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*****SNS*****

SPECIAL LETTER: REPAIRING BRAINS

By Matthew Klipstein

“SNS is one of my essential reads. Mark wields one of the sharpest intellectual axes I know, yet he doesn't really seem to have one to grind -- except perhaps the scientific search for the truth....”

– Robert Berkley, Managing Partner, GroupMV, West Tisbury, MA; in a forward of SNS to a friend.

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Future in Review (FiRe) 2010 Conference

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The logo for the Future in Review (FiRe) 2010 conference. It features the word 'FiRe' in a stylized, orange-to-red gradient font, with '2010' in a solid red font below it.

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Latest additions:

“CyberWar: Today and Tomorrow,” with Joseph Menn, author, *Fatal System Error*;

Climate Refugees: A first look at this Sundance film, with director and creator Michael Nash (don’t forget, last year’s FiRe Film *The Cove*, by Louie Psihoyos, just pulled the Academy Award for Best Documentary);

“Scaling Alternative Energy”: An Opening Night talk by world expert Nathan Lewis, George L. Argyros Professor of Chemistry, Caltech; and

“Tomorrow’s Sustainable Housing Today”: Real and proposed sustainable dwellings, with Robert Bornn, Founder, Building Circles Organization.

*This year’s theme: “**Emerging Platforms**”*: Handhelds, Smartphones, Media Players, Pads, e-Books, Netbooks, Smartbooks, and (Repairing) the Cloud.

Participants and Speakers include (but are not limited to):

Ray Ozzie, Chief Software Architect, Microsoft

Jen-Hsun Huang, CEO, NVIDIA

Paul Jacobs, CEO, Qualcomm

Steve Squyres, Principal Investigator of the Mars Exploration Rover Mission (MER) and Goldwin Smith Professor of Astronomy at Cornell University; on “Finding Life on Mars”

A New Panel: “The Business and Technology Behind Hollywood”

John Cramer, Science Fiction Author and Professor Emeritus, Physics, University of Washington; on “Quantum Time Reversal”

John Delaney, Professor of Oceanography and Jerome M. Paros Endowed Chair in Sensor Networks, and Director, Regional Scale Nodes Program, University of Washington; on building the world’s first broadband ocean-floor remote sensing network

Plus:

Eric Darmstaedter, CEO, ClearFuels Technology

Chris Hancock, CEO, AARNet

Ricardo Salinas, Chairman of the Board, Grupo Salinas

And many, many more (see “[Upcoming SNS Events](#)” for more details).

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Publisher's Note: I have known SNS member and entrepreneur Matthew Klipstein as an “e-friend” since he sold his first company to Corbis. After years of emailing me complex ideas, one day he just dropped off the map. Sometime later, he wrote me a short, rather halting email; his life had changed drastically, and he was open enough to share the details.

I have always had faith in Matthew, and told him so then.

A few weeks ago, in the onslaught of morning emails, I found a press release that, at first, was almost unbelievable. It had come from Matthew's new company, and that story forms the basis of this week's Special Letter. If you want inspiration, on almost any level, here it is. Matthew is very straightforward about his personal stake in wanting to find these discoveries, and in the likelihood that they have probably come too late to do his health any service. Even so, it would seem that his contribution may change the lives of millions, for the better, sometime soon.

I am proud to know Matthew, and also to announce that NeuroRepair, his company, has been selected as one of the FiReStarter companies to be highlighted at FiRe 2010.

I think you'll find this story as uplifting and amazing as I did. – mra.

➤ **Repairing Brains**

By Matthew Klipstein

For the first 40-some years of my life, I led a life that just always seemed to work out. No matter how foolish, or even downright stupid, I was about something, Fate ensured that it worked out just fine for me.

I have dozens of vignettes to substantiate this claim, but I suspect that those stories might take too much space. Let's just say that the Universe had apparently singled me out to lead a perfect life, and that's exactly what was happening.

I was “livin' the dream.” Having just sold my company, in a rather highly publicized deal, I had what most people would think of as a lot of money and all the accoutrements one might expect to go with that good fortune. I was in perfect health and relatively young. I was free to do anything, and I was having a blast. I was so consistently lucky that I came to think of it not as luck, but as my birthright. If the presumed odds against me were a million to one, I just assumed I would be the one.

I simply counted on things always going my way.

And they did, until one day they didn't.

The Decade of the Brain

On July 18, 1990, President Bush (the first) proclaimed the 1990s the Decade of the Brain. It was a nice thought. He noted that our understanding of the brain, how it works, what can go wrong, and how we might fix it, had “increased dramatically” in the preceding few years, and boldly predicted that we were on the verge of important breakthroughs in treating diseases of, and injuries to, the brain.

This was all sort of true. Our knowledge had increased from a dismal, pathetic, embarrassingly tiny amount to something just barely less dismal, pathetic, and embarrassingly tiny.

But I Couldn't Possibly Have a Stroke

Everyone knows that only the elderly; those with diabetes, hypertension, and other circulatory disorders; smokers; and the obese have strokes.

Not necessarily (e.g., see www.KidsHaveStrokes.org).

In mid-January 2000, on my 47th birthday, I was 5'11" and 180 lbs. I swam 400 meters every morning and worked out very hard at my gym four nights a week. I was bench pressing 150 kilos (330 lbs.). I was fastidious about my diet. My body fat was just slightly above professional body-builder level.

On March 14, 2000, I was playing in a beach volleyball tournament at Del Mar. My 6'5", 255-lb. partner dove for a ball and I ended up pinned between him and the sand, with his elbow lodged hard into the side of my neck. Beach volleyball can be a rough sport. I felt OK, and I didn't think much of it except “That's gonna leave a mark.”

Three days later, on the night of St. Patrick's Day, I woke up in the middle of the night, quite confused to find the entire left side of my body not quite working properly. I swung myself out of bed and promptly caught the floor with my face.

I couldn't walk. I couldn't stand up or move my left arm or leg. I was having difficulty speaking. I later learned that the elbow had hit me perfectly, in such a manner as to tear the interior lining of my carotid artery (called a “carotid dissection”). Blood flowing through the artery had pushed its way into the tear and bubbled the lining up, completely occluding the main artery that supplies blood to the right side of the brain. I had suffered a massive stroke in my sleep.

I was incarcerated in hospitals for just over three months. And, if you've never been trapped in a hospital, believe me, it is incarceration. I was physically helpless, and not permitted to do anything without a doctor's order. It must be a lot like Folsom Prison,

only I'm betting the hospital food was worse. I lost 25 pounds in those three months, and I had arrived there sporting 7% body fat.

In addition to the inedible food, every week some neurologist would visit me in my little hospital room and, in precisely these words, tell me: "Brain injuries never heal. There is no treatment. You will never recover. You'll get used to your disabilities." My response was not repeatable in polite company.

The awful part is not just that a doctor would say such a thing to a gravely injured, and terrified, patient, but that it was, and remains today, completely true – except for the "you'll get used to it" part.

Upon my release, I had what I thought was a clever idea: I'd start my own biotech company to find a way to repair neurological injury. I had no clue what I would be up against.

It was several more months before I was able to read, so my search had to wait. Eventually, however, I was able to struggle through Internet searches looking for anyone who might be doing promising research.

After several days of typing search requests with my one functional hand and trying to read Yahoo's responses with a brain that could barely read, I stumbled across Dr. James H. Fallon, professor of Anatomy and Neurobiology at the University of California, Irvine. Jim is a Sloan Scholar, an NIH RCDA research scholar, and a senior research Fulbright Fellow. He is, I think we can safely say, not unaccomplished.

Jim had been experimenting with a naturally occurring protein, called "Transforming Growth Factor-alpha" (TGF-a), for about 15 years. His lab was, in fact, the first to isolate this growth factor in the mammalian brain.

(Scientists should not be allowed to name things. Transforming Growth Factor-alpha is a horrible name. It sounds like something that causes cancer or does some other terrible "transformative" thing. Moreover, Transforming Growth Factor-alpha is virtually unrelated to Transforming Growth Factor-beta, so named because it happened to have been discovered in the same experiment.)

Jim had discovered that TGF-a has remarkable neurotrophic¹ and mitogenic² effects. That is, TGF-a stimulates a massive proliferation of adult pluripotent³ stem cells in the brain; these cells magically migrate from their place of origin in the ependymal⁴ layer that lines the ventricular wall adjacent to the striatum⁵, to the locus of damage, and then, again magically, differentiate into the kinds of cells that have been lost or damaged. (I know almost no biology or chemistry; one wonders how I got through four years of high school and four years of university without taking a single science class of any kind – so "magic" is about the best explanation I can give.)

I decided to call Dr. Fallon to see if we could meet. This was, of course, before I

realized that Jim gets calls like mine from distraught patients every week, and before I knew the first thing about scientific research at universities in America. I was unaware that almost everything that is said to a potential donor, by the researchers and their universities, is about the money. This is not an indication of nefarious intent, nor really even their fault. Research costs money, and, as if further evidence of a sad state of affairs were needed, the richest country in the world provides few established, reliable sources of funding.

I met Jim Fallon at my home, where he was kind enough to visit me. I (naively) told him that I had money to support his research, and I didn't care if we spent every dime if it would lead to a way to repair my injury and retrieve my life.

I became a Licensee of the University of California – or rather, NeuroRepair Inc. did. The University won't deal with an individual, so I created NeuroRepair.

NeuroRepair Inc. is a Delaware corporation in good standing, but it's really little more than a conduit from my personal checkbook to the many people and things that require money to accomplish my research goals. The company has no debt, no VC, and no outside investors of any sort. We can call it heroic or stupid – the truth is, “desperate” is a more accurate descriptor – but I have financed this entire venture myself. (My dealings with UC are too involved to describe here, and almost too comical to be believed.)

The Cost of Stroke

In December 2009, the Oxford University Press published an article in its journal *Age and Ageing*¹ calculating the 2008 cost of stroke in America at something around \$65.5 billion. The 2008 cost of stroke in the EU was approximately \$36.8 billion, and in the UK the cost came to about \$13.7 billion.

Bear in mind that these are largely direct medical costs and exclude much of the huge cost of lost productivity, and other costs borne by patients and their families. Additionally, this total of \$116 billion is for stroke alone, in a single year; it does not include such devastating diseases as Parkinson's, Alzheimer's, MS, atherosclerosis-related dementia, etc.

And this is just one year in the Industrialized West; it does not include the rest of the world. Worldwide, the cost of brain injury and disease is likely in excess of several hundred billion dollars per year.

So why are Big Pharmaceutical companies not all over this? There is, I'm sure, more than one answer. However, before NeuroRepair's discoveries, no one had a viable solution, and Big Pharma is disinclined to take the risks inherent in developing a therapeutic for stroke, which is enormously complex. They'd rather wait for someone else to do it, and then buy it after it has been fully proven.

Medical Research in the United States

Medical (and, I suspect, virtually all scientific) research in America is in a shameful state. The military seems to waste a lot of money, but they generally get the job done. Most non-military biomedical work is performed at major research universities and financed in an uncoordinated patchwork sort of way, by private and publicly held companies.

Probably no single educational institution in the world generates more Intellectual Property than the University of California. Lamentably, the University seems not to have a clue what to do with that IP once it has it. Some private institutions, such as Stanford University, do a fine job of turning IP into something tangible. UC does a great job of letting a naturally wasting asset waste away and, in the process, getting itself sued with some regularity.

Because the University of California, arguably one of the world's greatest institutions of higher learning, isn't quite organized enough to finance its own research and make money productizing the results, it requires professors and other researchers to find corporate sponsors who are expected to sign a draconian License Agreement under which the sponsor pays for everything and the University calls all the shots. The University owns everything discovered or invented, which the Sponsor may then pay more to license back – all of this so the University can, as often as not, allow these discoveries and inventions to fade, unused, to nothing. An example of this is the embryonic stem cell-inspired California Institute for Regenerative Medicine (CIRM), which was a beautiful idea. It has yet – I believe – to license a single patent.

So, NeuroRepair became a Licensee of the University, and I started pouring rather large amounts of money into Jim Fallon's lab. Not surprisingly, this relationship devolved into something of a spat between the University, which made all the decisions, and myself, who thought those decisions not particularly good. The result of this struggle was extraordinary and unique: my company became the sole owner of the truly remarkable IP created in Fallon's lab. The University assigned all rights to the Fallon IP and then, mercifully, got out of the way.

This was, as tech types like to say, a “nontrivial event.” To summarize: Jim Fallon had discovered, and I believe no one knowledgeable disputes this, that the particular growth factor called TGF- α , when administered to an injured or otherwise damaged brain, can stimulate what is collectively called “PMD”: (a) a massive Proliferation of endogenous adult stem cells; (b) the Migration of those cells to the locus of damage; and (c) the Differentiation of those cells into the type of cells that have been lost or damaged.

Patent Law and the U.S. Patent and Trademark Office

If you want to know why the United States doesn't lead the world in virtually every area

of science and research, look no further than the hot mess we call “patent law” and the travesty of the United States Patent and Trademark Office (USPTO). Adams and Madison did not provide for the granting of patents in the Constitution because they thought it unimportant. With the prescience we have come to expect, if not quite appreciate, from the Founding Fathers, they realized that patents could be vital to “the advancement of science and the useful arts.” (See U.S. Constitution, Article I, Section 8, Clause 8.)

Regrettably, this genius of forethought has degenerated into an arcane, largely asinine, collection of nonsensical rules fitted together by little more than mere *patois*.

An example of this is that one is entitled to a patent even if one has done little or no experimentation and has little or no understanding of how or why something might work. Just a guess can be enough to own the rights to future inventions. There exist purely prophetic US patents which are yet fully entitled to all of the protections and presumptions of legitimacy of a patent obtained by someone who actually understands his or her invention. These patents accomplish little other than to dissuade or completely block serious people from doing useful work.

Another illustration is this: “Obviousness” is a term of art in patent law used to describe something not patentable because it is obvious from some earlier patent or other publication. That, I think, makes sense. However, it has been a subject of debate among patent lawyers and judges whether there is a meaningful difference between that which is “obvious” and that which is “not non-obvious.”

One can forgive the evolution of some jargon in a specialized profession, but “obvious” is a common word in English with a well-established meaning one would think beyond argument. I could go on (and on), but let’s just say that working one’s way through the USPTO is a challenge.

Reversing Irreversible Damage

Recently, Jim Fallon’s group at UCI has published landmark articles in the journals *Neuroscience* and *The Journal of Stroke and Cerebrovascular Diseases* (<http://neurorepair.com/news.html>) that present convincing proof that TGF- α is, in fact, stunningly efficacious in repairing neurological damage.

Most remarkably, they demonstrate that the conventional wisdom that only acute brain injury can be treated is wrong. Virtually all current efforts by researchers around the world to repair brain damage are restricted to a “therapeutic window” of a few hours. Even if one were to get to a hospital that fast – which, generally, one doesn’t – the hospital would almost certainly dither your precious few hours away.

Although, so far, we have experimented only with stroke and Parkinson’s models in rats (even these little rodents are expensive; it will take a larger company than NeuroRepair

to satisfy FDA requirements and to do human clinical trials), we have shown that injuries as old as several years, in human terms, may be 100% functionally repaired. This is genuinely stunning news. Until now, almost no one has believed it possible to repair, much less reverse, neurological injury at all. Our demonstration of reversing “old” injuries is almost beyond the imagination of most researchers in the field. Without exaggeration, this could be the most important medical discovery since antibiotics.

A difficult challenge faced by anyone trying to administer a therapeutic to the brain is that the brain of humans and other mammals is isolated by the Blood Brain Barrier (BBB). In brief, the BBB consists of tightly woven, high-density cells in the capillaries of the brain. This barrier prevents all but a few very small and other specifically shaped molecules, such as steroids, from passing from the bloodstream into the Central Nervous System (CNS). Generally, in experiments (usually with animals), this problem is eliminated by inserting a canula directly into the brain.

For continued administration, the canula is usually attached to a mini-osmotic pump implanted under the skin of the back. This did not sound to me like something that I – or, I should think, any other patient – would wish to experience. So we were compelled to find another, less invasive, method of administering TGF- α to the brain.

Using a method first devised by Dr. William Frey (whose excellent work and kind cooperation we gratefully acknowledge) at the Regions Hospital Alzheimer’s Research Center in Minneapolis, we successfully administered TGF- α intranasally to rats with middle cerebral artery occlusion (MCAO) – induced ischemic stroke. So, at the same time as we were able to prove the efficacy of Transforming Growth Factor- α in repairing such stroke damage, we were also able to demonstrate that TGF- α may be administered without invasive surgery.

This is an amazing finding. It’s not, as you might expect, the sort of intranasal delivery familiar to your average cocaine addict. That merely permits a molecule to pass through the mucosa membrane and into the bloodstream. From the bloodstream, a large-ish molecule such as TGF- α is blocked from entering the brain by the BBB. If merely getting the growth factor into the bloodstream worked, we would simply have gone with intravenous delivery. Instead, using Dr. Frey’s method, a liquid solution containing TGF- α is snorted back – or, in the case of not entirely cooperative rats, simply placed – into the sinuses, where it collects on the olfactory nerve and the trigeminal nerve bundle and physically drips its way along the nerves to the brain.

(As an example of my previous point about prophetic patents: because an early Fallon patent application refers to “intranasal administration,” NeuroRepair owns the rights to intranasal administration of TGF- α for CNS repair – a good thing for NeuroRepair, in this case, but it’s not good law.)

After treatment, efficacy was proven histologically, by examining the brains of rats at the cellular level. Dr. Fallon’s team could see that the lesions created by the induced strokes were almost completely filled in, or rebuilt, with new neural tissue. The team

used behavioral tests to show that this new neural tissue was functioning properly. Employing both the “corner test” and “cylinder test,” we could see that the rats were using both forepaws for tasks, as they had before being injured.

Simply stated, a rat with a stroke, like a human, will experience a sudden inability to use the limbs on the affected side of its body (called “hemiplegia”). Both rats and people will compensate by trying to do everything with the one paw or hand that remains functional. When the treated rats reverted to using both front paws equally, we had clear evidence that their injury had been reversed. Untreated rats, and those treated with a “sham” (they went through the same treatment procedure but with a solution not containing TGF-a), did not show this recovery.

These papers, combined with other recent discoveries and inventions made by NeuroRepair and Dr. Fallon’s dedicated team of Ph.D. and postdoctoral researchers at UCI, will, we believe, finally get us past the obstructive objections of the USPTO and allow groundbreaking progress in this important field to be made.

Our Results

At NeuroRepair, we have demonstrated that a naturally occurring protein – Transforming Growth factor-alpha – can spectacularly, even completely, repair and reverse the damage caused by an injury to, or disease of, the brain, and restore nearly full function. We have shown in these preclinical studies that TGF-a has no known toxicity or other deleterious side effects. In fact, in the absence of an injury – that is, when administered to a healthy brain – TGF-a appears to do nothing at all. Importantly, not a single rat in our experiments showed any pathology or other anomaly caused by TGF-a.

And we have shown that TGF-a may be efficaciously administered via the nose, without the cost of, and dangers inherent in, open-cranium, or even “It’s just a tiny hole drilled in your skull through which we insert a needle,” surgery. By this method, the major impediment to our administering a large therapeutic molecule to the brain, the Blood Brain Barrier, has been circumvented.

The enormity of the discovery of TGF-a’s neurotrophic capability cannot be overstated. We may, and rather soon, traverse in one step from “Brain injuries never heal; there is no treatment; you will never recover; and, by the way, your life is ruined” to “You have a brain injury; we can fix it with these nose drops.”

The journey from Point A to Point B has been long, arduous, expensive, and painful, but Point B is within sight. One learns, along the way, to celebrate small victories. With a little luck, and perhaps some help from a pharmaceutical corporation, this may yet turn out to be a very large victory, indeed.

Ed. Note: Word definitions in 1-5 below are from Merriam-Webster.com.

¹ *Neurotrophic*: Relating to or dependent on the influence of nerves on the nutrition of tissue.

² *Mitogenic*: Of, producing, or stimulating mitosis.... a process that takes place in the nucleus of a dividing cell, involves typically a series of steps consisting of prophase, metaphase, anaphase, and telophase, and results in the formation of two new nuclei each having the same number of chromosomes as the parent nucleus.

³ *Pluripotent*: 1 : Not fixed as to developmental potentialities ; *especially* : capable of differentiating into one of many cell types <*pluripotent* stem cells>; 2 : capable of affecting more than one organ or tissue.

⁴ *Ependymal*: An epithelial membrane lining the ventricles of the brain and the canal of the spinal cord.

⁵ *Striatum* [or *neostriatum*]: The phylogenetically newer part of the corpus striatum consisting of the caudate nucleus and putamen.

⁶ See *Age and Ageing*: "Human and economic burden of stroke," by Antonio di Carlo; Oxford University Press, 2009: <http://ageing.oxfordjournals.org/cgi/content/full/38/1/4>.

About Matthew Klipstein



Matthew Klipstein graduated with Honors from the University of California at Berkeley and from the University of Colorado School of Law, where he was Comments editor of the *University of Colorado Law Review*.

Following law school, Matthew was a law clerk to The Hon. Hatfield Chilson, United States District Judge, District of Colorado. Thereafter, he returned to San Francisco, where he was co-founder and a partner in the law firm of Wolfe & Klipstein. At the age of 34, after nine years specializing in securities litigation in the federal courts,

Matthew retired from the practice of law and co-founded Digital Stock Inc., a pioneer and industry leader in digital storage and distribution of high-quality stock photography. Six years later, Digital Stock was acquired by Bill Gates' Corbis Corp. Matthew founded NeuroRepair Inc. in 2004.

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I want to thank Matthew for taking the time to write this Special Letter, and Sally Anderson for editing. Those interested in meeting Matthew, and hearing more about NeuroRepair's and James Fallon's amazing discoveries, can do so by joining him at FiRe 2010. This is exactly the kind of contribution that makes FiRe, and members like Matthew, different from their peers.

Your comments are always welcome.

Sincerely,

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SNS is the most accurate predictive letter covering the computer and telecom industries. It is personally read by the top managers at companies such as Intel, Microsoft, Dell, HP, Cisco, Sun, Google, Yahoo!, Ericsson, Telstra, and China Mobile, as well as by leading financial analysts at the world's top investment banks and venture capital funds, including Goldman Sachs, Merrill Lynch, Kleiner Perkins, Venrock, Warburg Pincus, and 3i. It is regularly quoted in top industry publications such as *BusinessWeek*, *WIRED*, *Barron's*, *Fortune*, *PC Magazine*, *ZDNet*, *Business 2.0*, the *Financial Times*, the *New York Times*, the *Wall Street Journal*, and elsewhere.

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➤ **About the Publisher**

Mark Anderson is CEO of the Strategic News Service. He is the founder of two software companies and of the Washington Technology Industry Association “Fast Pitch” Forum, Washington’s premier software investment conference; and has participated in the launch of many software startups. He regularly appears on the *CNN World News*, CNBC and CNBC Europe, Reuters TV, the BBC, Wall Street Review/KSDO, and National Public Radio programs. He is a member of the Merrill Lynch Technology Advisory Board, and is an advisor and/or investor in OVP Ventures, Ignition Partners, Mohr Davidow Ventures, the UCSD Calit2 Laboratory, the Global Advisory Council of the mPedigree Network (Ghana), SwedeTrade, The Family Circle (Europe), and the Australian American Leadership Dialogue.

Mark serves as chair of the Future in Review Conferences, SNS Project Inkwell, The Foresight Foundation, and Orca Relief Citizens Alliance.

➤ **Where’s Mark?**

- On April 21st and 22nd, Mark will again be speaking to the **Family Office Circle in Heidelberg**, moderating panels on “North America” and “Philanthropy in Action.”
- On May 5th, he will moderate a panel discussion on Information Technology, with Microsoft and Ericsson, at the **Sweden Week Business Focus Conference** in Seattle, at the Swedish Cultural Center.
- From May 11th to 14th, Mark will be hosting the 8th annual **Future in Review (FiRe) Conference** at the Terranea Resort in Palos Verdes, CA. (For details and registration, see www.futureinreview.com.)
- And on June 9th, he will be keynoting **Accenture’s 2010 Global CIO Forum** in Washington, D.C.

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