

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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NIH Challenge Grants in Health and Science Research

With \$200 million in funds allocated through the American Recovery and Reinvestment Act of 2009, the National Institutes of Health (NIH) has established a new initiative called the **NIH Challenge Grants in Health and Science Research** ("Challenge Grants"). The Challenge Grants program will support research on topic areas that address specific scientific and health research challenges and that would benefit from significant two-year jumpstart funds.

For the Challenge Grants, the NIH has identified fifteen (15) general topic areas focusing on specific knowledge gaps, scientific opportunities, new technologies, data generation, and research methods. Within the Bioethics Challenge Area, for example, the NIH has identified the five following topics:

- Unique Ethical Issues Posed by Emerging Technologies;
- Ethical Issues in Health Disparities and Access to Participation in Research;
- Ethical Issues Associated with Electronic Sharing of Health Information;
- Ethical Issues in the Translation of Genetic Knowledge to Clinical Practice; and
- Ethical Issues Raised by the Blurring between Treatment and Research.

The due date for Challenge Grant applications is April 27, 2009.

For more information, visit:

[click here](#)

[click here](#)

OHRP Seeking Comments on IRB Accountability

The Office for Human Research Protections ("OHRP") recently issued a notice of proposed rulemaking that would permit the agency to hold Institutional Review Boards ("IRBs") directly accountable for non-compliance, rather than solely pursuing the relevant institutional officials. Specifically, OHRP seeks input on the suggested allocation of responsibilities for institutional officials and IRBs and on barriers other than enforcement to institutional acceptance of external IRB review.

OHRP believes that a regulatory change in its enforcement authority may remove a significant obstacle that been cited as inhibiting institutions from relying on the review of an IRB operated by another institution or organization. OHRP hopes that if this policy change has the intended effect of encouraging institutions to participate in cooperative review

arrangements and to use the services of external IRBs, this will ultimately reduce administrative burdens associated with 45 CFR part 46 (the "Common Rule") implementation, without weakening human subject protections.

Comments on this proposal are due June 3, 2009 and may be sent via e-mail to IRBaccountability@hhs.gov, or via facsimile at 301-402-2071. OHRP's notice can be accessed at: [click here](#) or [click here](#).

Federal Judge Orders FDA to Let 17-Year-Olds Use Emergency Contraception Without a Prescription

On Monday, March 23rd, a federal district court judge in New York ruled that the Food & Drug Administration ("FDA") let politics cloud its judgment when it denied teenage girls over-the-counter access to Plan B, an emergency contraceptive (also known as the "morning-after pill").

According to the judge, the agency had "repeatedly and unreasonably" delayed issuing a decision on the medication during the Bush administration. He noted that the FDA's denial of non-prescription access to Plan B without age restriction was counter to the recommendation of the scientific panel that advised the agency on the drug. The judge also found that "the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use."

The judge ordered the federal agency to permit Barr Pharmaceuticals to make Plan B available to 17-year-olds without a prescription under the same conditions as it is now available to women age 18 and over. The agency must comply with the order within thirty (30) days.

The District Court opinion is available at [click here](#).

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

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