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IP Policy Forum: Drug Development - Translating Basic Research Into New Medicines - and This Issue of IPLR

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DRUG DEVELOPMENT – TRANSLATING BASIC RESEARCH INTO NEW MEDICINES – AND THIS ISSUE OF IPLR

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I was privileged to serve as U.S. Secretary of Health and Human Services (HHS) from 2001-2005, appointed by George W. Bush. HHS oversees the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). NIH is the main agency in the U.S. responsible for funding biomedical research—largely in our universities. During and after my tenure at HHS, I have seen exciting advances in biomedical and pharmaceutical research, including the development of many new medicines, and the sequencing of the human genome. This is an exciting time in history, where we now know more about human biology and are better positioned than ever before to develop new medicines. We are also seeing increased innovation and collaboration between universities and industrial partners, to address unmet medical needs. These scientists are attempting to bridge the large gap—referred to as the "valley of death"—between basic research discoveries in academic labs, and drugs in the clinic. NIH grant funding is increasingly being used to translate basic research into the next generation of therapeutics, effectively bridging this gap. This evolutionary change in how drugs are developed will not be without its new challenges, and this issue of the Marquette Intellectual Property Law Review (IPLR) discusses many of them: patenting of biologics-based drugs, drug repositioning in academic research labs, access to clinical trial data, and international IP issues surrounding access to medicines. Innovation in the science of drug development will inevitably be coupled to public policy debate that shapes the legal and regulatory structures that support these advances. The articles presented herein will further this important dialog.