



May 21, 2015

Committee on Energy & Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Representatives Upton, DeGette, Pallone, Pitts, and Green:

On behalf of more than 14,000 RELX Group (formerly Reed Elsevier) employees in the United States, I write to applaud the dedication and leadership that you and the Committee on Energy & Commerce have demonstrated by working in a bipartisan fashion toward accelerating health discovery and development in the 21st Century Cures Act – H.R. 6. I am especially supportive of the sections listed below. These additions will reduce burdens and otherwise incorporate sensible clarifications which seek to ensure that access to clinical information remains unburdened.

Through its subsidiaries Elsevier and LexisNexis, RELX Group is a world-leading provider of professional information solutions in the Science, Medical, Legal and Risk and Business sectors. Elsevier provides leading-edge information solutions that enhance the performance of science, health, and technology professionals, empowering them to make better decisions, deliver better care, and make groundbreaking discoveries that advance the boundaries of knowledge and human progress. Elsevier provides web-based, digital solutions — among them ScienceDirect, Scopus, Elsevier Research Intelligence, and ClinicalKey — and publishes nearly 2,200 journals, including The Lancet and Cell, and over 33,000 book titles, including a number of iconic reference works.

We applaud the Committee on Energy & Commerce for its bipartisan leadership in two areas in particular, and we offer our strong support for their inclusion in the 21st Century Cures Act.

Section 3041 – Exempting from Manufacturer Transparency Reporting Certain Transfers Used for Educational Purposes

RELX Group strongly supports the language in Section 3041, a modified version of Representatives Burgess and DeFazio's Protect Continuing Physician Education and Patient Care Act – H.R. 293. We believe that Representatives Burgess and DeFazio have correctly recognized the intent of Congress and its educational exclusion to the reporting requirement under the Sunshine Act. We strongly support the underlying congressionally conceived principles of transparency in the Sunshine Act, and agree that the exclusion to the reporting requirement for educational materials that directly benefit patients is appropriate. Peer-reviewed medical textbooks, medical journals, journal reprints, and continuing medical education are important tools which allow physicians to be better informed and therefore provide better care to patients. A 2001 Agency for Healthcare Research & Quality (AHRQ) study factsheet noted that “[i]t may take as long as one or two decades for original research to be put into routine clinical practice. Thus, the translation of research findings into sustainable improvements in clinical practice and patient outcomes remains a substantial obstacle to improving the quality of health care.” We applaud Dr. Burgess, Congressman DeFazio and the Committee for recognizing that there should be no unnecessary delay to improving quality of care and for including this common sense clarification to the Sunshine Act which properly reflects the original intent of Congress.

Sections 2241 – Health Software

RELX Group also supports the inclusion of the language in Section 2241, a modified version of the SOFTWARE Act, in the 21st Century Cures Act. We believe that Representatives Blackburn, Green and 38 others have found the proper balance of regulatory oversight needed while the drive for innovation in clinical software is preserved for informational decision support tools. We support the definitions of “medical software,” and “health software” which appropriately draw a distinction between software and content designed to be used in concert with the skills and training of a clinical professional, and software that would more directly interact with medical devices. Evidence-based clinical decision support tools help highly trained clinicians make real time decisions with a proven history of success at minimal risk. Our tools are supported by time-tested, evidence-based practice. Overregulation of such tools could severely burden the continued investment in and creation of newer and better ways to care for patients at lower cost. We applaud Representatives Blackburn and Green and the Committee for including this sensible approach to prevent overregulation to the detriment of innovation.

In addition, RELX Group strongly supports several other priority areas that will improve researchers’ ability to make scientific discoveries more rapidly. They include:

- promoting greater access to government data to for the purposes of further research;
- accelerating the discovery, development, and delivery of innovative cures, treatments, and preventive measures for patients through public-private collaboration;
- accessing, sharing, and using health data for research purposes in a manner consistent with responsible privacy practices;
- helping young and emerging scientists;
- prioritizing high risk, high reward research; and
- reducing administrative burdens for researchers.

We again congratulate the Energy & Commerce Committee for its work on this important legislation. Should you have any questions, please feel free to contact Adam Huftalen, Senior Manager of Government Affairs at 202.857.4644 or by email at adam.huftalen@relxgroup.com.

Warmest regards,



Youngsuk “Y. S.” Chi
Chairman, Elsevier
Director, Corporate Affairs, RELX Group

CC: Representatives Burgess, DeFazio, and Blackburn

ⁱ Translating Research Into Practice (TRIP)-II. Agency for Healthcare Research & Quality.
<http://archive.ahrq.gov/research/findings/factsheets/translating/tripfac/trip2fac.pdf>