the best way to get the best people. FDA has had consultants give us opinions about that. We've learned a lot in the process. I don't think we have it fully sorted out yet.

That work has been done with our Office of AIDS and Special Health Issues. Patricia Delaney is the cancer liaison there.

Patricia has been very instrumental in helping us with getting good patient representatives for our advisory committees. That's still an area that needs further work, and it's receiving further work.

But one of the other things we have been doing recently, partly as a result of our interest and partly as a result of their interest, is talking more with some of the groups that represent the interests of patients. Again, not nearly so much as I would like.

We have had meetings with, for example, the National Breast Cancer Coalition and the National Coalition for Cancer Survivorship.

CL: You are going out and meeting with patient advocacy groups?

DELAP: Oh, yes. We went to a recent NBCC meeting, and the most recent NCCS meeting was here in the Washington area. And we have talked with Eugene Schoenfield, who is active in the National Kidney Cancer Association.

We met with the staff [of these groups] and

talked about what our viewpoints were, and what their viewpoints were, and what we could do better, and what they saw that they thought that we could do better. But we need to do more of that, and we intend to do more of that.

We have been given the latitude to add some staff, and we are very close to adding several staff in the medical officer group, and I think that will enable us to do more of this kind of thing.

CL: Are the staff increases the result of the user fees?

DELAP: Yes. It's really a result of the user fees. We're significantly larger than we were, but it's hard to compare numbers. Up until a year ago, we were part of the Oncology and Pulmonary Division. Then, they split the two divisions, and further, separated the chemists, who had been counted as members of the two divisions. We went from a division of Oncology and Pulmonary Drug Products that had 80 some people in it to where we are now. At this moment, our plan is to go up to 39 people.

That sounds like half of 80, but that doesn't count the chemists, something like 11 people, who split off.

CL: How many people do you have now?

DELAP: Immediately after the split, we've been running at about 33 people. We've been told to add several additional people to that.

CL: Your staffing level is dictated from above?

DELAP: Yes. We're going to be in pretty good shape if we can identify and bring in the right people to get up to this somewhat higher level that we're authorized to go to now.

If we're still strapped after we get up to this somewhat higher level, I'm confident that our management is supportive. Even if additional user fee positions don't become available, our management has the ability to reallocate positions as people leave. So I think we could have some further growth, if we can support the need for it.

CL: How many medical officers are there now?

DELAP: We're at about 11 positions, medical oncologists, and we're looking at adding about five more to that count. We've got several people identified, so I'm optimistic that we will fill our available positions in the next few months.

I'm not sure what the proper number should be for government regulatory agencies. That kind of gets into politics, I guess. Are you a big government believer? Are you a small government believer? How big should it be?

FDA is, by government standards, not a very big agency, but, at the same time, it's relatively large, compared to regulatory agencies in other parts of the world. It depends on what people think our job is. If it's very narrowly defined as some paper comes in, we review it, and stamp yes or no on it, then that doesn't take as many people as if we're going to do these other things, like talking with patient groups.

My view is that those other activities are equally important.

CL: Are user fees covering the cost of reviews?

DELAP: I really can't answer that. I don't know how they figure out how much a review costs. We have several people spend a lot of time reading each application that comes in, so I suspect, if you apply the user fees against the salaries of the people that are directly assigned to actually do the review, it might be comparable.

We have to do time studies here, periodically. They put something up on the computer, and say, "Tell us how much time you spent, in the last two weeks, on this application, and on this application, and on this application." We have to keep track once in awhile.

CL: What are your top priorities for the next couple of years?

DELAP: We are intent on continuing to finish new drug reviews on time, or ahead of time. Finishing review of new Investigational New Drug applications within 30 days. Working with people fairly closely, so that we rarely have to put new INDs on hold. Similarly, on the New Drug Applications, we've been pretty successful in not only doing the reviews within the allotted time, but also working with the sponsors up to the point of the application, such that the applications that we get are usually pretty good, and we can usually get a good review on them.

We continue to work closely with sponsors, we continue to do our work in a timely fashion, and we just do our basic regulatory mission. That always has to remain priority No. 1.

Another thing that is at least equally important is working with some groups outside of government that are very much interested and invested in this process, like the advocacy groups. It's a very high priority.

The third thing is for us to do more to get our expectations and our standards and requirements out for public review, so that what we expect is better understood.

Those are the things I'm interested in.

Three Bomb Threats In A Week Cause Evacuations At NIH

(Continued from page 1)

"It is very unusual for us to receive this kind of a call at the detectives section," said George Ludington, a police spokesman. Ludington said police were unable to identify the caller's accent.

References to Waco and Oklahoma City would be uncharacteristic for a caller with a foreign accent, several observers said. The Waco raid is a landmark for domestic right-wing groups. The bombing in Oklahoma City marked the anniversary of the Waco raid. July 24 was not the anniversary of Waco and Oklahoma City.

The date comes closest to the first anniversary of the disclosure by NIH that 27 employees, including a pregnant postdoctoral fellow from China, had been exposed to phosphorus-32. A segment on that incident was rebroadcast on CBS news magazine 60 Minutes on July 21, three days before he bomb threat at NIH.

The contamination, involving a postoctoral fellow, was discovered on June 29, 1995. Two weeks later, officials determined that a water cooler in the vicinity of the postdoc's lab contained traces of P-32, and that 26 other employees had been exposed to the isotope.

The 60 Minutes segment pointed to a pattern of non-accidental radiation exposures in research laboratories, describing such poisonings as a form of pathological behavior by researchers (**The Cancer Letter**, Nov. 3, 1995).

NIH officials declined to comment on the bomb threats.

While the first threat could have represented an attempt to capture the spotlight by blocking Wisconsin Avenue during the lunch hour, two subsequent threats were directed at targets that figured in the P-32 case:

—On Monday, July 29, at 7:30 a.m., a note in an elevator at the NIH Building 37 said a bomb had been planted in the building, officials said. The bomb had been set to detonate at 12:30 p.m., the note said. Building 37 was the site of the exposures.

—At 10 a.m., an anonymous caller to the NIH Radiation Safety Branch said a bomb would go off in the RSB offices within five minutes.

RSB, located in the NIH Building 21, was the first agency to investigate the P-32 exposures.

Sources said the caller's voice had no unusual characteristics.

The two bomb threats were made a year after the 27 employees at Building 37 were formally notified about their exposure.

The notification letter was dated July 27, 1995. July 29, 1996, was the first business day following the one-year mark of that notification.

The Federal Bureau of Investigation, which is conducting a probe of the original contamination, is not involved in the investigation of the bomb threats, officials said.

"At the present time, FBI is not investigating the bomb threats," Special Agent Larry Foust said to **The Cancer Letter**. "FBI has made any resources available to NIH, which is taking the lead in the investigation." Foust declined to comment on the ongoing investigation of the P-32 case.

"There is no indication from NIH that there was any tie-in between the original case and the bomb threats," said Jim Joyner, a technical assistant at the Division of Nuclear Materials Safety at the Nuclear Regulatory Commission.

Last year, the highest level of exposure to P-32 was reported by Maryann Wenli Ma, then a researcher at NCI. Subsequently, Ma filed a complaint to NRC, in which she described her lab chief, NCI scientist John Weinstein, as a task-master obsessed with having her terminate her pregnancy.

"In this bizarre case anything is possible," Weinstein's attorney Fred Joseph said of the possible link between the contamination and the bomb threats.

"This just adds to the puzzle," Joseph said to **The Cancer Letter**. "Hopefully, [the bomb threats] will provide leads that will go toward exonerating my client." Ma's attorney Debra Katz said she sees no connection between the exposures and the bomb threats.

No one has been accused of wrongdoing in the case. Ma and husband Bill Wenling Zheng are currently employed at the National Institute on Deafness and Other Communication Disorders.

In the early morning hours of July 30, after a day of bomb threats and evacuations at NIH, Montgomery County police received a call from a young man who said explosives had been placed at the Children's Inn on NIH campus.

Police traced the call to a pay phone at Children's Inn, a facility for children undergoing treatment at the Clinical Center.

The caller, whose name was not released, turned out to be a teenager who was staying at the inn while accompanying a patient, officials said.