

Hall, Render, Killian, Heath & Lyman is a full service health law firm with offices in Indiana, Kentucky, Michigan and Wisconsin. Since the firm was founded by William S. Hall in 1967, Hall Render has focused its practice primarily in the area of health law and is now recognized as one of the nation's preeminent health law firms serving clients in multiple states. For more information about the firm please visit us at www.hallrender.com.

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OHRP Issues New Guidance on Informed Consent for Genetic Testing

The Office for Human Research Protections ("OHRP") recently issued guidance recommending changes to informed consent language for clinical research involving genetic testing. This guidance is based on the Genetic Information Nondiscrimination Act of 2008 ("GINA"), which prohibits discrimination in health coverage and employment based on an individual's genetic information.

The document, "Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards," provides OHRP's first formal guidance on this topic. Among other things, OHRP addresses the implications of GINA for investigators who conduct, and Institutional Review Boards ("IRBs") that review, genetic research. OHRP's guidance focuses on the criteria for IRB approval of research and the requirements for obtaining informed consent under the Department of Health and Human Services regulations for the protection of human subjects (45 CFR part 46). OHRP also recommends the use of language in clinical research informed consents notifying study participants of their rights under GINA.

OHRP's guidance document is available online at
<http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html>.

Congress Considers Bill Allowing State Law Tort Claims in Medical Device Cases

Earlier this month, the House Energy and Commerce Subcommittee on Health considered a bill (H.R. 1346) that would overturn the U.S. Supreme Court's decision in *Riegel v. Medtronic, Inc.*, No. 06-179 (U.S. Feb. 20, 2008), by specifying that state product liability lawsuits are not preempted by federal law.

The lawmakers who introduced the Medical Device Safety Act of 2009 in March of this year, House Energy and Commerce Committee Chairman Henry Waxman (D-CA) and Subcommittee on Health Chairman Frank Pallone, Jr. (D-NJ), said in a joint statement that the Court's decision "ignores both congressional intent and 30 years of experience in which federal regulation, through the U.S. Food and Drug Administration, and tort liability played complementary roles in protecting consumers from device risks."

In *Riegel*, the Court held the federal Medical Device Amendments of 1976 ("MDA") preempt state common law claims challenging the safety and effectiveness of a medical device that received premarket approval from

the federal Food and Drug Administration ("FDA").

A copy of H.R. 1346 is available online: [Here](#).

A similar bill has been introduced in the Senate. For more information on the House Subcommittee hearing, visit: [Here](#).

For more information about any of these topics, please contact your local counsel or Thomas D. Shrack at tshrack@hallrender.com or Leah Voigt Romano at lromano@hallrender.com.

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