

# DR. DAVID SINGER'S HEALTH REPORTS VOLUME 11 ISSUES 1-12

## RESEARCH & INFORMATION

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# HEALTH REPORT

VOLUME 11

ISSUE 1

## ADJUSTMENT PUTS BABY IN THE RIGHT POSITION!

When a baby somehow gets in the wrong position to easily make its way down the birth canal, the MDs only solution is a cesarean section delivery. Chiropractic intervention may provide a far better solution than cesarean delivery.

A fine case in point comes from the recent success of a mother-to-be in the Monterey, California, area. The 36-year-old woman who was 32 weeks pregnant received word from her obstetrician that her baby was in a high risk position in her womb. Ultrasound showed that the baby was actually turned a full 180 degrees from the normal head-down position.

Rather than face the possibility of a cesarean delivery, the woman sought the help of a chiropractor skilled in doing an adjustment that could turn the baby a full 180 degrees. The Doctor of Chiropractic consulted was skilled in an adjustment known as the Webster In-Utero Constraint Technique. (In-Utero refers to “intrauterine,” which means “occurring or situated within the uterus or womb.”)

Basically, what occurs is that forces external to the developing fetus obstruct its normal movement. These “constraints” can prevent the developing fetus from attaining a proper head-down position. Today, nearly 13% of all cesarean deliveries performed are due to this breech presentation.

The Webster Technique can be performed by a growing number of Chiropractors and involves specialized analytical knowledge and ability to make a series of correct adjustments. Analysis involves checking the proper relationship of the bones of the pelvic area.

The adjustment involves a 2-step process. Light force is applied to the sacrum (one of the pelvic bones) in Step 1. This is followed by an analysis of muscle tension or spasm in the stomach and relieving this in Step 2. Together, the causes of the constraints on the baby in the uterus that may lead to cesarean delivery are able to be relieved.

The California woman said this about her treatment, “I felt great relief after the first adjustment.” She received just two adjustments from her chiropractor. A new ultrasound showed the baby was now in the proper head-down position. “Immediately after the first treatment I felt he moved,” the woman said.

It should be noted that for this treatment to produce the proper results it should be done prior to the 34th week of delivery. After that time, success rates have been shown to decline.

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ISSUE 2

## CHILDREN ON WHEELED SHOES MAY BE SUSCEPTIBLE TO INJURIES!

Have you ever almost been run over by a child rolling along seemingly out of control on shoes with wheels?

The popularity of these shoes and the safety hazards they have been known to cause has lead some shopping mall proprietors to outlaw them in their stores. Some 4 million pairs of these “wheeled shoes” have been sold, so that puts a lot of kids out there who could either injure themselves or others.

Recently, the American Chiropractic Association took a look at these shoes in terms of how they can actually cause problems for children. The most obvious cause of injury would be falls suffered while on the skating shoes. Injuries to the head, wrist, elbow and ankle are the most common. With the wheels in the back of the shoes, skaters are forced to lean back to make them perform properly and can easily lose their balance.

Problems can also occur for children in a less obvious manner, and this has to do with the way they are forced to walk on the “shoes with wheels” when they are not rolling along. According to Dr. Steven Conway, a member of the American Chiropractic Association, “When wearing the shoes on a surface that isn’t skatable, children must walk on their toes. This altered gait forces their posture into unnatural positions, and if worn regularly for walking, this could potentially cause strain on growing bodies, especially in the foot, ankle and lower back.”

Some tips for safe use of the “wheeled shoes” would include: wearing safety equipment like helmets, wrist guards, elbow and knee pads. Shoes should be worn for recreation only with wheels removed when using them as sneakers. Of course, children should be aware of their surroundings and pedestrians when skating.

Should an injury occur or painful situations develop from skating, parents would be wise to take their child to a chiropractor for an evaluation of their neuromuscular skeletal system. Children may actually suffer some of the pains experienced by higher level athletes when they skate. A visit to a chiropractor may go a long way to help their young bodies develop properly.

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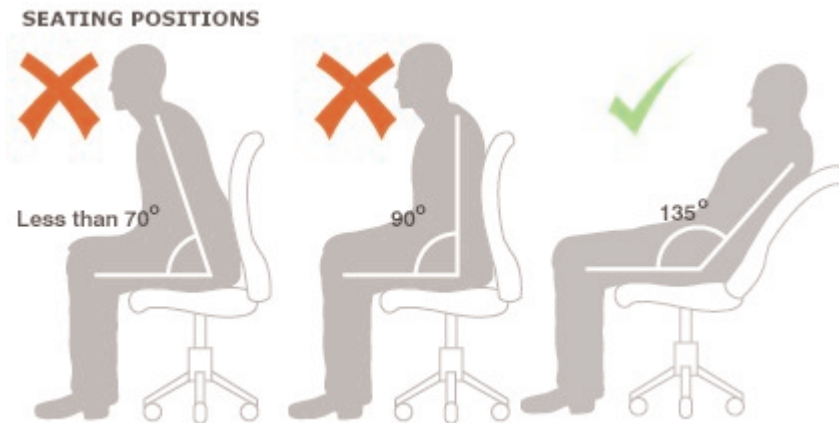
ISSUE 3

## SITTING BACK MAY BE BETTER THAN SITTING UP!

Anyone who has ever been “yelled at” or reprimanded for poor posture for preferring a “slouching” position to sitting up straight may find something of interest in this most recent research into correct sitting.

Researchers in Aberdeen, Scotland, lead by a doctor working out of a Canadian hospital determined that the “slouching” position may actually be far better for the back and spine than the “sit up straight” position most of us learned in school. Dr. Waseem Bashir of the Department of Radiology and Diagnostic Imaging at the University of Alberta Hospital in Canada lead the study.

MRI studies were performed on 22 volunteers placed in three different sitting positions as shown here:



The MRIs were examined to measure spinal angles plus spinal disk height and movement across the different positions. It was determined that excessive disk movement indicated a potential for problems.

According to the findings, the relaxed position of 135 degrees was determined to be the best as it created the least amount of movement or stress. The 90 degree, upright position was proclaimed the worst. “Sitting in a sound anatomic position is essential since the strain put on the spine and its associated ligaments over time can lead to pain, deformity and chronic illness,” said Dr. Bashir.

“We are not created to sit down for long hours,” added Dr. Bashir. “But somehow modern life requires the vast majority of the global population to work in a seated position. This made our search for the optimal sitting position all the more important.”

## STUDY OF 5,400 YEAR OLD “ICE MAN” MUMMY FINDS ACUPUNCTURE TATTOOS MATCHING HIS AILMENTS

A 5,400-year-old mummified man found in 1991 in a melting glacier in the mountains of Northern Italy bears a complicated system of bluish-black tattoos running along his back, right knee and left ankle, in the form of simple stripes or crosses that closely match Acupuncture locations.

Although the discovery of the oldest preserved human being ever found has had tremendous archaeological value, the tattoos so intrigued scientific investigators that experts from three Acupuncture societies were asked to examine the locations of the tattoos.

Nine tattoos were identified as being located directly on, or within six millimeters of, traditional Acupuncture points. Two more were located on an Acupuncture Meridian. One tattoo was used as a local point. The remaining three tattoos were situated between 6-13mm from the closest Acupuncture point, but later studies revealed that the mummy's skin had been twisted by pressure from the glacier, which could mean these tattoos were actually exactly on the Acupuncture points.

This could mean that Acupuncture was practiced more than 2,000 years before its supposed origins in China, and in a different part of the world.

### **Tattoos Match Mummy's Physical Problems**

Even more amazing, studies of the ice man's body reveal that the tattooed Acupuncture points are those that would treat his major ailments. Forensic studies show he suffered from arthritis in the hip joints, knees, ankles and lumbar spine, and nine of the mummy's 15 tattoos are located on the meridian commonly associated with treating back pain. In fact, one of the mummy's cross-shaped tattoos is located on point UB60, which is considered by several texts a “master point for back pain.”

Forensic analysis also revealed that his intestines were filled with whipworm eggs, which can cause severe abdominal pain. Five tattoos corresponded with points that are traditionally used to treat stomach disorders.

“The fact that corresponding groups of points were marked by tattoos, not randomly selected points, seems especially intriguing,” the researchers noted. “From an acupuncturist's viewpoint, the combination of points selected represents a meaningful therapeutic regimen.”

“Taken together,” the scientists added, “the tattoos could be viewed as a medical report from the stone age, or possibly as a guide to self-treatment marking where to puncture when pains occur.”

Named Otz, after the valley in which it was discovered, the mummy was remarkably well preserved, as were most of his clothing, tools and weapons. Scientist have examined the mummy's remains thoroughly, learning much about the everyday life of ancient Europeans.

## MASSAGE AND ACUPUNCTURE EFFECTIVE IN REDUCING PAIN AFTER CANCER SURGERY

Massage and Acupuncture effectively decrease pain and depression following surgery in cancer patients, according to a recent study at the University of California, San Francisco.

The randomized controlled clinical trial, reported in the *Journal of Pain and Symptom Management*, compared the post-operative symptoms of pain, nausea and depression and the cost of symptom-related medications in two groups of hospitalized patients during the first three days after cancer-related surgery.

One group received a massage and Acupuncture in addition to the usual post-operative medications, while a second group had just medication. There was a significant decrease in both pain and depressive mood among patients receiving massage and Acupuncture therapy.

During the three-day post-operative period, patients used an 11-point (0-10) numeric rating scale to rank the severity of current pain and of pain during the previous 24 hours. Acupuncture/massage patients scored a 1.1 point improvement in pain level on the first post-operative day, while the medication group only scored a 0.1 improvement. Over the three days of the study, the Acupuncture/massage patients reported a pain improvement of 1.8, compared to only 0.3 in the control group.

“This is a significant finding,” said Dr. Wolf Mehling, lead author and UCSF assistant professor of family and community medicine. “We know that integration of these therapies has shown short-term benefit on psychological well-being, but there has not been strong evidence to support it until now.”

As for the cost comparison, the study showed a reduction in anti-anxiety and sleep medication costs.

“This preliminary data suggests looking at this further, with a larger control group and an ability to better assess individual medication usage,” Dr. Mehling said.

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ISSUE 6

## **CDC: AUTISM RATES RISING ACROSS USA, NEW JERSEY FAR HIGHER THAN OTHER STATES!**

The Centers for Disease Control (CDC) has released its first study of the number of 8-year-old children diagnosed with autism in selected areas of 14 states across the country, and the numbers are disturbingly higher than expected.

The report includes statistics gathered in 2000 and 2002 covering nearly 600,000 8-year-old children, or nearly 15% of all 8-year-olds in the country. The report shows overall autism prevalence averaging 6.6 per 1000 children (1 in 150), although the statistics varied widely from area to area. For example, in Alabama it was 3.3 per 1000, in Georgia and Utah around 7.5 per 1000, and in New Jersey, the worst state, it was 9.9 out of 1000 8-year-olds with some form of autism.

Autism strikes roughly three times as many boys as girls, and seems to have no preference for white, black or Hispanic children. New cases diagnosed nationally have been estimated at 67 every day, with an estimated cost to society of about \$35 billion a year.

An earlier survey in the 1980s by UCLA and the University of Utah found about one child in every 2500 in Utah with autism, much lower than the new statistics of 7.5 per 1000.

Kim Moody, former director of the Autism Society of Utah, told the *Salt Lake City Standard-Examiner* that the number of children diagnosed in the state with autism has “steadily increased” since the 1980s.

Psychiatrists and psychologists in the field generally claim that the increased prevalence is due to better diagnosis. But even taking that into account, Moody told the newspaper, there is still “a huge increase” in the overall number of kids diagnosed with autism. “If this were some other type of disease, they would call this an epidemic,” Moody said.

The Children’s Health Act of 2000 authorized CDC to create the Autism and Developmental Disabilities Monitoring (ADDM) Network. Since the network’s inception, CDC has funded programs in 16 sites covering 17 states—Alabama, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Illinois, Maryland, Missouri, New Jersey, North Carolina, Pennsylvania, South Carolina, Utah, West Virginia, and Wisconsin.

Autism Spectrum Disorders (ASDs) are considered by the medical profession to be life-long developmental disabilities. However, some alternative approaches, including nutritional and other therapies, have had success with reversing the symptoms of autism.

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ISSUE 7

## DRUG GIANT PFIZER CITED FOR ILLEGAL DRUG TESTING ON NIGERIAN CHILDREN

Pharmaceutical giant Pfizer Inc. has violated international law by covertly testing an unapproved drug on children with brain infections during a 1996 epidemic in Nigeria, according to a Nigerian government report.

The official report remained secret for five years in spite of inquiries from the media and attorneys representing the families of children who were subjects of the illegal drug experiments. The Washington Post, which first broke the news about Pfizer's Nigerian drug testing in 2000, received a copy of the long-unreleased government report last year from an anonymous source who feared for his/her safety.

Pfizer's unauthorized testing of the unproven drug on nearly 100 children and infants was never authorized by the Nigerian government. Pfizer's experiment was "an illegal trial of an unregistered drug," the Nigerian panel concluded, and the Washington Post reported in its expose a "clear case of exploitation of the ignorant."

### Approval Letter Faked By Local Official

An alleged letter of approval from a Nigerian medical ethics committee turned out to have been faked by the company's lead researcher in Kano, the report said. The former director of Nigeria's version of the FDA said the agency had been unaware of the experiment. He told the panel that he "viewed the conduct of the trial by Pfizer as an act of deception and misuse of privilege."

The drug used in the test, called Trovan, had never been given to children with meningitis, the report said. Pfizer also filed no records showing that the children or their parents were informed they were being used as subjects of an experiment.

Pfizer's tests were conducted at a hospital in the city of Kano, where children suffering from a deadly strain of meningitis were being treated by volunteers from Doctors Without Borders. According to Pfizer, its work was "purely philanthropic" to help fight the meningitis, measles and cholera epidemic which ultimately killed more than 15,000 Africans. The government report invalidated the company's explanation, saying that Pfizer physicians completed their trial and left while "the epidemic was still raging," said the Washington Post article.

When Pfizer's drug testing in Nigeria first came to public attention in December 2000 from the Washington Post article, it was met in Nigeria with street demonstrations, lawsuits and demands for reform. The article revealed the results of a year-long investigation into overseas pharmaceutical testing by several drug companies, showing that it was part of a growing trend to test unproven drugs on often unsuspecting third-world patients.

The report said the treatment of two children during the experiment represented unspecified "serious deviations" from the trial's protocol and concluded that those deviations compromised their care. One was a 10-year-old girl identified only as Patient No. 0069, who was given the experimental antibiotic for three days as her condition deteriorated. She died without receiving any other antibiotic.

Rep. Tom Lantos of California, the senior Democrat on the International Relations Committee, described the report's findings as "absolutely appalling" and called on Pfizer to open its records. "I think it borders on the criminal that the large pharmaceutical companies, both here and in Europe, are using these poor, illiterate and uninformed people as guinea pigs," Lantos said.

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ISSUE 8

## FDA DIRECTS ADHD DRUG MANUFACTURERS TO NOTIFY PATIENTS ABOUT CARDIOVASCULAR AND MENTAL DANGERS

The U.S. Food and Drug Administration (FDA) has directed the manufacturers of all drug products approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) to develop Patient Medication Guides to alert patients that possible cardiovascular risks and adverse mental symptoms are associated with the medicines. The Guides are intended to advise them of precautions that can be taken.

An FDA review of reports of serious cardiovascular adverse events in patients taking usual doses of ADHD products revealed reports of sudden death in patients with underlying serious heart problems or defects, and reports of stroke and heart attack in adults with certain risk factors.

Another FDA review of ADHD medicines revealed a slight increased risk (about 1 per 1,000) for drug-related psychiatric adverse events, such as hearing voices, becoming suspicious for no reason, or becoming manic, even in patients who did not have previous psychiatric problems.

ADHD is an alleged condition that is said to affect 3 to 7 percent of school-aged children and approximately 4 percent of adults. There is no scientific research actually proving the existence of ADHD as an actual disease or condition. The three main symptoms are inattention, hyperactivity, and impulsivity. People labeled as suffering from ADHD may have difficulty in school, troubled relationships and low self-esteem.

In May 2006, the FDA directed manufacturers of these products to revise product labeling for doctors to reflect concerns about adverse cardiovascular and psychiatric events. These changes were based on recommendations from the FDA Pediatric Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

The medicines that are the focus of the directive include the following 15 products:

- ◆ Adderall (mixed salts of a single entity amphetamine product) Tablets
- ◆ Adderall XR (mixed salts of a single entity amphetamine product) Capsules
- ◆ Concerta (methylphenidate hydrochloride) Extended-Release Tablets
- ◆ Daytrana (methylphenidate) Transdermal System
- ◆ Desoxyn (methamphetamine HCl) Tablets
- ◆ Dexedrine (dextroamphetamine sulfate) Spansule Capsules and Tablets
- ◆ Focalin (dexmethylphenidate hydrochloride) Tablets
- ◆ Focalin XR (dexmethylphenidate hydrochloride) Extended-Release Capsules
- ◆ Metadate CD (methylphenidate hydrochloride) Extended-Release Capsules
- ◆ Methylin (methylphenidate hydrochloride) Oral Solution
- ◆ Methylin (methylphenidate hydrochloride) Chewable Tablets
- ◆ Ritalin (methylphenidate hydrochloride) Tablets
- ◆ Ritalin SR (methylphenidate hydrochloride) Sustained-Release Tablets
- ◆ Ritalin LA (methylphenidate hydrochloride) Extended-Release Capsules
- ◆ Strattera (atomoxetine HCl) Capsules

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ISSUE 9

## CHIEF MEDICAL OFFICER BLOWS WHISTLE ON JOHNSON & JOHNSON

The former Chief Medical Officer of Johnson & Johnson subsidiary Ethicon, Inc., has sued the company for wrongful dismissal, claiming he was fired unlawfully for insisting on recalls of products because of health and safety concerns.

Dr. Joel Lippman's suit in a Middlesex County, N.J. court claims that during his 15 years in high ranking medical positions at Ethicon and Ortho McNeil, another J&J division, the company repeatedly released or refused to recall dangerous products to which he objected, including the Ortho Evra birth control patch, Intergel, Panacryl Sutures and others that have since spurred hundreds of product liability lawsuits.

Lippman says he objected to the release of the Panacryl suture, "whose use resulted in numerous adverse events," but Ortho released it anyway and continued to receive reports of "adverse events." He says he objected to the release of ProCeed, a "mesh product," but Ortho released it anyway, until the FDA forced a recall. He says he told Ethicon it must inform surgeons that an endoscopic applicator leaks chromium during use, but Ethicon refused. He says he was fired less than a month after insisting that Ethicon recall a product called DFK24, used in heart bypass surgery, because its tip fell off and had to be fished out of the aorta.

Lippman, who was vice president of clinical trials at Ortho-McNeil and worldwide vice president of medical affairs at Ethicon before he was fired on May 15, 2006, alleges he began having problems at J&J after he called attention to product safety problems and serious health risks linked to Ortho Evra, "which released dangerously high levels of estrogen into patients," according to the lawsuit.

He claims that from 1998 to 2000, his last two years at Ortho, he "raised serious health concerns about two pharmaceutical products: Ortho-Prefest, a hormonal menopausal product, which did not have adequate safety data to prove that it protected against uterine cancer as did other therapies, and the Evra patch, which released dangerously high levels of estrogen into patients. The clinical research had revealed that the estrogen dose released by the Evra patch as a means of birth control may increase the risk of deep venous thrombosis and pulmonary embolisms."

J&J in a statement said Lippman was fired "as a result of inappropriate conduct and mismanagement of responsibilities unrelated to the allegations he raises in the lawsuit."

Lippman's attorney Bruce McMoran said, "We would hope that the bringing of this type of suit would encourage companies not to retaliate against employees who blow the whistle."

# HEALTH REPORT

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Issue 10

## HEALTHCARE GROUP REACHES SETTLEMENT OVER ALLEGED ANTICOMPETITIVE PRACTICES

Connecticut Attorney General Richard Blumenthal has announced a settlement that disbands an anticompetitive, exclusive “secret society” of healthcare industry vendors and chief executives from the nation’s premier hospitals and healthcare institutions.

Florida-based Healthcare Research and Development Institute, LLC (HRDI) has agreed to change its organizational and membership structure and policies under an antitrust settlement with Blumenthal’s office, and to pay Connecticut \$150,000. The Florida Attorney General’s office — in HRDI’s home state — has joined Connecticut in the agreement.

Under the settlement, HRDI is dissolving and is changing from a for-profit to a not-for-profit company called the Health Education Network (HEN). Hospital suppliers cannot join or have financial ties with HEN for three years, after which time they can join under certain conditions. In its new form, the new entity will make annual disclosures to its affiliated hospitals about its financial condition, as well as information on the makeup of its membership, their activities, the dues for participation, and any corporate affiliations of officers and directors.

### Agreement Shatters “Secret Society”

“Today’s settlement shatters an anticompetitive secret society — an elite and exclusive club — of premiere hospital executives and select healthcare supply businesses,” Connecticut’s Blumenthal said. “Healthcare Research and Development Institute would have been better named Healthcare Titans of America — an organization where the most powerful vendors and hospital CEOs enjoyed lucrative marketing opportunities, and lavish accommodations.

“HRDI claimed to offer healthcare consulting services to industry players. In reality, it was an exclusive network that shut out potential competitors in various healthcare markets — everything from pharmaceuticals, syringes, medical devices and financial and consulting services.”

In reality, Blumenthal said, the organization was an anticompetitive club, where only select corporations from the healthcare supply industry were permitted membership.

Blumenthal said these practices threatened to inflate healthcare costs to patients and taxpayers — stifling competition in almost every healthcare supply and services market.

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## MEDICAL LIABILITY LAWSUITS STYMIE SCIENTIFIC MEDICAL RESEARCH

Medical liability lawsuits are hampering progress in research seeking to establish links between neurological illness and environmental factors produced by industry.

In an article in the journal *Neurology*, a team of scientists and lawyers warns that demands from court cases for testimony and research information to support litigation impairs researchers' efforts to complete their work trying to identify compounds that contribute to a wide variety of diseases, including Parkinson's disease, Alzheimer's disease and amyotrophic lateral sclerosis (ALS).

Brad A. Racette, M.D., associate professor of neurology at Washington University School of Medicine in St. Louis and lead author of the article says having to respond to torrents of subpoenas for research data about his studies linking welding to Parkinson's disease has slowed or stopped his follow-up research.

"Participation in the legal system can be a huge burden on a researcher's schedule," Racette said. "There comes a point where a scientist needs the right to be able to say, testifying in court is not what I'm supposed to be doing, I'm supposed to be studying disease."

### **Industry's Attempts to Discredit Researchers Also a Problem, Article States**

The authors note that the substantial financial interests at stake in lawsuits often leads to biased research by well-paid expert witnesses, or campaigns to discredit research and those who conduct it. They cite the example of a Texas doctor overdiagnosing silicosis when he had a financial interest in the number of patients diagnosed. And the doctor who first linked lead exposure to low IQ levels in children was attacked by the lead industry, alleging academic fraud and other baseless charges. But Needleman's results were later proven true, resulting in the removal of lead from gasoline and paint.

Parties involved in lawsuits often demand extensive disclosure of scientific data that not only disrupts research but also threatens the privacy of patients and research volunteers. Although the federal Health Insurance Portability and Accountability Act (HIPAA) prohibits release of data that can be used to identify patients, data demanded by lawyers may still permit research subjects to be identified.

"To protect patient privacy and the value of our research data, we need specific, across-the-board restrictions on information that can be released in the courtroom," Racette said. "For example, Illinois has a law that designates medical research data as protected. That should be a model for other states."

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ISSUE 12

## LEGAL LIABILITY, NOT IMPROVED HEALTHCARE, MAY BE SPUR TO DEVELOP 'PERSONALIZED MEDICINE'

Legal liability is the driver that could dramatically hasten the development of "personalized medicine", according to a newly published article by genetics and law experts.

Broadly, personalized medicine is defined as using information about a person's genetic makeup to tailor strategies for the detection, treatment or prevention of disease. It can specifically refer to the use of a medicine only after it has been shown to be compatible with, or not dangerous to, a patient's specific genetic makeup.

Such testing, called pharmacogenomic testing, is rarely performed at present, and most hospitals and few physicians have access to such technology. But side effects from prescription drugs kill more than 100,000 people a year, according to *The Journal of the American Medical Association*, and experts say that many such deaths could be prevented by prescribing a drug only after genetic testing on a patient has shown it to be safe for that patient.

Testing could reveal a polymorphism (a common variation or mutation in DNA) or some biomarker (a molecular marker associated with some biological function) that shows susceptibility to a specific drug. Armed with this knowledge, physicians can tailor drug treatments for each patient and avoid trouble.

### Legal Trouble, Not Health Trouble

Although personalized medicine appears to offer more predictable outcomes and overall better healthcare, it is the threat of medical malpractice lawsuits that will drive its development and wider use, according to many legal experts.

Healthcare consumers (and their lawyers) are going to become more familiar with the existence of the technology, and failure to use it will lead to a new class of litigation when faulty diagnostics and prescription drug side effects lead to patient injury or death.

"Individuals injured by adverse drug effects are increasingly likely to bring lawsuits alleging that they have a polymorphism or biomarker conferring susceptibility to the drug that should have been identified and used to alter their drug treatment," wrote Gary Marchant, executive director of the Center for the Study of Law, Science & Technology at Arizona State University (ASU), in the article "Legal Pressures And Incentives For Personalized Medicine," published in the current issue of *Personalized Medicine*, a journal of Future Medicine.

The incorporation of personalized medicine into everyday clinical practice faces significant hurdles, the authors wrote. These include scientific uncertainty about the validity of data, social concerns about the potential uses of genetic information, and economic concerns about the costs and benefits of pharmacogenomics.

These concerns are likely to slow the pace at which it becomes a part of medicine, but the authors assert, the risk of liability for not employing pharmacogenomic testing may speed the pace of its adoption.

While drug manufacturers, health insurers, and even pharmacists face some liability risks, physicians are most at risk for lawsuits alleging that they did not recommend genetic tests before prescribing drugs that may harm patients with genetic vulnerabilities. "Physicians are the sitting ducks in this new class of litigation," says Marchant, "both because they lack the legal defenses available to other parties, and many doctors have not received the training in genetics they need in the new world of personalized medicine."

Already, a number of filed lawsuits claim physicians can be liable for not recommending or performing certain genetic tests, and that, even when they do, they can be held negligent in the performance of the tests, and the interpretation and communication of them.

The next step, predict Marchant and his colleagues, will be lawsuits for failing to recommend genetic tests before prescribing medications, and the first such lawsuits have already been filed against a drug manufacturer.

"If significant liability does occur, its effect will be dramatic, as potentially liable parties will need to undertake immediate and significant changes to protect against large legal liabilities," the authors concluded. "Manufacturers and healthcare providers, and the attorneys representing them, should start preparing now for preventing and defending a new class of personalized medicine lawsuits."