A Drug's Journey

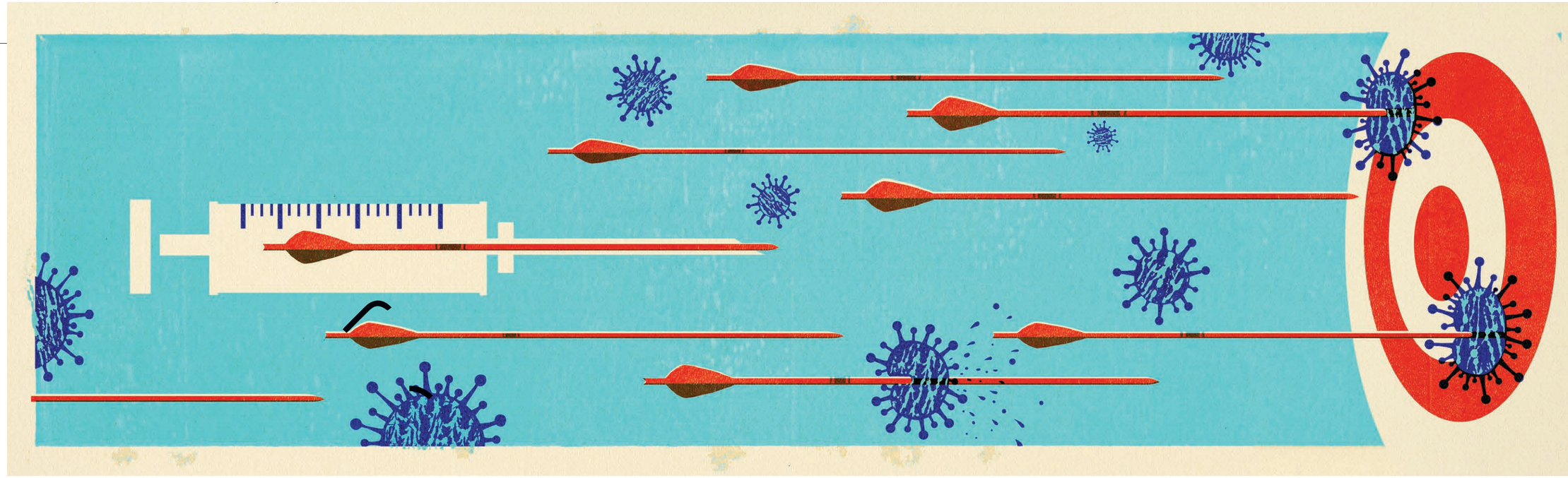
How lawyers make cures happen.

As the world's scientists race to find a vaccine for Covid-19, all eyes are on the biopharmaceutical industry. The time, money, and human resources needed to bring new drugs to market are enormous. Even before the pandemic hit, pharma was big business, growing by leaps and bounds to keep up with the burgeoning demand for treatments and cures for a host of diseases. One may think of pharma as within the purview primarily of scientists and engineers. But working alongside those who develop and produce new therapies are legions of lawyers who make sure that the legal i's are dotted and t's are crossed as a drug makes its arduous journey from idea to trials to finished product and beyond.

We wondered what, *exactly*, do lawyers in pharma do, what specialties do they bring to the process, and where along the drug development timeline do their skills intersect with the science, manufacture, sales, and marketing of the drugs being made?

The questions were put to Nikki Hadas '97, senior vice president and chief legal officer at Akebia Therapeutics in Cambridge, and her legal intern, BC Law student Iris Ryou '21. The information graphic at right provides their answers.

RESEARCHED AND WRITTEN BY NIKKI HADAS '97 AND IRIS RYOU '21



DRUG DEVELOPMENT

New Drugs

Medicines currently in development worldwide / **16,000**

Cost to Develop

$985 million
Median, 2009-2018

$2.8 billion
Most expensive: Oncology and immune-modulatory, 2009-2018

Success Rates (2000-2015)

13.8% / Phase 1 to Approval for all drugs

33.4% / **Highest:** Infectious diseases and ophthalmology

3.4% / **Lowest:** Cancer

Timeframe

10 / Years from discovery to commercialization (average)

3-6 / Years for initial discovery: Understanding the disease or condition and choosing a molecule to target

6-7 / Years for clinical development: Three consecutive phases

1/2-2 / Years for FDA review and scale up to manufacture

MASSACHUSETTS BIOPHARMA

47%
Increase in jobs since 2010

500
Biotech companies in the state

$4.8 billion / Venture capital investment 2018

12.4 million / Added square feet of commercial space in 10 years, a 70% increase

265,000,000
Number of patients receiving MA companies' therapies in the United States

2 billion / Number of patients receiving MA companies' therapies worldwide

LEGAL TOUCHPOINTS

INTELLECTUAL PROPERTY

1. During drug discovery and research phases, Intellectual Property (IP) lawyers identify key inventions and prepare and prosecute patent applications to protect them. This continues throughout drug development and commercialization, as new inventions are conceived and reduced to practice. Working with commercial and regulatory teams, IP lawyers select brand names that can be registered as trademarks for drug products and satisfy FDA regulatory requirements.

2. From initial discovery to marketplace, IP lawyers routinely conduct landscape analyses and monitor patents filed by companies with potentially competing products or patents. They may file invalidity or opposition actions to those blocking patents, defend such actions brought by other companies or institutions, and negotiate license agreements with those whose patents may cover the company's product.

3. IP lawyers bring actions against competitors who infringe the company's patents or trademarks or misappropriate trade secrets. They bring infringement suits against companies that seek to market a generic or biosimilar version of the company's innovator drug products.

CORPORATE • SECURITIES

1. Corporate lawyers provide legal support for financings and other capital raises to obtain the funds to develop a new medicine. The funds may be used for research, clinical trials, manufacturing, and other development activities.

2. Corporate lawyers support partnering activities, for example, collaborations with other biopharmaceutical companies that may have specific expertise and provide financial support for a drug's development. In such a setup, they draft and negotiate the collaboration agreement that forms the basis of the relationship and support the collaboration for the duration of the relationship.

CONTRACTS

1. When a company collaborates with an academic institution, hospital, or clinic on research, contract attorneys draft and negotiate the agreement between the parties.

2. Contract attorneys draft and negotiate agreements such as clinical trial agreements with sites performing clinical studies of a drug, contracts with vendors and consultants who support a drug's development, and supply agreements with drug substance and drug product manufacturers.

COMMERCIAL • COMPLIANCE

1. Commercial lawyers review marketing materials for a drug in preparation for launch and afterward ensure marketing materials comply with laws and regulations. They review educational and scientific materials, presentations, and publications to ensure compliance with rules regarding scientific exchange of medical information.

2. Compliance lawyers draft policies, train pharmaceutical sales representatives and other personnel, as well as conduct live monitoring and periodic audits to ensure personnel comply with laws and regulations, specifically, those related to product promotion and interactions with health care providers.

Sources: *PhRMA, "Biopharmaceutical R&D: The Process Behind New Medicines" (2015); "Innovation in the Pharmaceutical Industry: New Estimates of R&D costs,"* Journal of Health Economics; *"Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018,"* JAMA; *Pharmaprojects.*

Illustration by **DAN BEJAR**