An Opportunity for Demand Side Innovation

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Rebecca S. Eisenberg & W. Nicholas Price II, *Promoting Healthcare Innovation on the Demand Side*, **Oxford Academic J.L. & Biosciences** (2017).

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The intersection of healthcare information goods, resulting products, and the legal system is frequently reduced to unhelpful binary generalizations such as "regulation (particularly drug safety and data laws) impedes innovation." Eisenberg and Price helpfully consign such caricatures to the past, substituting far more nuanced (and a lot more interesting) reflections on healthcare and innovation.

Their primary contribution is to describe a different idea of innovation; one based on the demand side rather than the supply side. This is to be contrasted with the "Innovation Law Beyond Intellectual Property (IP)" literature which has examined non-IP mechanisms such as grants, prizes, or insurance to incentivize innovation without utilizing exclusionary patent rights. Those approaches, while they may have been shaped on the demand side, are executed on the supply side (such as a government subsidy paid to a drug company to encourage production of an unprofitable drug). In contrast, Eisenberg and Price are interested in true demand-side innovation based on the data accessible to payers; providers or insurers and, optimally, vertically integrated stakeholders such as large HMOs. These payers, the authors argue, could leverage the enormous clinical and prescribing data sets they can access "to develop new information about drug toxicity, comparative effectiveness, precision medicine, and to perform other forms of innovation." If successful, "[t]he incentives of payers to cut costs… could be a corrective counterweight to the incentives of product sellers to maximize their own patent-protected profits."

This counterbalancing idea is a smart one given the poorly functioning marketplace that is healthcare's fate. Currently, supply-side pharmaceutical companies can transfer their information goods into IP-protected profit centers. Thereafter, even major payers such as private insurance companies have difficulty negotiating down drug prices while federal law embarrassingly prohibits price negotiation for Medicare Part D drugs. Essentially, Eisenberg and Price are encouraging payers to undertake roles such as "new technology assessment" (NTA) that in other healthcare systems are undertaken by regulatory or independent agencies. For example, the UK's National Institute for Health and Care Excellence and the German Institute for Quality and Efficiency in Health Care evaluate new drugs on the basis of their comparative or cost effectiveness. Their findings determine whether such drugs are included in the national formulary (UK) or subject to reference pricing (Germany). There are few regulatory analogs in the U.S. and the closest one, the Patient-Centered Outcomes Research Institute (PCORI), is expressly prohibited from using the classic NTA outcome measure, the quality-adjusted life year.

The authors recognize that the opportunity for demand-side innovation faces practical barriers. The data

required is often hopelessly fragmented; payers may have the opportunity to innovate but, the vertically integrated aside, few will have the incentive; and (because no paper on innovation is complete without a criticism of dear HIPAA) they argue that data laws may hinder access to or use of clinical data. Equally, the examples the authors give of government programs that could help demand-side innovation (Meaningful Use, the FDA Sentinel System, and PCORI) are hardly shining examples of regulatory home runs. However, maybe some of the provisions of the recently enacted 21st Century Cures Act will turn those around. That legislation also raises the interesting question whether those on the supply side increasingly will be interested in demand-side data given the increasing role of patient experience and clinical data in the drug approval process.

The decline in the number of breakthrough drugs suggests supply-side innovation is slowing, and the authors also note the pharmaceutical industry's ambivalence to a successful precision medicine initiative. Equally, we may not yet have reached the inflection point for data-driven analysis on the demand side, and we are a long way from realizing the benefits of patient access to useful information built on such data. However, although the balance of innovation power remains on the supply side, Eisenberg and Price provocatively suggest that should change. If the authors' predictions play out it will be interesting to see whether the result will be demand-led safer and cheaper products, or whether the supply side will demand increased IP and other rewards to reassert the supply-side imbalance.

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