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#### HEALTH CARE LAW

##### THE HATCH-WAXMAN ACT'S SIDE EFFECTS: PRECAUTIONS FOR BIOSIMILARS

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The Drug Price Competition and Patent Term Restoration Act of 1984 (generally known as the Hatch-Waxman Act, or “Hatch-Waxman”) was designed to expedite regulatory approval of generic drugs while simultaneously preserving incentives for innovators to invest in the research and development of new drugs. While Hatch-Waxman has undoubtedly achieved its aim of creating a robust generic pharmaceuticals market, it has also produced several unanticipated consequences. Its changes to the federal regulatory scheme have yielded convoluted products liability rules, upsetting the conventional notion that the seller of a defective product is liable for harm caused by its intended use. In addition, its modifications to patent law have had the perverse effects of propagating patents of questionable value and encouraging potentially anti-competitive agreements between generic and brand name manufacturers.

Hatch-Waxman’s emergent repercussions are particularly salient in light of the recent passage of the Biologics Price Competition and Innovation Act (BPCIA). The BPCIA, enacted as part of the Patient Protection and Affordable Care Act of 2010, crafted a compromise between pioneer and follow-on biologics manufacturers patterned after Hatch-Waxman’s regulatory scheme for pharmaceuticals. This Article reviews Hatch-Waxman unintended effects, and suggests that they should serve as precautionary guideposts for

implementation of the BPCIA. The FDA and lawmakers should heed these potential pitfalls and proactively confront unavoidable tradeoffs between safety, cost, and access to therapeutic biologics.

REDEFINING MEDICAL NECESSITY: A CONSUMER-DRIVEN SOLUTION  
TO THE U.S. HEALTH CARE CRISIS

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The American health care system is plagued by high costs and poor public health outcomes, due in part to the overuse of costly diagnostic tests and treatments. In 2009, the Institute of Medicine estimated that unnecessary care wastes \$750 billion, equivalent to about 30 percent of health care spending. Moreover, overtreatment can directly harm patients as a result of surgical complications, drug toxicity, and hospital-acquired infections.

Yet while the problem of medical waste has long been recognized, solving the problem has proven elusive. In part, this difficulty is due to perverse economic incentives for physicians and hospitals, which still primarily receive reimbursement on a fee-for-service basis. Providers are financially motivated under this system to generate a higher volume of invasive procedures independent of their likely benefits. Patients generally lack the information needed to decline unnecessary services, even when they wish to actively share in medical decision-making, and a strong cultural bias pushes both patients and physicians to “do more,” even when evidence suggests that doing more may result in harm. In the 1990s, managed health care organizations attempted to rein in health care waste by stringently reviewing and prospectively denying payment for unnecessary tests and treatments, but that experiment was a political failure. Similarly, attempts to reduce overuse by shifting financial risk directly onto providers through capitated payment mechanisms have had limited success. The ability of these mechanisms to limit waste is compromised by the real or perceived incentive to also reduce spending on appropriate care.

We propose a new conception of medical necessity that will reduce inappropriate care by allowing informed consumers to actively participate in decisions about their medical care. Where evidence-based guidelines are available, medical necessity should be determined on the basis of an objective, multi-level Matrix of Appropriateness rather than the subjective binary decision of an insurance company’s medical reviewer. Such Matrices have already been created by systematically combining published evidence with expert judgment to create clinically detailed, evidence-based, multi-level medical necessity ratings for elective procedures based on individual patient characteristics. In our proposed system, if a patient desires a service proposed by a physician under clinical circumstances that receive low medical necessity ratings, the third-party payer would offer to cover the service but at a sliding co-payment scale imposing greater patient cost sharing based on the service’s appropriateness. This system would preserve patient choice while discouraging the overuse of costly treatments that

provide little marginal value, reducing medical waste and improving the overall value of medical care.

## COMMENTS

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