

**MEDICAL RESEARCH LAW & POLICY
REPORT® INDEX-SUMMARY**

— Vol. 9, No. 1-24, pp. 1-808
— Jan. 6, 2010 - Dec. 15, 2010

NOTE ON ALPHABETIZATION: *This subject index is arranged alphabetically word-by-word. For example, the heading NEW YORK precedes the heading NEWSPAPERS.*

A

**AAHRPP (ASS'N FOR ACCREDITATION OF
HUMAN RESEARCH PROTECTION
PROGRAMS) See ACCREDITATION AND
CERTIFICATION**

ACCREDITATION AND CERTIFICATION

Announcement of accreditations, 218
Korean institutions accreditation by AAHRPP, 409
Reaccreditation extension by AAHRPP, 20
Russian clinical trials, 585

ADA See AMERICANS WITH DISABILITIES ACT

ADVERSE EVENTS

Public access to data, 22

AIDS AND HIV

Colo. reporting, 26
Patents
—Effectiveness evaluation methods (U.S., rev grant), 685
—International patent pool, 613
—Stanford, AIDS therapy, rights assignment (Fed. Cir.), 13; patents and Bayh-Dole (U.S., briefs sought), 397
Women, underrepresentation in studies, 621

ALABAMA

Nuclear waste, interstate disposal compact with N.C. (U.S., oral arg), 54

ALIENS

H-1B visa petitions received, 250

**AMERICAN RECOVERY AND
REINVESTMENT ACT (ARRA)**

Construction grants, NIH controls, 221

AMERICANS WITH DISABILITIES ACT

Polio vaccine creator suit (E.D. Pa.), 647

ANIMAL TESTING

N.Y. mental health office records (N.Y. Sup. Ct.), 749
Petition to limit, 245
Primates
—Kan. Univ., primate mistreatment claims, 384
—N.M. governor appeals for chimpanzees, 563; chimps to stay at Alamogordo, 627
—UC Santa Cruz animal rights case (N.D. Cal.), 459
Sheep decompression death alleged (Wis. Cir. Ct.), 417
U.K., intimidating workers, 590; sentencing, 697
Updated guide, 375

ANTIBIOTICS

Trovan. *See* TROVAN

APPLICATIONS

Ceftobiprole application rejection, 21
Exemptions from investigational new drug application requirement, 655
Parallel review by FDA and CMS, 786
Pediatric research and medical device applications, 213; rule pulled, 454

APPROVALS

Cardiovascular devices, data quality, *JAMA* report, 17
Conditional approval system. *See* LEGISLATION, FEDERAL, HR 4732

Direct-to-consumer genetic test kits, FDA policy, 385
Midodrine hydrochloride, proposed retraction of approval, 527

**ARRA See AMERICAN RECOVERY AND
REINVESTMENT ACT (ARRA)**

AUSTRALIA

Breast cancer, gene patent challenge (Fed. Ct. Austl.), 367
Privacy rules, 80
Research misconduct panel, 255

AVANDIA

Clinical trial halted, 478
Diabetes drug withdrawal recommendation, 447; access restricted, 630
Heart attack suit (E.D. Tex.), 788

B

**BIOTECHNOLOGY See GENETICS AND
BIOTECHNOLOGY**

BIOTERRORISM See TERRORISM

**BUDGET, U.S. See specific agencies and
departments**

C

CALIFORNIA

Cord blood, state program, 588; UC collection bill, 628
Informed consent emergency exemption, 457
Mishandling body parts
—Andre suit, no duty to families (Cal. Ct. App.), 562
—Waters and Cohen suits, no duty to families (Cal. Ct. App.), 252
Stem cell research
—Acceptable research material rule, In Brief, 113
—Bond measure, 760
—Consolidating CIRM requirements, 83
—Cooperation with Wis., 412
—Donation of embryos, 113
—Funding bills approved by panel, 180
—Grants
— —Early transaction awards, 694
— —Investigator incentives, 286
— —Status of institutions, CIRM report, 83
—Loan, guidelines approval, 113
—Outreach to industry, 790
—Oversight of CIRM, Senate bill, 146; action suspended, 316; approved, 561
—Pact with Md., 728
—Strategic review, 626

CANADA

Digital archive of published health research, 283
Nanotechnology, interim policy, 225
Ontario research funding, 282

CANCER

Blood Brain Barrier Disruption, experimental treatment (D. Or.), 273
Breast cancer
—Australia, gene patent challenge (Fed. Ct. Austl.), 367
—New clinical trial model, 212
Capps research proposal, 207
Cholesterol drugs link to cancer unlikely, 29
Clinical trials
—Beth Israel study enrollment suspension, 695
—Iowa coverage mandate, 146
—Merck global network, 378
—Phase III trial design, 785
Duke researcher resignation, 763
Isolated DNA, patent challenge (S.D.N.Y.), 103; patents invalid, Special Report, 228; webinar, Special Report, 353; notice of appeal, 398; recusal

sought (Fed. Cir.), 477; brief filed, 515; BNA Insights, 594; comments, 652; briefs (Fed. Cir.), Special Report, 705
Medicare, PET scans for bone metastasis of cancer, 216
NCI Cooperative Group Program, overhaul sought, 245
Plagiarism and falsifying research, no federal jurisdiction (E.D. Pa.), 29
Registries
—La. tumor registry, 25
—N.J. cancer registry, 762
—Wash. registry, 492
—Wis. registry, 492
Texas
—Cancer Prevention and Research Inst., 26; rules, 148
—Funding, 84
Univ. of Ill. cancer drug royalties (7th Cir.), 479
Univ. of Miami halts cancer study, 566
Univ. of Pittsburgh prostate cancer research dispute (W.D. Pa.), 12

**CDC See CENTERS FOR DISEASE CONTROL
AND PREVENTION (CDC)**

CEFTOBIPROLE

Skin infection drug application rejection, 21

**CENTERS FOR DISEASE CONTROL AND
PREVENTION (CDC)**

Conflicts of interest, HHS IG report, 29
Grassley questions travel costs, 150

CHILDREN'S HEALTH CARE

Autism link to vaccines, U.K. MDs guilty, 85
Bone cancer, "experimental treatment" coverage denial (S.D. Ohio), 73
Brain damage study in newborns (D. Mass.), 608
Ill. newborn screening, 84
Me. birth defects, 761
Pediatric research
—Ethics and overseas research, 555
—Experimental cardiac procedure blamed for death (3rd Cir.), 718
—Medical device applications, 213; rule pulled, 454
—Rare pediatric diseases, Senate hearing, 485
—Toxic exposure and medical monitoring (3rd Cir.), 580

CIALIS

ED drug inventorship (Fed. Cir.), 243; (U.S., rev sought), 658

CLINICAL TRIALS

Adaptive designs, FDA draft guidance, 145
Allergy treatment study, alleged breach of contract (S.D. Ill.), 206
Alzheimer's trial database, 374
Antibiotic noninferiority trials, 758
Avandia trial halted, 478
Bayesian statistical methods for medical devices, 111
Biosimilar trials urged, 486
Bone cement trials (E.D. Pa.), 794
Cancer
—Beth Israel study enrollment suspension, 695
—Iowa coverage mandate, 146
—Merck global network, 378
—Phase III trial design, 785
Children, high or unclear bias risk in trials, 49
Compliance assessment sealed (N.J. Super. Ct. App. Div.), 380
Coordinators move to competitor (D. Mass.), 445
Duke researcher suspension, 493
Flaws in clinical trials, CRO reports, 138
Gays and lesbians, bias probe sought, 246
HIV studies, women underrepresented, 621
International developments
—Developing nations, need for local partners, 531
—Foreign study data usage, 417
—India, new restrictions, 111

CLINICAL TRIALS —Contd.

International developments —Contd.

—Russian rules, 585

Investigational device exemption, preemption, 752

NCI Cooperative Group Program, overhaul sought, 245

New clinical trial model, 212

N.Y. medical research consortium, 413

Non-inferiority trials, 145; FDA policy, 559

Physician participation decline, 403

Postmarket research

—FDA report, 725

—IOM report, 449

Reimbursement for new technologies, 153

Safety, FDA reporting rule, 612

Stem cell research

—Clearance from FDA, 750

—Enrollment, 651

—Trial enrollment, 651

Suicide link, 346; assessing risk, 586

Tax issues, Special Report, 733

TOGA, investigational use exemption (E.D.N.Y.), 784

Trovan clinical trial injuries (U.S., brief filed), 368; (rev den), 401

Univ. of Rochester pain drug initiative, 691

Unlawful clinical trials (E.D. Pa.), 664

Warfarin, Medicare coverage, 16

CLONING

Ohio, human cloning ban, 220

COLLEGES AND UNIVERSITIES

Ariz. State, Havasupai blood samples settlement (Ariz. Super. Ct.), 271; informed consent, 444; HHS panel examines, 501

Baylor conflict-of-interest compliance, NIH concerns, 86

Columbia Univ. PET center, 459

Conflicts of interest

—Research projects and transfers to startups, 260

—Specific colleges. *See* specific colleges, *this heading*

—University research projects and transfers to startups, 260

Cornell, DNA patent claims (D. Del.), 342

Duke researcher suspension, 493; resignation, 763

George Washington Univ. brain damage study in newborns (D. Mass.), 608

Harvard

—Biologist, misconduct in research probe, 565

—Conflicts of interest, 491

—Oncomouse patentability questioned, 364

Household help subsidies and attracting women to science, 79

Intellectual property ownership and Bayh-Dole, 651

Johns Hopkins

—Cellular proteins pact (Del. Ch.), 11

—Montgomery County, Md., pact, 147

Kan. Univ., primate mistreatment claims, 384

Medical schools. *See* specific schools, *this heading*

Minority disparities, HHS university awards, 623

NIH grants, 247

Northrop Grumman IT research, 175

Ohio

—Centers of Excellence in Biomedicine and Health Care, 147

—Proctor & Gamble collaboration pact, 284

Ohio State Univ.

—Confidentiality of survey records (Ohio Ct. App.), 108

—Misdiagnosis whistleblowing, retaliation claim (S.D. Ohio), 366; dismissal, 481

Patents

—Specific colleges. *See* specific colleges, *this heading*

—Universities filings, survey, 170

Portland State Univ., Or. biotech funding, 114

St. Louis Univ., new medical research center, 113; ex-Pfizer staff, 148

Stanford

—AIDS therapy, rights assignment (Fed. Cir.), 13; patents and Bayh-Dole (U.S., briefs sought), 397

—Conflicts of interest, continuing medical education program, 13

Tech transfer, 659

Tulane peptide analog patent suit (D.D.C.), 28

UC Berkeley collection of freshman cell samples, 347; ban sought, 490; retooled, 522

UC cord blood collection, 628

UC Santa Cruz animal rights case (N.D. Cal.), 459

UCLA

—HIPAA violations, researcher sentencing (C.D. Cal.), 288

—Mishandling body parts

—*Andre* suit, no duty to families (Cal. Ct. App.), 562

—*Waters* and *Cohen* suits, no duty to families (Cal. Ct. App.), 252

Univ. of Ill.

—Cancer drug royalties (7th Cir.), 479

—SHARPS center, federal grant, 254

Univ. of Medicine & Dentistry grant application (D.N.J.), 696

Univ. of Miami

—Cancer study halted, 566

—Defamation claim by medical student (S.D. Fla.), 107

Univ. of Minn.

—Conflict of interest policy, 284; implemented, 523

—Death of participant, 791

—Melanoma study, 348

Univ. of Mo. life sciences startup funding, 114

Univ. of N.C. standardized licensing pact, 285

Univ. of Pittsburgh prostate cancer research dispute (W.D. Pa.), 12

Univ. of Rochester pain drug initiative, 691

Univ. of Wis. conflict of interest probe, 524

Vanderbilt databank of de-identified DNA samples, 47

COLORADO

AIDS reporting, 26

Physicians, disclosures for license renewals, 381

COMPARATIVE EFFECTIVENESS

Academic detail funding, 249

Appropriate comparators, industry strategies, 153

Balanced views urged, 653

Cost control and comparative effectiveness research, 406

Drug access, 452

Federal infrastructure changes urged, 451

Health reform. *See* LEGISLATION, FEDERAL, HR 3590

Impact of research, issues, 215

National clinical research infrastructure, 757

NIH grants, 172

Nonpharmacological interventions compared with drugs, 173

Patient participation, 487

Premier health alliance, 788

RAC auditing deferrals, 552

Relevancy to all patient populations, 371

Scientific basis for research, 406

Stakeholder comments, 516; participation, 725

Task force, HHS future activity, 120

Tracking database, 759

Unresolved issues, 453

CONFERENCES AND MEETINGS

Ass'n for the Accreditation of Human Research

Projects, 259; 259

Center for Business Intelligence

—Fourth Annual Forum on Tracking State Laws and Aggregate Spend, 557

—“Reimbursement Strategies for Medical Devices and Diagnostics,” 153

Friends of Cancer Research, 407

NIH, Does Your Research Raise Security Concerns?, 615

Public Responsibility in Medicine & Research

—Advancing Ethical Research: Uniting, People, Principles, and Practices, 798

—Conflicting Interest and Conflicting Expectations:

Challenges Presented by NIH's New Rule, 667

Research!America forum, 756

Seventh Annual Pharmaceutical Compliance Conf., 88

Sharing Convergent Strategies for Comparative Effectiveness Research, 406

Tax Council Policy Institute, 143

WIPO Intergovernmental Comm. on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 23

CONFLICTS OF INTEREST

Academia-industry ties, webinar, 18

Academic medical center policies, 755

AMA resolution, 411

Baylor compliance, NIH concerns, 86

CDC management, HHS IG report, 29

Development of drugs affected, 689

Discipline for NIH ethics officer, 698

Enforcement issues, HHS IG plans, 93

Enhanced federal regulation sought, 486

Fair market value and documentation, 425

FDA, CRS report, 177

Federal reporting law, effects, 376

Grassley questions NIH travel costs, 150; discipline for ethics officer, 698

Harvard, 491

Journal editors, disclosure form, 401

Medical devices, Grassley queries FDA, 697

Natl. Ass'n on Mental Illness drugmaker donations, 288

Outlook 2010, 5

Partnerships seen as essential, 408

Pfizer payment disclosure, 216

Physicians

—Decline in MD-industry ties, 723

—Ethics code for medical specialty societies, 279

—Initiative in addressing conflicts, 20

—Orthopedic devices, payments to MDs, 583

—Positive attitudes toward industry ties, 408

—Psychiatry, transparency in industry ties sought, 214

—Streamlining disclosure, FDA action sought, 724

—Teaching hospitals and MD-industry ties, 407

Public support for disclosure, study, 278

Semiannual agenda for NIH, 272; proposed rule, 335;

discussed, 499; HHS panel comments, 503;

speakers comment, 667

Senate report on “ghostwriting,” 415

Stanford continuing medical education program, 13

State rules

—Mass. gift disclosure law, 760

—Tex. rules, 26

Stricter disclosure by researchers, 452

Univ. of Minn.

—Melanoma study, 348

—Policy, 284; implemented, 523

Univ. of Wis. probe, 524

University research projects and transfers to startups, 260

VA advisor and Medtronic, 794

CONGRESS, U.S.

Ed. Note: This heading is used for administrative actions only. For coverage of legislation by bill number, see LEGISLATION, FEDERAL. For information on measures not yet assigned bill numbers see specific subject headings.

Hill Watch, 219

CONNECTICUT

Grants for Alzheimer's and diabetes, 347

CRIMINAL PROSECUTIONS

Body parts valuation (Cal. Ct. App.), 660

Bone cement trials (E.D. Pa.), 794

Hedge fund insider trading (S.D.N.Y.), 731

Sweden, destruction of data by researcher, 731

Unlawful clinical trials (E.D. Pa.), 664

D

DELAWARE

Medical records data in research, 457

DEVICES *See* MEDICAL DEVICES

E

E-HEALTH

Lance Armstrong Foundation official, BNA Interview, 592

Md. medical care database and data collection, 55

Meaningful use of EHR

—Changes sought by congressional leaders, 214

—Final rules, 450

—Patient safety, study planned, 623

—Proposed CMS rule, 14; patient consent issues, 175

—Redefinition, congressional letter, 143

Outlook 2010, 5

Safety monitoring. *See* SAFETY

SHARP grants, 217

White paper on E-records, HHS preparing, 141

EHR (ELECTRONIC HEALTH RECORDS) *See* E-HEALTH

ENFORCEMENT POLICY

Agenda from FDA, 787

HIPAA privacy rule. *See* HEALTH INSURANCE

PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Human subject protection. *See* HUMAN SUBJECT PROTECTION

Outlook 2010, 5

Recent administrative actions, chart, 30; 59; 90; 116; 151; 185; 222; 256; 289; 352; 387; 420; 461; 494; 529; 568; 591; 634; 665; 699; 764; 795

Scrutiny of drugs and devices in 2010, BNA Insights, 122

Trends in drug and device enforcement, 88

ENVIRONMENTAL PROTECTION

BP spill and cleanup workers, 410

Ft. Dietrick biocontainment labs environmental impact, 181

Pesticide study subjects, EPA rule, 613

Radioactive materials. *See* RADIOACTIVE MATERIAL

EPICOR

Nutraceutical, use by Ankeny, Iowa, workers, 729

ERISA

Bone cancer, “experimental treatment” coverage denial (S.D. Ohio), 73

EUROPEAN UNION (EU)

Fee movement of researchers sought, 142

Research needs, 24

Soya, patent protection for genetic modification, 445

Stem cell bank services, no VAT exemption, 371

EXPERIMENTAL TREATMENTS

Bone cancer treatment, coverage denial (S.D. Ohio), 73

Clinical trials. *See* CLINICAL TRIALS

F

FABRAZYME

Fabry disease drug shortage, 551; NIH “march-in” rights, 783

FALSE CLAIMS

Catholic Healthcare West, qui tam suit untimely (9th Cir.), 115; (U.S., rev den), 662

St. Jude qui tam suit (D. Mass.), 526; federal intervention sought, 581

Training grant (S.D.N.Y.), 526

FDA *See* FOOD AND DRUG ADMINISTRATION (FDA)

FINANCIAL INDUSTRY STABILIZATION

Medical research and stimulus funding, report, 139

FLORIDA

Grant applications, 83; proposed rule, 148

IRB rules, 26

Jackson Labs, funding for research facility, 286

FOOD AND DRUG ADMINISTRATION (FDA)

Advancing regulatory science, 654

Appointments, science advisor, 24

Conflicts of interest, CRS report, 177

Criminal investigations unit, response to GAO report, 182

FY2011 budget, 411; Senate panel approves, 455

Grassley questions travel costs, 150

Interagency chemical assessment program, 488

Management planning, GAO report, 221

Regulatory science advancement, 212

Transparency

—Advisory panels, 279

—Proposal issued, 344

FRAUD AND ABUSE

Alzheimer's study whistleblower suit (D. Mass.), 662; no evidence for falsity, 730

Authorship credit dispute (E.D. Pa.), 340

Bone cement trials (E.D. Pa.), 794

Conflicts of interest. *See* CONFLICTS OF INTEREST

False claims, Catholic Healthcare West, qui tam suit (9th Cir.), 115; (U.S., rev den), 662

Imaging device approvals, whistleblowers, 631

Kickbacks

—Boston Scientific resolution, 28

—Physician group settles (S.D. Ohio), 415

Misconduct in research

—Anesthesiologist, pain drug data fabrication admission (D. Mass.), 56; guilty plea, 150; sentenced, 415

—Australian panel, 255

—Autism link to vaccines, U.K. MDs guilty, 85; *Lancet* retraction, 116; MDs struck from register, 350

—Bogus papers in scientific journals, 756

—Cancer, plagiarism and falsifying research, no federal jurisdiction (E.D. Pa.), 29

—Changed FDA procedures, IRB role, Special Report, 155

—Cost of probes, 567

—Data falsification, proposed rule, 138

—Debarment by HHS, no injunction (D.D.C.), 383

—Defamation claim by medical student against Univ. of Miami (S.D. Fla.), 107

—Duke researcher suspension, 493; resignation, 763

—Harvard biologist, 565

—Integrity studies, HHS grants, 145

—Paxil clinical trial records (E.D. La.), 589

—Retraction sought by Mayo Clinic, 384

—Univ. of Medicine & Dentistry grant application (D.N.J.), 696

NIH grant fraud allegations (S.D.N.Y.), 27; reconsideration denied, 350; verdict challenged, 793

G

GENETIC DISCRIMINATION

GINA. *See* GENETIC INFORMATION NONDISCRIMINATION ACT (GINA)

Iowa ban, 287

GENETIC INFORMATION

NONDISCRIMINATION ACT (GINA)

CRS report, 217

EEOC final rule, 719

Mont. rule, 382

GENETICS AND BIOTECHNOLOGY

Advisory panel not renewed by HHS, 645

Agricultural biotechnology, USDA agenda, 76

Bioethics panel nominees, 247

Biomarkers and surrogate endpoints, 345

Biosimilars

—Clinical trials urged, 486

—Pathway, stakeholders comment, 721

Cleveland as high-tech hub, 381

Commercial genetic test regulation, 484

Death blamed on gene therapy (C.D. Ill.), 167

Direct-to-consumer testing

—FDA policy, 385

—Regulation urged, 624

—Risks and oversight, 556

Epigenetics research and environmental risks, 281

GINA. *See* GENETIC INFORMATION

NONDISCRIMINATION ACT (GINA)

Havasupai blood samples, Ariz. State settlement (Ariz. Super. Ct.), 271; HHS panel examines, 501

Informed consent issues, 618

Maryland

—Budget, biotechnology funding, 82

—Construction of biotechnology facility, 253

—Johns Hopkins pact with Montgomery County, 147

Mix-up of genetic tests, House hearing, 418

Newborn screening

—Guidance from HRSA, 277

—Minn. newborn blood screening, 562

—Neb. newborn screening, 26

Ohio

—Birth defects data system, 414

—Centers of Excellence in Biomedicine and Health Care, 147

Patents

—Australia, breast cancer gene patent challenge (Fed. Ct. Austl.), 367

—Cornell, DNA patent claims (D. Del.), 342

—Exception to infringement for gene patents, HHS report, 119

—Isolated DNA, patent challenge (S.D.N.Y.), 103; patents invalid, Special Report, 228; webinar, Special Report, 353; notice of appeal, 398; recusal sought (Fed. Cir.), 477; brief filed, 515; BNA

Insights, 594; comments, 652; briefs (Fed. Cir.), Special Report, 705

—Licensing of diagnostics and therapeutics, 137

—Myriad gene patent dispute with PTO (S.D.N.Y.), 40

—Patentability of genetic sequences, BNA Insights, 428

—Soya, patent protection for genetic modification, 445

Personal genetic testing kits

—House hearings, 343

—Walgreens plans, 342

Personalized medicine, holistic approach, FDA chief

comments, 140

Plant modifications, USDA auditing standard, 657

Registry for genetic tests, NIH program, 210

Synthetic biology

—President's bioethics meeting, Special Report, 464

—Recombinant DNA study sites, 427

—Screening framework guidance from HHS, 649

—Vaccines, House hearing, 339

—Viral genome study limits, guidelines from NIH, 276

Tex. newborn blood collection settlement (W.D. Tex.), 25

UC Berkeley collection of freshman cell samples, 347;

ban sought, 490; retooled, 522

Vanderbilt databank of de-identified DNA samples, 47

GINA *See* GENETIC INFORMATION

NONDISCRIMINATION ACT (GINA)

GRANTS

Alzheimer's study whistleblower suit (D. Mass.), 662; no evidence for falsity, 730

Burnham Institute gets grant, 83

Colleges receiving NIH grants, 247

GRANTS —Contd.

Conn., Alzheimer's and diabetes, 347
Coordination by NIH and FDA, 134; public comment, 369
DOD reimbursement rates rates, inconsistencies, 589
E-health, SHARP grants, 217
Exclusion of researcher, reinstatement of retaliation claim (6th Cir.), 87
Fla. applications, 83; proposed rule, 148; grants, 694
Fraud allegations (S.D.N.Y.), 27; reconsideration denied, 350; verdict challenged, 793
Improper construction grant award by NIH, 387
Innovation grants, 283
Integrity studies, HHS grants, 145
International IRB cooperation, 80
Minority disparities, HHS university awards, 623
New Jersey
—Brain injuries, 55
—Spinal cord research, 348; Sep. announcement, 628
Nimble authority for NIH, 276
Stem cell research. *See generally* STEM CELL RESEARCH
Tex. cancer funding, 84; rules, 525
Therapeutic discovery project program, 717
Training grant false claims (S.D.N.Y.), 526
Univ. of Ill. SHARPS center, federal grant, 254
Univ. of Medicine & Dentistry grant application (D.N.J.), 696

GUATEMALA

Syphilis study, 607; findings recounted, 687; comments from CDC and NIH, 724

H

HEALTH AND HUMAN SERVICES DEPARTMENT (HHS)

Appointments, science panel, 191
Genetics advisory panel not renewed, 645
Harmonization of regulations and guidance, panel formed, 188

HEALTH CARE REFORM, FEDERAL

Comparative effectiveness. *See* LEGISLATION, FEDERAL, HR 3590, HR 4872
Effective compliance by medical research organizations, 423
Outline of reform law provisions, CRS report, 658
Outlook 2010, 5
Patient-centered research board, 614

HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH (HITECH) ACT

Effect of reporting requirements on research, 292
HIPAA changes, 669; BNA Insights, 736

HEALTH INSURANCE

Autism therapy coverage denial (E.D. Tenn.), 135
Experimental surgery
—Cancer, coverage denial (D. Or.), 399
—Laser surgery coverage denial (N.J. Super. Ct.), 553
Spinal surgery coverage (Mich. Ct. App.), 81

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

De-identification tester, 53
HITECH changes, 669; BNA Insights, 736
Informed consent, proposed changes, 441; agency support, 702
Privacy rule
—Business associates, HHS proposed rule imminent, 250
—Enforcement by HHS civil rights office announced, 250
—Final rules expected, 669
—Protecting privacy, BNA Insights, 671
—UCLA researcher sentencing (C.D. Cal.), 288

HHS *See* HEALTH AND HUMAN SERVICES DEPARTMENT (HHS)

HIPAA *See* HEALTH INSURANCE

PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

HITECH ACT *See* HEALTH INFORMATION

TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH (HITECH) ACT

HUMAN SUBJECT PROTECTION

Assessing risks, 657
Cold War experiments suit (N.D. Cal.), 648
Columbia Univ. PET center, 459
Community hospitals, 462
Compliance oversight cases decline, 797
Contraception requirement at issue, 620
Data retention, OHRP guidance, 619
Decisionally impaired research subjects. *See* INFORMED CONSENT
Evidence-based human research programs, 259
FAQ from OHRP, 653
Federalwide Assurance draft changes, 701; expected in May 2011, 800
Flexibility in OHRP rules, 93
Guatemala syphilis study, 607; findings recounted, 687; comments from CDC and NIH, 724; reexamination of rules, 749
Human Subject Protection (HSP)/BioResearch Monitoring (BIMO) Initiative, 625
Improvement, 2010 OHRP policy, 9
Investigator disqualification, FDA guidance, 386
IRBs. *See* INSTITUTIONAL REVIEW BOARDS (IRBs)
N.Y.C. health worker retaliation suit (N.Y. Sup. Ct.), 663
“Noninvasive procedure,” clarification from OHRP, 656
OMB advisor comments, 800
Peer review data, federal privilege (D. Del.), 338
Pesticide study subjects, EPA rule, 613
Quality improvement initiatives oversight, 370
Russia, health insurance requirement, 625
Stricter rules at EPA (2nd Cir.), 409
Students who fail to show up for research appointments, penalties, 50
Survey of protection programs, 402
Univ. of Miami halts cancer study, 566
VA quality indicators, 801
Veterans human experimentation suit against CIA, DOD, Army (N.D. Cal.), 57
Va. rules, 180
YouTube posting by OHRP, 456

I

ILLINOIS

Newborn screening, 84
Stem cell research grants, 254

INDIA

Clinical trials, new restrictions, 111

INFORMATION NETWORKS AND TECHNOLOGY

Alzheimer's trial database, 374
Clinical research and IT investment, 110
E-health. *See* E-HEALTH
Medtronic MD payments, website, 377
Northrop Grumman IT research, 175
Safety Report Portal, FDA-NIH announce, 345
Stem cell treatments, website, 375
Univ. of Louisville clinical trial website breach, 381

INFORMED CONSENT

Accuracy of forms at issue, 372
AMA resolution, 411
Cal. emergency exemption, 457
Cancer center forged signatures, 565

Comprehension of forms, 518
Coroner's retaining body part without consent of family (Cal. Ct. App.), 412
Decisionally impaired subjects, applicable state laws, 258
Eye implant, noneconomic damage cap (S.D. Ohio), 400
Genetic research issues, 618
Havasupai tribe and Ariz. State Univ., 444; HHS panel examines, 501
HIPAA, proposed changes, 441; agency support, 702
Mishandling body parts
—Andre suit, no duty to families (Cal. Ct. App.), 562
—Waters and Cohen suits, no duty to families (Cal. Ct. App.), 252
Opt-in standard for biological materials, 798
Opting out of health data collection, 789
Posting of forms online suggested, 687
Specific language, FDA proposed rule, 19
Stent implant claims (3rd Cir.), 167
Third-party gamete donor consent, 140
Translated consent forms, 489
U.K. unauthorized tissue and organ removal, 763

INSTITUTIONAL REVIEW BOARDS (IRBs)

Fla. rules, 26
Grants from NIH, 80
Guidance
—Conflicts of interest, NIH rules, 667
—Draft guidance from FDA, 42
—FAQs from OHRP, 209
—Finalized guidance expected from OHRP, 187; final guidance issued, 784
Multi-site studies, 645
Protection of study subjects, data sought, 583
Public access to reviews, 22

INTELLECTUAL PROPERTY

Academic Inventors' Bill of Rights, 213
Fabryzyme shortage, 551
International developments, genetics and biodiversity, 691
Malaria product development partnership, 521
Patents. *See* PATENTS
Plagiarism charges affirmed (3rd Cir.), 480
Technology transfer, House hearing, 364
Traditional knowledge and folklore, WIPO initiative, 521
University ownership and Bayh-Dole, 651
Written description requirement (Fed. Cir.), 203

INTERNATIONAL DEVELOPMENTS

Clinical trials, foreign study data usage, 417
HIV international patent pool, 613
Intellectual property, genetics, and biodiversity, 691
Traditional knowledge and folklore, WIPO initiative, 521

INTERNET

Informed consent, posting of forms online suggested, 687

IOWA

Cancer clinical trial coverage mandate, 146
Epicor use by Ankeny, Iowa, workers, 729
Genetic discrimination ban signed, 287

IPLX

Investigational drug, access (N.D.N.Y.), 695

IRBs *See* INSTITUTIONAL REVIEW BOARDS (IRBs)

J

JURISDICTION

Cancer, plagiarism and falsifying research, no federal jurisdiction (E.D. Pa.), 29
Embryo ownership, no subject matter jurisdiction (8th Cir.), 208

L

LEGISLATION, FEDERAL

HConRes

—328, Bayh-Dole 30th anniversary, 751

HR

- 3590, Patient Protection and Affordable Health Act, includes effectiveness research, signed, 201
 - 4213, Tax Extenders Act, would extend R&D tax credit, 54
 - 4732, Compassionate Access Act, Watson, would create conditional approval system at FDA, 171
 - 4872, Health Care and Education Reconciliation Act, would make changes to HR 3590, signed, 201
 - 5116, America Competes Reauthorization Act, nanotechnology, 283
 - 6081, Stem Cell Therapeutic and Research Authorization Act, S 3751 is companion, 518
- #### S
- 914, Cures Acceleration Network (CAN) Act, Specter, would create agency to advance science into practice, 201
 - 1203, Grow Research Opportunities With Tax credits' Help (GROWTH) Act, 52
 - 2942, Nanotechnology Safety Act, Prior and Cardin, establishing FDA program, 109
 - 3751, Stem Cell Therapeutic and Research Authorization Act, HR 6081 is companion, 518
 - 3766, Stem Cell Research Advancement Act, would allow funding, 169; passage pushed, 719
 - 4808, Stem Cell Research Advancement Act, DeGette and Castle, would allow funding, 169

LOUISIANA

Physician licensing, 414
Tumor registry, 25

M

MAINE

Birth defects, 761

MARYLAND

Biotechnology
—Budget, 82
—Facility construction, 253
—Johns Hopkins pact with Montgomery County, 147
Medical care database and data collection, 55
Nanobiotechnology benefits study, 253
Stem cell research
—Funding, 253
—Pact with Cal., 728

MASSACHUSETTS

Gift disclosure law, 760

MEDICAL DEVICES

Agenda from FDA, 787
Clinical trials, Bayesian statistical methods, 111
Conflicts of interest, Grassley queries FDA, 697
Humanitarian use devices, 454
Imaging device approvals, whistleblowers, 631
Investigational device exemption, preemption, 752
New science, FDA workshop, 22
Parallel review by FDA and CMS, 786
Pediatric research and medical device applications, 213; rule pulled, 454
TOGA, investigational use exemption (E.D.N.Y.), 784

MEDICARE

Evidence development and reimbursement, 174
Indirect medical education adjustments (7th Cir.), 551
PET scans for bone metastasis of cancer, 216
Resident reimbursement and Mich. hospital (E.D. Mich.), 56
Secondary payers and contract negotiation, 498
Stem cell treatment coverage, 517
Warfarin clinical trials, 16

MENTAL HEALTH

Ohio research rule, 629

MERGERS AND ACQUISITIONS

deCODE Genetics subsidiary sale, 74

MERIDIA

Diet drug, withdrawal planned, 650

MICHIGAN

Stem cell research, spinal surgery coverage (Mich. Ct. App.), 81

MINNESOTA

Newborn blood screening, 562

MINORITIES

Disparities, HHS university awards, 623
Havasupai tribe and Ariz. State Univ., 444; HHS panel examines, 501

MISCONDUCT IN RESEARCH *See* RESEARCH AND DEVELOPMENT (R&D)

N

NANOTECHNOLOGY

America COMPETES Act, House priorities, 75; reauthorization, *see* LEGISLATION, FEDERAL, HR 5116
Canada, interim policy, 225
Collaboration, White House science advisors report, 177
Coordinating policy, White House meeting, 225
Md. nanobiotechnology benefits study, 253
Natl. Nanotechnology Initiative, House priorities, 75
Registry, 560
Safety
—FDA program. *See* LEGISLATION, FEDERAL, S 2942
—Toxicity research urged, 224
—White House panel raises issues, 224
Strategic plan from federal agencies, 693

NATIONAL INSTITUTES OF HEALTH (NIH)

Appointments
—Cancer chief sworn in, 456
—Child health chief named, 488
—Principal deputy named, 559
Budget
—Basic research funding, congressional briefing, 176
—Director comments, 275
—FY2011 budget proposal, 71; relative purchasing power, 373
—Governors' letter, 246
—Stimulus funding, report, 75
Conflicts of interest
—Baylor compliance, NIH concerns, 86
—Discipline for NIH ethics officer, 698
—Final policy expected from NIH, 796
Grants. *See* GRANTS
Grassley questions travel costs, 150; discipline for ethics officer, 698
NCI Cooperative Group Program, overhaul sought, 245
Peer review data, federal privilege (D. Del.), 338
Recovery Act spending
—Construction grants, HHS IG report, 633
—GAO report, 632
Research activities report, 625
Semiannual agenda, 272; proposed rule, 335; discussed, 499; HHS panel comments, 503; speakers comment, 667
Translational medicine center, 786

NEBRASKA

Newborn screening, 26

NEW JERSEY

Brain injury grants, 55; award options, 564

Cancer registry, 762
Spinal cord research grants, 348

NEW MEXICO

Chimpanzees, governor appeals for, 563; USDA probe sought, 761

NEW YORK

Animal testing, mental health office records (N.Y. Sup. Ct.), 749
Clinical trials, medical research consortium, 413
Human subject protection, health worker retaliation suit (N.Y. Sup. Ct.), 663
Stem cell research funding, 220

NIGERIA

Clinical trial injuries and Trovan (U.S., brief filed), 368; (rev den), 401; limited discovery (S.D.N.Y.), 689
Disbursement of Trovan settlement, 73

NIH *See* NATIONAL INSTITUTES OF HEALTH (NIH)

NORTH CAROLINA

Nuclear waste, interstate disposal compact with Ala. (U.S., oral arg), 54; no liability for N.C., 377; equitable claims, 525

O

OFFICE OF HUMAN SUBJECT PROTECTIONS (OHRP)

Associate director leaving, 703
Human subject protection. *See* HUMAN SUBJECT PROTECTION
IRBs. *See* INSTITUTIONAL REVIEW BOARDS (IRBs)

OHIO

Akron as biomaterials innovation hub, 492
Birth defects data system, 414
Centers of Excellence in Biomedicine and Health Care, 147
Cleveland as high-tech hub, 381
Human cloning ban proposal, 220
Mental health research, 629
Proctor & Gamble collaboration pact, 284
Radioactive material rules proposed, 525; issued, 661

OHRP *See* OFFICE OF HUMAN SUBJECT PROTECTIONS (OHRP)

OKLAHOMA

Stem cell research reporting rule, 84; system, 492

OREGON

Long-term care rules, 149
Portland State Univ., state biotech funding, 114
Research rules, 149

ORPHAN DRUGS

Increase in product designations, study, 76
Workshops, FDA hosting, 52

P

PATENTS

AIDS/HIV
—Drug evaluation methods (U.S., rev grant), 685
—International patent pool, 613
Bayh-Dole
—30th anniversary
—Challenges, Special Report, 803
—Commencement. *See* LEGISLATION, FEDERAL, HConRes 328
—Tweaks suggested, 751
Cialis inventorship (Fed. Cir.), 243; (U.S., rev sought), 658
Cornell, DNA patent claims (D. Del.), 342

PATENTS —Contd.

Genetics

- Australia, breast cancer gene patent challenge (Fed. Ct. Austl.), 367
- Cornell, DNA patent claims (D. Del.), 342
- Exception to infringement for gene patents, HHS report, 119
- Isolated DNA, patent challenge (S.D.N.Y.), 103; patents invalid, Special Report, 228; webinar, Special Report, 353; notice of appeal, 398; recusal sought (Fed. Cir.), 477; brief filed, 515; BNA Insights, 594; comments, 652; briefs (Fed. Cir.), Special Report, 705
- Licensing of diagnostics and therapeutics, 137
- Myriad gene patent dispute with PTO (S.D.N.Y.), 40
- Patentability of genetic sequences, BNA Insights, 428
- Soya, patent protection for genetic modification, 445
- Mouse strain license agreement (N.D. Cal.), 72; disclosure-dedication rule, 363
- Oncomouse patentability questioned, 364
- Stanford, AIDS therapy, assignment of rights (Fed. Cir.), 13; patents and Bayh-Dole (U.S., briefs sought), 397
- Stem cell research
 - Related patents analysis, 171
 - WARF patent invalid for obviousness (B.P.A.I.), 269
- Tulane peptide analog patent suit (D.D.C.), 28
- Univ. of Ill. cancer drug royalties (7th Cir.), 479
- Univ. of Mo. life sciences startup funding, 114
- Universities filings, survey, 170
- Wis. Alumni Research Found. joint patent licensing (7th Cir.), 44

PAXIL

- Falsified clinical trial records (E.D. La.), 589

PEDIATRIC RESEARCH *See* CHILDREN'S HEALTH CARE

PERSONALIZED MEDICINE

- Holistic approach, FDA chief comments, 140
- National system advocacy, 405

PHYSICIANS

Conflicts of interest

- Decline in MD-industry ties, 723
- Ethics code for medical specialty societies, 279
- Initiative in addressing conflicts, 20
- Medtronic MD payments, website, 377
- Orthopedic devices, payments to MDs, 583
- Positive attitudes toward industry ties, 408
- Psychiatry, transparency in industry ties sought, 214
- Streamlining disclosure, FDA action sought, 724
- Teaching hospitals and MD-industry ties, 407

Licensing

- Colo., disclosures for license renewals, 381
- La. licensing, 381
- Physician-investigator duties, 659
- UK, stem cell physician sanctioned, 630

POSTMARKETING RESEARCH

- Midodrine hydrochloride, proposed retraction of approval, 527

PRIVACY AND CONFIDENTIALITY

Del. medical records data in research, 457

HIPAA

- Business associates, HHS proposed rule imminent, 250
- Civil rights office, 669
- Enforcement by HHS civil rights office announced, 250
- Protecting privacy, BNA Insights, 671
- UCLA researcher sentencing (C.D. Cal.), 288
- HITECH Act and drug research, 532
- Ohio State Univ., confidentiality of survey records (Ohio Ct. App.), 108

- Opting out of health data collection, 789

Outlook 2010, 5

- Request for information from HHS, 280

Restrictive standards, effect on research, 169

- Sweden, destruction of data by researcher, 731

- Tex. newborn blood collection settlement (W.D. Tex.), 25

PRODUCT LIABILITY

- Avandia heart attack suit (E.D. Tex.), 788

- Strict liability, federal jurisdiction (C.D. Cal.), 402

PTO (PATENT AND TRADEMARK OFFICE)

See generally PATENTS

Q

QUALITY ASSURANCE

- Evaluating patient outcomes, 179

R

RADIOACTIVE MATERIAL

- Classification system, possible NRC revisions, 178

Countermeasures for exposure, 558

- Nuclear waste, interstate disposal compact between Ala. and N.C. (U.S., oral arg), 54; no liability for N.C., 377; equitable claims, 525

- Ohio rules proposed, 525; issued, 661

RESEARCH AND DEVELOPMENT (R&D)

- Access to federally-funded research, House

roundtable, 48; open access debate, 482

- Akron as biomaterials innovation hub, 492

- Alzheimer's funding sought, 142

- Antibacterial drugs, FDA guidance, 370

- Antimicrobial drugs, FDA guidance, 560

- Archived publication access, federally-funded research, 23

Biomedical research

- Funding decline, 47

- NIST standards, 133

- Policy framework urged, 586

- Social science and biospecimens, 456

- Brain damage study in newborns (D. Mass.), 608

- Budget, federal science priorities, 487

- Canada digital archive of published health research, 283

Cancer

- Capps research proposal, 207

- Plagiarism and falsifying research, no federal jurisdiction (E.D. Pa.), 29

- Tex. Cancer Prevention and Research Inst., 26; rules, 148

- Univ. of Pittsburgh prostate cancer research dispute (W.D. Pa.), 12

- Cleveland as high-tech hub, 381

- Clinical and Translational Science Awards from NIH, 453

- Conflicts of interest rules, development of drugs affected, 689

- Contract research organizations, 690

- Coordination by NIH and FDA, grants, 134; public comment, 369

- Data sharing by FDA and CMS, 611

- Dual use research, 411

- EU research needs, 24

- Federal patient-centered research board, 614

Funding

- Election 2010, Special Report, 765

- Fla., Jackson Labs research facility, 286

- Health reform, effect on funding, 259

- Jobs, effect of research funding, 374

- NIH budget. *See* NATIONAL INSTITUTES OF HEALTH (NIH)

- Ontario research funding, 282

- Recovery Act spending

- Construction grants, HHS IG report, 633

- GAO report, 632

- Research!America forum, 756

- Stimulus funding, report, 75

- Health IT funding, HHS awards, 21

- Hepatitis C, FDA draft guidance, 587

- HITECH Act and drug research, 532

- Human subject protection. *See* HUMAN SUBJECT PROTECTION

- Implantable defibrillators, AHRQ and American College of Cardiology, 112

- Improving new drug development process, 248

- Johns Hopkins cellular proteins pact (Del. Ch.), 11

- Life sciences reports from Natl. Academies Press, 658

- Malaria treatment propriety data, 343

- Medicalized weapons, ethics issues, 78

- Minority subject enrollment, 251

Misconduct in research

- Anesthesiologist, pain drug data fabrication admission (D. Mass.), 56; guilty plea, 150; sentenced, 415

- Australian panel, 255

- Autism link to vaccines, U.K. MDs guilty, 85; *Lancet* retraction, 116; MDs struck from register, 350

- Bogus papers in scientific journals, 756

- Cancer, plagiarism and falsifying research, no federal jurisdiction (E.D. Pa.), 29

- Changed FDA procedures, IRB role, Special Report, 155

- Cost of probes, 567

- Data falsification, proposed rule, 138

- Debarment by HHS, no injunction (D.D.C.), 383

- Defamation claim by medical student against Univ. of Miami (S.D. Fla.), 107

- Duke cancer researcher resignation, 763

- Harvard biologist, 565

- Integrity studies, HHS grants, 145

- Paxil clinical trial records (E.D. La.), 589

- Retraction sought by Mayo Clinic, 384

- Univ. of Medicine & Dentistry grant application (D.N.J.), 696

- Modern drug design theories questioned, 656

- Natl. Toxicology Program, 692

- Offsetting costs with tax credits and incentives, BNA Insights, 505

- Outlook 2010, 5

- Paperwork burden, 785

- Physician-investigator duties, 659

- Portland State Univ., Or. biotech funding, 114

- Pregnancy and drugs, FDA collaboration with private researchers, 22

- Public disclosures and drug development, BNA Insights, 767

- Qualification of drug development tools, 691

R&D tax credit

- Extension. *See* LEGISLATION, FEDERAL, HR 4213, S 1203

- Flexibility at Obama administration, 143

- GOP senators seek improvements, 144

- St. Louis Univ., new medical research center, 113; ex-Pfizer staff, 148

- Stem cell research. *See* STEM CELL RESEARCH

- Stimulus funding and medical research, report, 139

- Stroke research, BNA Insights, 534

- Traditional business model criticized, 517

- Transition to treatment. *See* LEGISLATION, FEDERAL, S 914

- Translational medicine center at NIH, 786

- Translational research, FDA promotion, 94

- U.S. global leadership in medical innovation, 410

Women

- HIV studies, women underrepresented, 621

- Progress in research, 621

RUSSIA

Clinical trials

- Accreditation, 585

- Health insurance requirement, 625

- Medicines circulation law signed, 250

S

SAFETY

Avandia. *See* AVANDIA
Clinical trials, FDA reporting rule, 612
Contamination at Pfizer facility, jury award for fired scientist (D. Conn.), 206
EHR and patient safety, 623
Nanotechnology
—FDA program. *See* LEGISLATION, FEDERAL, S 2942
—Toxicity research urged, 224
—White House panel raises issues, 224
Radiation dosing, 80
Safety Report Portal, FDA-NIH announces, 345
Sentinel Initiative, FDA safety monitoring system, 50;
Harvard Pilgrim contract award, 51
Tissue sample management, HHS panel FAQs, 189

SECURITIES

Harvard Scientific misstatements (7th Cir.), 615
Sequenom genetic studies, class action settlement (S.D. Cal.), 86

SPAIN

Patient-oriented innovation pushed, 218

STEM CELL RESEARCH

California
—Acceptable research material rule, In Brief, 113
—Amended rules, 458
—Bond measure, 760
—Consolidating CIRM requirements, 83
—Cooperation with Wis., 412
—Donation of embryos, 113
—Funding bills approved by panel, 180
—Grants
— —Early transaction awards, 694
— —Investigator incentives, 286
— —Status of institutions, CIRM report, 83
—Loan, guidelines approval, 113
—Outreach to industry, 790
—Oversight of CIRM, Senate bill, 146; action suspended, 316; approved, 561
—Pact with Md., 728
—Strategic review, 626
Clinical trials
—Clearance from FDA, 750
—Enrollment, 651
—Trial enrollment, 651
Definition of human embryo stem cells, NIH, 134
EU, stem cell bank services, no VAT exemption, 371
Evaluating treatments, website, 375
Funding
—California. *See* California, *this heading*
—First hESC line, approval recommendation, 74
—Ill. grants, 254
—Implementation. *See* LEGISLATION, FEDERAL, HR 6081, S 4808, S 3751, S 3766
—Induced pluripotent stem cells, NIH grant, 77
—Md. funding, 253
—N.Y. funding, 220
—Regenerative medicine financing, 647
—Wicker opposes, 610
Guidelines
—Natl. Academies, 337
—NIH guidelines challenged (D.C. Cir.), 397; enjoined (D.D.C.), 547; order stayed, 579; injunction lifted, 605
Human study cleared by FDA, 479
Md. pact with Cal., 728
Medicare coverage, 517
Okla. reporting rule, 84; system, 492
Patents
—Related patents analysis, 171
—WARF patent invalid for obviousness (B.P.A.I.), 269
Potential new treatments, testing on pluripotent stem cells, 248

Registry, NIH adds 13 lines, 273; more lines added, 404

Third-party gamete donor consent, 140
Transplant coverage denial (D. Neb.), 211
U.K. physician sanctioned, 630

SUPREME COURT, U.S.

AIDS/HIV
—Drug evaluation methods (rev grant), 685
—Stanford AIDS therapy, rights assignment (briefs sought), 397
—University patents and Bayh-Dole (briefs sought), 397
Anthrax vaccine approval upheld (rev den), 136
Cialis inventorship (rev sought), 658
Nigeria, Trovan clinical trial injuries (brief filed), 368; (rev den), 401; limited discovery (S.D.N.Y.), 689
Nuclear waste, interstate disposal compact between Ala. and N.C. (oral arg), 54; no liability for N.C., 377

SWEDEN

Destruction of data by researcher, 731

T

TAXATION

Clinical trials, Special Report, 733
Offsetting costs with tax credits and incentives, BNA Insights, 505
R&D credit extension. *See* LEGISLATION, FEDERAL, HR 4213, S 1203

TERRORISM

Biodefense chief needed, 617
Boston biocontainment lab evaluation, 754
Detecting biological events, GAO recommendations, 16
Dual use
—Life scientists educational materials, 583
—Transparency and stakeholder education, 615
Emergency countermeasures, HHS strategy, 554
Ft. Dietrick biocontainment labs environmental impact, 181
Ideological approaches to developing countermeasures, 281
Options for Congress, CRS reports, 520
Project BioShield challenges, CRS report, 78; update, 455
Sequence-based system urged, 519
Shortcomings in DHS lab assessment, 753

TEXAS

Cancer
—Funding, 84; rules, 525
—Prevention and Research Inst., 26; rules issued, 148
Conflicts of interest rules, 26
Privacy, newborn blood collection settlement (W.D. Tex.), 25

TROVAN

Antibiotic clinical trial injuries (U.S., brief filed), 368; (rev den), 401; limited discovery (S.D.N.Y.), 689
Nigerian settlement disbursement ground rules, 73

U

UNITED KINGDOM (UK)

Animal testing, intimidating workers, 590; sentencing, 697
Informed consent, unauthorized tissue and organ removal, 763
Stem cell physician sanctioned, 630

V

VACCINES

Anthrax vaccine approval upheld (U.S., rev den), 136
Autism link to vaccines, U.K. MDs guilty, 85; *Lancet* retraction, 116; MDs struck from register, 350

Polio vaccine creator ADA suit (E.D. Pa.), 647
Synthetic biology, House hearing, 339

VETERAN'S AFFAIRS

Conflicts of interest, VA advisor and Medtronic, 794
Human experimentation suit against CIA, DOD, Army (N.D. Cal.), 57; partial dismissal, 85
Human subject protection quality indicators, 801
Oncologists disbarment, hearing denial, 181

VIRGINIA

Human subject rules, 180

VYTORIN

Cholesterol drugs link to cancer unlikely, 29

W

WARFARIN

Anticoagulant drug, Medicare clinical trials, 16

WASHINGTON

Cancer registry, 492

WEIGHT LOSS PRODUCTS AND PROGRAMS

Meridia, withdrawal planned, 650

WISCONSIN

Cancer registry, 492

WOMEN

HIV studies, women underrepresented, 621
Progress in research, 621

Z

ZETIA

Cholesterol drugs link to cancer unlikely, 29