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21st Century Cures Act Benefits Biopharma Co. Data Use

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One of the most important provisions of the 21st Century Cures Act,[1] signed by the president on Dec. 13, is the substantial change in the historic, restrictive position of the U.S. Food and Drug Administration regarding what evidence can be provided by drug manufacturers to buyers and prescribers regarding the performance of drugs and biologics. The new act, at Section 3037, authorizes for the first time the dissemination of health care economic information (HEI) for use by those selecting drugs and biologics for coverage and reimbursement. The broad authorization to use HEI is likely to be one of the most far-reaching practical changes for the biopharma industry resulting from the act, for both product manufacturers and for payors, and can be expected to significantly transform the selection process of drugs and biologics and the evidence developed to promote their use.


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Specifically, the new act authorizes provision to "a payor, formulary committee or other similar entity" responsible for "the selection of drugs for coverage or reimbursement" of health care economic information. The act specifically eliminates the requirement that information provided to such entities be based only "on competent and reliable scientific evidence," a provision that has been relied on by the FDA to attempt to restrict the dissemination of health care information to evidence derived from controlled, double-blinded, clinical trials.[2] While health care economic information has increasingly been demanded by payors, in view of concerns regarding comparative and cost effectiveness, the absence of any clear legal authorization for provision of such information has hampered its development and dissemination.

Key Takeaways

- Broad definition of HEI clearly allows for broad comparisons of therapies, including surgery and dietary changes, as well as comparisons to other drugs and biologics
- Suggests ability to use economic evidence and analyses, including health care outcomes effectiveness research and epidemiological analyses
- Requires no implementing actions by FDA
- Supports growing efforts by payors and manufacturers to successfully develop risk-sharing and performance-based agreements
- Provides further pressure on FDA to change its restrictive rules on using truthful and nonmisleading information in off-label promotion

The new act expressly broadens evidence that can be provided to payors to also include health care economic information, and defines such information broadly, to include:

> … any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention or to no intervention.

This broad definition clearly allows for broad comparisons of therapies, including medical devices, surgery, dietary changes, rehabilitation and exercise, as well as comparisons to other drugs or biologics. It also clearly contemplates the ability to use economic evidence and analyses, including outcomes effectiveness research and epidemiological and retrospective analyses, regarding which the FDA would have objected to previously. Importantly, unlike some other provisions of the new act, this provision requires no implementing action by the FDA. The provision's self-executing nature thus will make efforts by the FDA to restrict the use of HEI under the new act significantly more difficult than with respect to other provisions of the act which will require FDA action to implement.

The rise in spending on drugs, to a record $425 billion in 2015,[3] has focused payors on efforts to assure that drugs they select have real-world positive effects on their covered patients.[4] This provision strongly supports the growing efforts in recent years of payors and manufacturers to develop "risk-sharing" or "performance-based" agreements, which have presented the promise of more closely calibrating drug selection and use to patient outcomes and potentially aiding in cost containment.[5] Over the past year, numerous risk-sharing and performance-contracting agreements have been reported, in which drug selection and pricing/discounting are dependent on measurable goals and provision and development of health care economic information:

- Harvard Pilgrim Health Care contract with Amgen (for Repatha)
- Cigna and Express Scripts agreements with Amgen (for Repatha) and Sanofi/Regeneron (for Praluent)
- CVS Health value-based agreement with Amgen (for Repatha)

- Cigna outcomes-based contract with Merck (for Januvia)
- Aetna and Cigna outcomes-based contracts with Novartis (for Entresto)

Several payors, including Wellpoint and United BioSource, have developed principles for conducting and providing HEI to assist them in selection decisions,[6] and the new act will encourage the spread and further development of these efforts by payors and formulary committees. Responding to this demand will require expansion by product manufacturers of their capabilities to develop and defend HEI that they submit in support of their products and the prices desired for them.

While the act precludes dissemination of health care economic information that relates only to an unapproved, off-label indication, the new authorization to disseminate health care economic information to assist payors and formulary committees and others responsible for selecting drugs likely will also provide additional pressure on the FDA to implement changes in its restrictive rules regarding dissemination of truthful and nonmisleading information regarding off-label uses of approved drugs and biologics.

Changes in the FDA's restrictive approach to off-label promotion, accelerated by a series of judicial reverses suffered by the agency, are controversial, including among some in the medical community concerned regarding the movement away from sole reliance on clinical studies.[7] The new act, however, is consistent with the position recently expressed by the two leading biopharma industry associations, PhRMA and BIO, who suggested principles for the sharing and development of truthful and nonmisleading information about medicines, noting that "biopharmaceutical companies should be able to communicate certain information to insurance providers, pharmacy health benefit managers and government health programs, so they may consider whether to reimburse for the medicine and account for the potential cost of the new medicine."[8]

The increasing demand for HEI, and the ability to use it under the act where it need only "relate" to an on-label use, provided there is "a conspicuous and prominent statement describing any material differences" between the HEI and the product's label, will provide broad opportunities to biopharma manufacturers to provide HEI. While the FDA will be unable to readily prevent dissemination of health care economic information authorized by the new act, the agency can be expected to closely review and potentially take action against use of HEI that it concludes is insufficiently supported. To effectively do so, the FDA would likely need to hire economists who can properly evaluate the HEI being disseminated. Similarly, while the Federal Trade Commission has not commonly reviewed prescription drug and biologics promotion, it may be more likely to do so with respect to use of HEI, in view of its large economic analysis staff and capabilities in assessing use of economic information in product promotion.

The new act's clear authorization for use of HEI, and its broad definition of what constitutes HEI, thus can be expected to result in a substantial transformation of drug promotion and payor selection decisions, with significant effects on competition and promotion in the biopharma industry.

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[1] H.R. 34, Pub. L. 114-255 (signed Dec. 13, 2016).

[2] See K. Sanzo & S. Mahinka, "Prescription Drug Promotion and Marketing," in Food and Drug Law and Regulation 409, 437-438 (3d ed. 2015).

[3] IMS Health, National Sales Perspectives (January 2016).

[4] See "Health Insurers Push to Tie Drug Prices to Outcomes," Wall Street Journal (May 1, 2016).

[5] See J. Cohen, A. Malins & Z. Shahpurwala, "Compared to U.S. Practice, Evidence-Based Reviews in Europe Appear to Lead to Lower Prices for Some Drugs," 32 Health Affairs 762 (April 2013).

[6] See S. Mahinka, " Imperative: Comparative Effectiveness Research," LMG Life Sciences Guide 2013, 18, 20.

[7] See C. Robertson & A. Kesselheim, "Regulating Off-Label Promotion – A Critical Test," New England J. of Medicine 2313, NEJM.org (Nov. 2, 2016).

[8] PhRMA and BIO, "Principles on Responsible Sharing of Truthful and Non-Misleading Information About Medicines with Health Care Professionals and Payers", at 4 (July 27, 2016).
