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Amidst an explosion in digital health investment, increasingly frequent cybersecurity attacks, and a scattered health information privacy regulatory framework, the digital health marketplace requires a clear, measured approach to consumer safety, data privacy, and cybersecurity legal requirements. While scholars have generally proposed increased regulatory activity in cybersecurity, they generally have not taken a multi-disciplinary approach, integrating technology and law to advance a consolidated regulatory framework for digital health. Leveraging existing U.S. Food and Drug Administration (FDA) processes with enhanced oversight will create the framework necessary to simultaneously protect patients while providing clear direction for businesses producing digital health products and services. The Federal Food, Drug, and Cosmetic Act is well-positioned to regulate cybersecurity for the United States digital health marketplace.

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The use of data has huge implications for our economic interests both domestically and globally. In healthcare, the free exchange of such data may help consumers make better health decisions and engage in their care. Practitioners could avoid costly mistakes and duplicate testing, and the government could evaluate the actual value of services provided. This paper looks at the regulation of health information both domestically and internationally with a focus on Canada, our largest trading partner. Often, regulatory schemes harmonized between our two countries pave the way for further harmonization efforts internationally.

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Inappropriate and underregulated use of antibiotics threaten public health by increasing antibiotic resistance of bacterial infections, and in turn, making them more difficult to treat. This article emphasizes the need for legally binding standards to reduce misuse and stimulate the development of antibiotic drugs. It suggests that the Food and Drug Administration (FDA) impose a Risk Evaluation and Mitigation Strategy (REMS) restriction on novel antibiotic drug products to conserve their use and prevent misuse. Further, this article urges Congress to implement statutory reform to incentivize innovation in antibiotic development. Passing new statutory and regulatory guidelines will take time, coordination, and perseverance. Until a new regulatory regime surrounding antibiotics is established, policymakers should work within existing statutory frameworks to curb resistance by using the Orphan Drug Act (ODA) to spur antibiotic innovation and the Controlled Substance Act (CSA) to promote antibiotic conservation.