Will proposed bills find new political life?

Several could impact human subjects research

There have been a handful of bills introduced in the past few years that could have an impact human subjects research.

Although these have not succeeded in past Congressional sessions, several research ethics experts say there is a possibility the same bills will find greater success in 2009 and beyond as a new Congress and President Barack Obama make some changes.

Here are the most likely bills to be given a second look:

• **S. 3807** — The Fair Access to Clinical Trials (FACT) Act: First introduced by Sen. Christopher Dodd (D-CT) in 2005 as S. 470, the FACT Act would require the Food and Drug Administration (FDA) to expand the clinicaltrials.gov database to create a national data base that could be viewed by the public. It would include details about ongoing clinical trials and their findings, whether or not these were published. Sen. Michael B. Enzi (R-WY) introduced S. 3807 in 2006, and it received a hearing, but no further action.

• **HR 5605** — Physician Payments Sunshine Act of 2008: This bill would amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies that receive reimbursement under Medicare, Medicaid, or SCHIP.

• **HR 7140** — Human subjects research protection: U.S. Rep Diana DeGette (D-CO) introduced in September, 2008, an amendment to the Public Health Service Act, for the protection of human subjects in research. The bill was referred to the subcommittee on health.

• HR 7141 — Human embryonic stem cell research: DeGette sponsored an amendment to the Public Health Service Act to provide for human embryonic stem cell research and to direct NIH to issue guidelines for such stem cell research. The amendment was referred to the House subcommittee on health in September, 2008. ■