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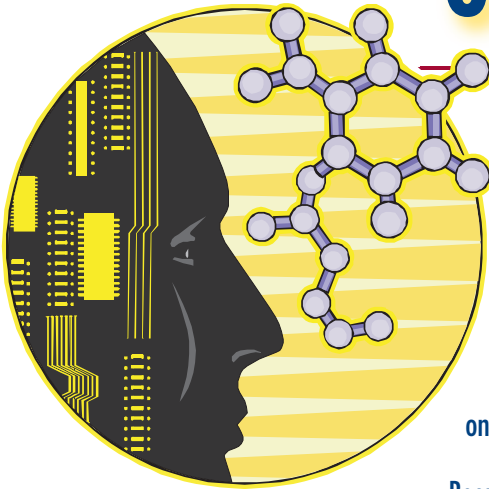
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NEW LAW BANS GENETIC DISCRIMINATION



Add genetic information to the growing list of employer anti-bias concerns. The Genetic Information Nondiscrimination Act, signed into law in May, will take effect next year — heralding either Aldous Huxley's *Brave New World*, or a scientifically enlightened society, depending on your point of view.

Recent mapping of the human genome has allowed researchers to gain greater insight into many genetically linked diseases. Today, tests that examine DNA, key proteins, enzyme levels, and chromosomes can uncover genetic predisposition for a variety of conditions — from certain types of cancer to diabetes, heart disease, and more than 1,000 other illnesses.

The problem Congress sought to correct?

Knowledge of such risk might encourage employers and health insurers to screen applicants based on genetic disposition and make decisions based upon that knowledge. That, in turn, could discourage patients from being tested or participating in research studies, and restrict healthcare providers from ordering tests to determine the best course of action.

The new law is designed to prohibit genetic discrimination, while advancing research that would help prevent, diagnose, and treat hereditary health conditions.

Specifically, the Act ~

- Prohibits health insurers from using a patient's genetic information to deny insurance coverage or raise premiums
- Prevents employers from using genetic information to make employment-related decisions
- Bans insurers and employers from requiring individuals to take genetic tests
- Prohibits the disclosure of genetic information by insurers or employers

The Act does not cover life insurance, disability insurance, or long-term care insurance. Nor does it prohibit discrimination against an individual with a disease.

What should you do?

Since the law won't take effect for health insurers until May 2009, and for employers until November 2009, there's no immediate need for action. But employers will want to ensure that genetic information is not disclosed, or used as a factor in hiring or other employment decisions. Although the new law doesn't create a protected category (such as race, color, or sex), genetic discrimination must now join the list of prohibited activities, and should become part of employment policies. Please call our office if you'd like to discuss this further or need assistance.



Turning ideas to reality?

How to protect your intellectual property during development

During an RFP or pre-purchase-order phase, automotive suppliers make substantial investments in time and money, working to gain product acceptance, validation, and—ultimately—an award of work from a customer. Many times, the supplier's

work yields significant innovations in the product sought by the customer. These innovations may be contained in CAD data, Finite Element Analysis, and product prototypes sent to the customer, all of which comprise valuable intellectual property for the automotive industry. And that IP is deserving of protection.

So what happens when these innovations are turned over to a prospective customer during an RFP or pre-purchase-order phase, with no guarantee the supplier will be awarded a contract for work? Is there a way to reduce the chance that said customer will claim this development IP as its own? Fail to pay? Or, worse yet, use the ideas and award the work to a competitor? Fortunately, the answer is yes.

Option 1: The Interim Agreement

One tactic available is an Interim Agreement, a contract establishing the supplier as owner of development IP. Although they usually won't initiate it, automotive customers are accustomed to using such documents—sometimes called technical collaboration, cooperation, trial, or evaluation agreements. A word of caution: non-disclosure or confidentiality agreements, unless properly modified in a substantial manner, won't serve the same purpose since they fail to address the concept of development IP. An Interim Agreement does a good job of telling the story of ownership in development IP to customer personnel who are not intimately involved in the project, as well as competing suppliers, future judges or arbitrators, and other third parties. When presented, the agreement gives individuals pause before acting in disregard of a supplier's rights in development IP.

Option 2: Registration or Provisional Patents

It may be possible to register development IP under relevant intellectual property law if time permits and the supplier has clearly established ownership of the IP. Filing a provisional patent can be an expedient means of filing a patent when time constraints are an issue, but ownership is not.

Option 3: Tactical Moves

Smart suppliers often employ other methods to protect intellectual property. Among their strategies: disclosing the content of alloys, but keeping secret the production processes used to achieve molecular bonding or other physical properties; or locking up IP by delivering embedded software in object code only.

In any case, whenever appropriate, suppliers should consider labeling materials provided to a customer with proper patent, copyright, trademark, or trade secret notices. Doing so serves to put individuals on notice that supplier materials may be subject to third-party IP ownership claims of another.

Securing ownership of development IP is limited only by the supplier's creativity, adeptness, and diplomacy—and some sound legal advice, when needed. Call our team if we can help.

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With this issue, **Hot Points** celebrates its **15th** year!



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HEADS UP!

Sweeping change could be in store for Michigan's constitution

As *Hot Points* goes to press, a proposal that would dramatically alter the state constitution may be headed for the November ballot.

Reform Michigan Government Now (RMGN) claims to have been successful in its quest to gather a sufficient number of valid signatures to bring the proposal before voters—however a number of legal challenges still stand in the way at this time.

If it survives those tests and is passed this fall, the proposal would amend 24 sections of the Michigan constitution and add four new sections. Almost every aspect of state

government could be affected—from the size, structure, and salary of our judiciary, to a reduction in the state's legislature, revised redistricting plans, and a number of major election changes.

In other words, if you live or do business in Michigan, this ballot proposal would impact you.

To keep abreast of current court actions and the status of RMGN's ballot proposal, visit our Website and click on Alerts.

Be aware. Be informed. Be prepared.
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UNDERSTANDING CLINICAL TRIALS

(What you don't know could hurt you)

A critical part of the medical product-development cycle, clinical trials carry many benefits. They can provide patients with access to the latest drugs and technologies when standard therapies

no longer work. They advance scientific knowledge for researchers. And they help healthcare providers and payors learn what interventions are most likely to be effective at preventing, diagnosing, and treating disease.

The problem? Recent violations of basic ethical standards have eroded public trust and made recruitment difficult. Faced with well-publicized lapses in regulatory oversight, the FDA and other government agencies have redoubled their enforcement efforts. Concerns about financing for-profit manufacturers' cost for R&D have caused both public and private payors to significantly tighten reimbursement policies.

Before you engage in clinical research, you should consider these proactive steps to avoid regulatory, civil, or criminal exposure.

1. Know what the FDA regulates

The Food and Drug Administration (FDA) regulates most human research involving drugs or devices used to prevent, diagnose, treat, mitigate, or cure various diseases and conditions—including products already approved for marketing in the U.S. Not regulated is clinical practice (for example, a physician's decision to prescribe an approved drug "off-label" for clinical use).

2. Identify the sponsor

Clinical trials may be sponsored by a research institution, drug or device company, or healthcare provider. Sponsors have specific responsibilities, including submission of applications and permits, selecting researchers, monitoring investigations, and filing reports to the FDA. Unless you and your staff are trained and able to assume all the attendant responsibilities, you should not become a sponsor. If you're conducting a trial for a manufacturer, be sure the contract clearly identifies that manufacturer as the trial's sponsor.

3. Secure necessary permits

Research involving new drugs and devices often requires an Investigational New Drug (IND) application or Investigational Device Exemption (IDE). Failure to submit the proper application may result in FDA sanctions.

4. Assemble a knowledgeable staff

A well-trained research staff will help ensure regulatory compliance, the smooth handling of applications, and successful recruitment of participants. It's important to clearly notify staff of protocols and expectations, and to document in writing, delegation of any research-related tasks to staff or contracted third parties.

5. Draft clear, consistent documents

Clinical studies may be governed not only by federal and state regulations, but also by multiple documents such as sponsor-investigator agreements, written protocols, and informed-consent forms. All these documents should be clear and consistent, and reviewed by the IRB. To avoid vague or ambiguous language, create a protocol summary that researchers and staff can use as reference.

6. Institute effective billing procedures

Your staff should be fully acquainted with billing and reimbursement practices to ensure compliance with current Medicare, Medicaid, and private payor rules. Be sure to maintain good communications between the research team and sites where participants receive clinical services so as to avoid duplicate billing.

7. Monitor and audit

Most researchers and physicians participate in clinical studies to contribute to scientific progress, help patients, and even benefit from positive PR. But the process is not immune to fraud and abuse. False statements designed to enroll volunteers, payments in exchange for referrals, and fabrication of study data are just a few of the possible abuses, and sponsors and investigators may be held responsible even if they take swift and appropriate corrective action. If you suspect a problem in the conduct or oversight of a study, consult experienced legal counsel for assistance.

OUR HEALTH LAW PRACTICE IS GROWING

Chicago and Ann Arbor attorneys join the team

We've expanded our Health Law and Life Sciences practices with the recent addition of several attorneys with extensive knowledge and experience. Joining Miller Canfield as principals in our newly opened

Chicago office are Michele B. Bush and Charles F. MacKelvie, along with attorney Heather A. Tullio. Rachel Nosowsky comes to our firm as senior counsel in the Ann Arbor office from the University of Michigan's legal staff.

Earlier this year, our firm hired Billee Lightvoet Ward in Kalamazoo and Grand Rapids. Ward is a former corporate attorney at Borgess Health Alliance, Inc. With the addition of these leading health lawyers, we're uniquely able to handle complex, cutting-edge health law matters, provide

"been-there, analyzed-that" expertise to all areas of health law, and expand our extensive knowledge of issues facing clients in the rapidly emerging life sciences and biotech industries.

Miller Canfield's 30 experienced health law attorneys represent hospitals, physicians, and other healthcare providers in regulatory, transactional, and litigation matters. How can we help you?

Michele B. Bush

- Focuses on general corporate and health law
- Specializes in transactional and regulatory matters, physician/hospital joint ventures, managed care, and alternate delivery systems
- Prior to joining Miller Canfield, served as associate general counsel for Advocate Health Care, one of the largest vertically integrated health systems in the country



Michele B. Bush

Charles F. MacKelvie

- 34-year veteran health care and business lawyer
- Focuses on Medicare, transactional, regulatory, administrative, nonprofit, corporate, tax and governance litigation matters
- Has argued more than 300 cases before the Department of Health and Human Services' Provider Reimbursement Review Board
- Served as general and special counsel to numerous hospitals and health systems



Charles F. MacKelvie

Rachel Nosowsky

- Focuses on human subject research and FDA regulation; corporate governance, ethics and compliance; medical staff bylaws, credentialing and peer review; patient privacy; and clinical services contracting
- Has extensive experience representing hospitals, academic medical centers, physician groups, clinical labs, managed care plans, and other healthcare providers and payors



Rachel Nosowsky

DRUG TESTING IN THE WORKPLACE



Recent Canadian court decisions strike a balance between safety at work and individual rights

When it comes to testing employees for drug and alcohol use, Canada's employers are advised to take into account the impact of Human Rights legislation, which generally prohibits discrimination on the basis of disability—and dependence on drugs or alcohol is considered to be just that. But does Human Rights legislation trump health and safety risks posed by on-the-job employees working under the influence?

Recent Court of Appeal rulings say no.

While the value of Human Rights legislation is paramount for an employee, the courts ruled it must be viewed within a larger legal framework—one that considers the welfare of all employees. "Extending human rights protections resulting in placing the lives of others at risk flies in the face of logic," the Justices concluded.

Generally, the courts have allowed testing in specific circumstances—as a condition of hire prior to a safety-sensitive job, after a substance-related incident, or as a condition for return to work.

Canada's Occupational Health and Safety legislation places the onus on employers to provide due diligence in minimizing or eliminating potential safety risks—including making certain an impaired employee who is declared unfit for work is barred from the worksite and kept off public roads. What's more, Bill C45 (a 2004 amendment to the Criminal Code of Canada) holds corporations criminally liable if those in charge fail to take reasonable steps to guard the safety of all their workers, as well as the public. The amended legislation has affected the way companies deal with drug and alcohol issues, and will continue its impact well into the future.

As a result, companies are writing new policies that focus on an employee's fitness for work, the prevention of accidents and injuries, a safe workplace, and public safety.

To justify drug and alcohol testing, policies should rationally connect directly to the performance of a job. In reviewing such policies, human rights tribunals and the courts have focused on the reasons why a policy was established (in a belief that the thinking that led to the policy is as important as the policy itself) and whether the policy was implemented as a result of the company's specific work requirements. It's imperative that the process of developing drug and alcohol-testing policies be undertaken in consultation with key representatives of the organization.



While each policy will be unique to that employer, all policies should follow some basic guidelines:

- Be written and communicated to all employees
- Provide clear direction on the purpose of testing, who is covered, and under what circumstances
- Outline rules and responsibilities
- Emphasize the importance of obtaining assistance with a substance problem before it impacts work, and provide employees with access to assistance
- State the conditions for return to work, including aftercare requirements
- Include procedures for investigating a possible policy violation
- Establish the consequences for a policy violation
- Set forth conditions for continued employment

Today's employers must deal effectively with employees who may pose a safety risk, while balancing the requirements of the Human Rights Code. In addition, employee policies should reflect their company's culture and values, the fundamentals of their business, and the regulatory environment in which they operate. Contact our office if you would like assistance with this challenging issue.

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Issues in Labor & Employment Law

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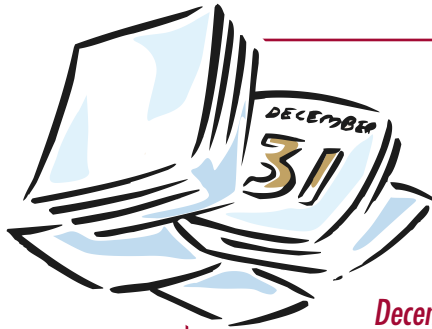
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**It's almost here...
The Deferred Compensation
Deadline Is Coming Soon**

December 31, 2008. That's the date by which you must have your documents in place for all deferred compensation arrangements to comply with Internal Revenue Code 409A.

To be subject to this law, your deferred compensation arrangement needn't be formal—executive retirement plans, stock option plans, or severance plans, for example. The deferred compensation arrangement could be verbal, or contained in any number of other employment documents.

The point is: rules apply whenever compensation is promised to an employee, former employee, director, or independent contractor in one year, and paid in another. All existing deferred compensation arrangements should be reviewed immediately for compliance. There are severe penalties for failing to meet the deadline, and the IRS has said there'll be no further extensions.

If you have questions, please contact a member of Miller Canfield's employee benefits team. You may also want to refer to an article in the Winter 2007 *Hot Points*, which can be found on our Website.

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