2021 Spring Newsletter

The Center for Integration of Science and Industry at Bentley University proudly announces the third issue of its biannual newsletter. Despite continued challenges presented by COVID-19, we have hosted and participated in virtual events, continued to publish our work, and expanded our team. We are excited to continue our collaboration with the WestHealth organization on some of our projects.

Please visit our website for more updates.

Reforming the Business of Pharmaceutical Innovation

The pharmaceutical industry is continuously changing. Today, however, change is being driven by business and consumers rather than science and technology. We explored this path forward with discussants during our sponsored workshop series in March.

For decades, changes in the pharmaceutical industry have been led by the emergence of powerful new technologies, ranging from genetic engineering, genomics, and structural biology, to combinatorial chemistry and informatics.
Today, consumers, patients, employees, and taxpayers are driving innovation by demanding greater value from new medicines, patient-centered innovation, lower drug prices, increased corporate and governmental accountability, and a seat at the table as stakeholders in shaping the priorities, product portfolios, and profits of the biopharmaceutical industry.

A central theme of our workshops was articulated by Ed Freeman, who commented on the interdependency of the many stakeholders in the pharmaceutical business as well as the fallacy of separating the interests of business from those of society. These interdependencies were evident in new research described by Frank Lichtenberg, who demonstrated the ongoing impact of pharmaceutical innovation on longevity as well as by discussions of new therapies for previously untreatable diseases, the measurable value (QALYs) provided by new pharmaceutical products, and incremental innovations that improve compliance or offer therapeutic options to those not adequately treated by existing products. Interdependencies were also evident in discussions of the roles played by the public and private sector in drug development and measurement of the economic and health impacts of pharmaceutical innovation.

There are also many conflicts. Rick Alexander articulated this problem by asking what happens when the interests of shareholders and other stakeholders diverge. Cynthia Clark addressed the structures of corporate government, which can often be exploited to give shareholders disproportionate power over other stakeholders. These conflicts are manifest in the perception that drug prices are too high, that companies are too profitable, and that companies are profiteering from taxpayer investments in biomedical research; in the limited efficacy of many new therapies in clinical trials and limited progress towards addressing global health needs; in the exploitation of government-granted monopolies for new drugs and government funded research for shareholder benefit; and in the growing economic inequalities exacerbated by stock-based executive compensation and buybacks.

Among the issues addressed during the workshops was the need for greater transparency regarding the costs of developing and commercializing new drugs, the contributions of both the public and private sectors to pharmaceutical
innovation, the role of government-granted monopolies in pharmaceutical markets and profits, and the equity of the benefits that accrue to shareholders and other societal stakeholders. There was also discussion of the need to reformulate the balance of risk and reward associated with technology transfer, assure high standards of safety and efficacy of products granted expedited approvals, and to either rationalize or regulate drug pricing. Other themes were the need to better define the roles of public policy and market forces, the multiplex value arising from pharmaceutical innovation, and how to effectively invent, implement, and sustain meaningful changes without disrupting future innovation.

The roles of various stakeholders in pharmaceutical innovation provided a frame of reference throughout these discussions. Reforming the business of pharmaceutical industry requires that we recognize the contributions, capabilities, and constraints of many disparate stakeholders, respect that their interests and incentives often diverge, and fully realize the synergies between consumers, markets, science, healthcare, business, and government to provide benefits equitably to each stakeho. The impetus for change is too urgent, the insights of science are too powerful, and the resources of industry are too great not to be optimistic about the future.

Please visit our [website](#) for more information about our workshops.

**Publications**

“Late-Stage Product Development and Approvals by Biotechnology Companies After Initial Public Offering, 1997-2016” reports that 319 biotech companies completed IPOs from 1997-2016, contributing to 367 phase 3 products and 144 approvals. Companies had a 78% probability of a product reaching phase 3 and a 52% probability of approval. Small-molecule drugs represented 74% of products reaching phase 3 and 78% of approvals. Reformulations represented 36% of phase 3 products and 46% of
approvals. Approvals included 78 new molecular entities (NMEs), of which 44% were first-in-class.

“Comparing long-term value creation after biotech and non-biotech IPOs, 1997-2016” reports that the financial structure of biotech companies is distinctly different from non-biotech companies. However, biotech and non-biotech companies had equivalent growth in market cap and shareholder value, and both cohorts exhibited a high-risk/high-reward pattern of return. We conclude that biotech company value creation after IPO resembles that of non-biotech companies.

“NIH funding for vaccine readiness before the COVID-19 pandemic” reports that between 2000-2019, the NIH contributed $17.2 billion towards published research on vaccine technologies, enabling the rapid development of COVID-19 vaccines. This supports the importance of sustained public sector funding for foundational technologies in the rapid response to emerging public health threats.

News & Events
In March 2018, we published a study on the “Contribution of NIH funding to new drug approvals 2010–2016,” demonstrating that every one of the 210 drugs approved in this time period traces its origin back to basic research supported by the NIH. The work, published in PNAS, continues to have an impact on public health policy. Michael Hiltzik wrote two articles in the LA Times referencing it in the context of the COVID-19 pandemic. The first article, published in November 2020, quoted the study in the context of NIH funding support of those 210 new drugs approved from 2010-2016. The second article, published in January 2021, highlighted the NIH involvement in COVID vaccine development and stated that “almost no drugs reach market in the US,” citing our work.
Also in January, Fred Ledley shared his insights on the profitability of pharmaceutical companies with The Academic Minute, a 2.5 minute daily module featuring university researchers from across the globe. Fred explained,

“Are pharmaceutical companies excessively profitable? This question cannot be answered by comparing financial numbers, but requires us to ask what is fair or unfair and it requires us to understand what constitutes a successful business, one that is capable of discovering and producing the drugs that the public needs. It also requires us to recognize that the drugs these companies produce are essential for people’s lives, and that the affordability and availability of drugs is not only a business issue, but also an issue of social justice and even human rights.”

In February 2021, Fred Ledley joined Hannah Kuchler (Financial Times) as a co-panelist for a discussion during a Bentley sponsored fireside chat, “Economics and Politics of COVID-19 Vaccine Financing.” He explained the role of NIH funding in the development of COVID vaccines and how this technology transfers to industry.

New Member Highlights
The Center for Integration of Science and Industry welcomed several new members to its team this year.

Juliana Harrison joined the Center as a Program Assistant in November 2020. She received her BS in Marketing and Liberal Studies (Health and Industry) from Bentley University and is pursuing an MBA. Her primary responsibilities consist of a variety of administrative, programming, and communications work to ensure smooth operation of the Center. This includes effective coordination and support of the Center’s meetings, events, filing system, publications, website, social media, and external relationships. She passionate about traveling and Italian cuisine.
Edward W. Zhou, PharmD, joined the Center as a Post-Doctoral Fellow in February 2021. He received his Doctor of Pharmacy degree from Massachusetts College of Pharmacy and Health Sciences. During his predoctoral internship, Edward worked with Pfizer Global Regulatory Affairs in organizing internal and public information databases for the pending FDA Oncologic Drugs Advisory Committee review. During his Newton-Wellesley Hospital rotation, Edward created adjustable python code packages for interpreting health outcome metrics from EPIC metadata. He has co-authored several peer-reviewed publications at Brigham and Women’s Hospital, Harvard Medical School, which focus on the identification of drug targets and novel pharmacotherapeutics for neurological disorders. His activities include the integration of research algorithms into existing database frameworks and the improvement of search field functionality and accuracy to expand the scope of future research projects. He is also passionate about Indian cuisine, cycling, and video game modding.

Research assistant Sarah Al-Masri is pursuing a Bachelor’s degree in Economics and Finance at Bentley University. She takes interest in Macroeconomics and Development Economics and her ultimate goal is to get her PhD. Sarah is interested in the Center’s mission, specifically how science can create public and social value. At Bentley, she is a peer tutor, a Worldview ambassador, and a member of the Bentley Open Market Committee and Women in Economics. She also plays the violin and is heavily involved in Alpha Psi Omega, the theater group at Bentley. Previously, Sarah has worked as a Broker Assistant (Intern) at AB Invest and a Market Risk Intern at Bank Al Etihad; both in Amman, Jordan, her hometown.
Research assistant Nishant Nagalia is a Junior in the Honors Program pursuing a Bachelor’s degree in Economics and Finance. At Bentley, he has held an executive board position for Bentley’s South Asian Student Association, and has worked both in the Economics Department and for Bentley’s Division 1 Hockey Team. Nishant previously interned for DoubleCheck Research, a tech consulting firm dealing with win/loss analysis, as a Research Associate. He will be interning at FactSet this summer in their Client Solutions Department and hopes to join a management consulting firm after graduation.

Research Assistant Elizabeth Czarniak is pursuing a Bachelor’s degree in Data Analytics with a Business Studies minor. She plans to graduate in August to begin a Master’s Program in Quantitative Biomedical Sciences at Dartmouth College in September, where she will pursue her passions for healthcare and Data Analytics. At Bentley, she is a Peer Academic Advisor and a member of the Alpha Phi Omega Service Fraternity. She enjoys fitness and spending time with her family during her free time.

**Alumni**

The Center sends well wishes to the 3 members who have recently “graduated”:

- Ekaterina “Kat” Cleary (Exponent)
- Franklin Bright (Vertex)
- Prateet Shah (Deloitte)

Center alumnus Kat Cleary took a dive into children’s book writing and is self-publishing her first picture book, “Adventures of Pierre the Munchkin” this Spring. Inspired by true events, the story is a whimsical dive into the secret life of her outdoor kitty, Pierre. Once published in hardcover, a copy will be donated to the Bentley University library.