JUNE 2026

WILSON SONSINI

THE LIFE SCIENCES REPORT

FDA Update: Accelerating New Therapies in the Midst of New Controversies

By Eva Yin (Partner, Seattle) and Dan Orr (Senior Counsel)

U.S. Food and Drug Administration (FDA) Commissioner Martin A. Makary resigned on May 12, 2026.[1] His chief priority for the FDA had been "accelerating cures"[2] and he sought to reevaluate "legacy processes at the agency that slow down decisions."[3] Over the past year, the FDA released a flurry of sometimes controversial policies to advance these goals. It is unclear how those programs and priorities will change after his departure.

Incentives for Domestic Manufacturing

About 80 percent of active pharmaceutical ingredients and over 90 percent of biologics are imported from outside the U.S.[4] Reliance on foreign pharmaceutical manufacturing has limited the Trump administration's tariff policy and has made onshoring of pharmaceutical manufacturing a national priority.[5]

The Commissioner's National Priority Vouchers (CNPV) was announced early in Makary's tenure. The CNPV program provides a nontransferable voucher for approval of a product that advances certain "national priorities," such as increasing domestic drug manufacturing or addressing an unmet public health need.[6] The voucher cuts FDA review time for the product from 10 months to less than two months and a final approval decision is made through a "collaborative tumor board-style."[7] The FDA has awarded 18 CNPV vouchers to date.[8] For example, the FDA approved the first-ever dual adeno-associated virus vector-based gene therapy under the CNPV program in 61 days after filing, the fastest Biologics License Application approval in modern FDA history.[9]

The agency has launched two other programs to bolster domestic manufacturing in the last year.

- The FDA PreCheck Program streamlines review of manufacturing facilities identified in marketing applications.[10]

In This Issue

[1] Rachel Roubein & Dan Diamond, FDA chief resigns amid agency turmoil, *Washington Post* (May 12, 2026), https://www.washingtonpost.com/health/2026/05/12/fda-chief-plans-resign-amid-agency-turmoil.

[2] Martin A. Makary, MD, MPH & Vinay Prasad, MD, MPH, *Priorities for a New FDA*, JAMA (June 10, 2025), https://doi.org/10.1001/jama.2025.10116.

[3] *Id.*

[4] FDA, FDA Globalization (Jan. 29, 2026), https://www.fda.gov/international-programs/fda-globalization.

[5] EO 14293, Regulatory Relief to Promote Domestic Production of Critical Medicines, 90 Fed. Reg. 19,615 (May. 8, 2025).

[6] FDA, FAQs: Commissioner's National Priority Voucher Program (June 17, 2025), https://www.fda.gov/news-events/press-announcements/faqs-commissioners-national-priority-voucher-program.

[7] FDA, Commissioner's National Priority Voucher (CNPV) Pilot Program, https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program (last visited: Apr. 22, 2026)

[8] *Id.*

[9] FDA, FDA Approves First-Ever Gene Therapy for Treatment of Genetic Hearing Loss Under National Priority Voucher Program (April 23, 2026), https://www.fda.gov/news-events/press-announcements/fda-approves-first-ever-gene-therapy-treatment-genetic-hearing-loss-under-national-priority-voucher.

[10] U.S. Food and Drug Administration, FDA Announces New FDA PreCheck Program to Boost U.S. Drug Manufacturing (Aug. 7, 2025), https://www.fda.gov/news-events/press-announcements/fda-announces-new-fda-precheck-program-boost-us-drug-manufacturing.

Continued on page 2...

FDA Update: Accelerating New Therapies . . . *(Continued from page 1)*

- The Advanced Manufacturing Technologies Designation Program encourages innovation of new manufacturing technology, such as continuous manufacturing, 3D printed drugs, and modular platforms.[11]

Both programs offer enhanced communication with the FDA and the ability to submit manufacturing data into a master file that can be incorporated by reference in a marketing application. The goal is to accelerate marketing approvals for products made in U.S. manufacturing facilities.

New Programs for Individualized and Orphan Therapies

The FDA has also sought to expedite approval of individualized therapies and treatments for rare diseases (orphan drugs). The FDA first announced the proposed "Plausible Mechanism" framework for individual and small group therapies in an interview on satellite radio.[12] The framework provides for FDA approval of new therapies that treat ultra-rare genetic conditions with as little clinical data as an N-of-1 patient study. Approval would then be confirmed using post-approval confirmatory data.[13] The agency issued draft guidance concerning the framework in February 2026.[14]

In September 2025, the agency released three new guidance documents concerning development of cell and gene therapy (CGT) products. The guidances have new advice concerning qualifying CGTs for expedited review[15], alternative clinical trial designs for small populations[16], and post-approval confirmatory data.[17] All three stress the importance of early interaction with the FDA, and the need for long-term planning with regulatory requirements throughout a product's lifecycle.

Congress also gave orphan therapies a boost. The Consolidated Appropriations Act of 2026 (CAA) reauthorizes the Rare Pediatric Disease Priority Review Voucher (PRV) program through September 2029, restoring a key incentive to develop therapies for rare pediatric diseases.[18]

Under the PRV program, a sponsor that obtains approval of a new drug or biologic to treat a rare pediatric disease can obtain a transferable voucher for priority review of a subsequent application.[19] The voucher reduces FDA review time for that application from 10 months to about six months. Because the vouchers are transferable, they are sold at rates of over $100 million.

In addition, the CAA clarifies that orphan drug exclusivity applies to the "same approved use or indication within a rare disease," rather than the entire rare disease or condition. The change abrogates the U.S. Court of Appeals for the Eleventh Circuit's decision in *Catalyst v. Becerra*[20] and aligns the statutory text with the FDA's longstanding policy.[21]

FDA Proposed Exclusion of Semaglutide, Tirzepatide, and Liraglutide on the 503B Bulks List

In April 2026, after reviewing nominations, the FDA announced its proposal to exclude semaglutide, tirzepatide, and liraglutide from the 503B

---

[11] U.S. Food and Drug Administration, Advanced Manufacturing Technologies Designation Program - Guidance for Industry (Dec. 2024), at 4, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/advanced-manufacturing-technologies-designation-program.

[12] Tristan Manalac, *Makary Discusses Expedited Rare Disease Approvals Pathway, 'Public Distrust' in New Interview*, Biospace (Apr. 21, 2025), https://www.biospace.com/policy/makary-discusses-expedited-rare-disease-approvals-pathway-public-distrust-in-new-interview.

[13] *See* FDA, *Considerations for the Use of the Plausible Mechanism Framework to Develop Individualized Therapies That Target Specific Genetic Conditions with Known Biological Cause - Draft Guidance for Industry* (Feb. 2026), https://www.fda.gov/media/191247/download.

[14] *Id.*

[15] FDA, *Expedited Programs for Regenerative Medicine Therapies for Serious Conditions: Draft Guidance for Industry* (Sept. 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-regenerative-medicine-therapies-serious-conditions-0.

[16] FDA, *Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations: Draft Guidance for Industry* (Sept. 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/innovative-designs-clinical-trials-cellular-and-gene-therapy-products-small-populations.

[17] FDA, *Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products: Draft Guidance for Industry* (Sept. 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postapproval-methods-capture-safety-and-efficacy-data-cell-and-gene-therapy-products.

[18] Consolidated Appropriations Act (CAA), 2026, Pub. L. No. 119-75 (2026), §§ 6601 - 6605.

[19] 21 U.S.C. § 360ff.

[20] *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021).

[21] FDA, *Clarification of Orphan-Drug Exclusivity Following Catalyst Pharms., Inc. v. Becerra; Notification*, 88 Fed. Reg. 4086 (Jan. 24, 2023); CAA, note __ above, at § 6605(a)(1).

Continued on page 3...

FDA Update: Accelerating New Therapies . . . *(Continued from page 2)*

Bulks List, finding no clinical need for outsourcing facilities to compound these drugs from bulk substances.[22] The FDA is accepting comments from interested parties by June 29, 2026, after which the FDA is expected to announce its final determination.

FDA Initiatives for Expediting Clinical Trials

In April 2026, recognizing the lag time between clinical data and decision-making processes, which can be a bottleneck in drug development, the FDA unveiled two major steps towards the implementation of real-time clinical trials (RTCT), including the initiation of two proof-of-concept clinical trials that will report endpoints and data signals to the agency in real time and a Request for Information (RFI) regarding a proposed pilot program for RTCT, which is expected to launch this summer. The agency hopes this modern approach will allow FDA scientists to review "safety signals and endpoints in real time as a trial progresses. This will help us accelerate promising therapies, and build toward our ultimate goal of running real-time, continuous trials across all phases of drug development."[23]

In January 2026, the FDA, in collaboration with the European Medicines Agency, published 10 guiding principles for using artificial intelligence (AI) in drug development.[24] The FDA continues to encourage sponsors and other stakeholders to engage with the FDA regarding the use of AI in drug development and has announced several engagement options, including: CDER Center for Clinical Trial Innovation (C3TI), Complex Innovative Trial Design Meeting Program (CID), Emerging Drug Safety Technology Program (EDSTP), Model-Informed Drug Development Paired Meeting Program (MIDD), and Real-World Evidence (RWE) Program, among others.[25]

But Some New Policies Are Controversial

Former Commissioner Makary announced various new FDA policies in the media, rather than through the notice-and-comment procedures required by the Administrative Procedure Act (APA) and the agency's Good Guidance Practices. These "podium policies" proved controversial. Two directors of the agency's Center for Drug Evaluation and Research were appointed and resigned in the past year citing doubts about their legality.[26] Some policies, such as changes to vaccine advisory boards, have already been challenged in court as violations of the APA.[27]

What remains uncertain is how many of these policies will continue in an era when judicial scrutiny of federal agencies is increasing, and the FDA is forced to balance directives from the White House with the interests of industry, patients, payors, and the medical community.[28] One thing is clear, though, former Commissioner Makary's resignation only creates more uncertainty.

Eva Yin
(206) 883-2572
eyin@wsgr.com

Dan Orr
(202) 973-8902
dorr@wsgr.com

---

[22] FDA, FDA Proposes to Exclude Semaglutide, Tirzepatide, and Liraglutide on 503B Bulks List (April 30, 2026), https://www.fda.gov/news-events/press-announcements/fda-proposes-exclude-semaglutide-tirzepatide-and-liraglutide-503b-bulks-list; see also FDA, Notice, List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 91 Fed. Reg. 23431 (May 1, 2026), https://www.federalregister.gov/documents/2026/05/01/2026-08552/list-of-bulk-drug-substances-for-which-there-is-a-clinical-need-under-section-503b-of-the-federal.

[23] FDA, FDA Announces Major Steps to Implement Real-Time Clinical Trials (April 28, 2026), https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials.

[24] FDA, Guiding Principles of Good AI Practice in Drug Development (January 2026), https://www.fda.gov/about-fda/artificial-intelligence-drug-development/guiding-principles-good-ai-practice-drug-development.

[25] FDA, External Engagements with FDA for Artificial Intelligence in Drug Development (May 1, 2026), https://www.fda.gov/about-fda/artificial-intelligence-drug-development/external-engagements-fda-artificial-intelligence-drug-development.

[26] Dan Diamond and Rachel Roubein, Top FDA drug regulator raises alarms about expediting approvals, Washington Post (Nov. 21, 2025), https://www.washingtonpost.com/health/2025/11/21/fda-regulator-richard-pazdur-concerns

[27] *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916-BEM, 2026 WL 733828 (D. Mass. Mar. 16, 2026) (invaliding appointment of new advisory board members and vacating board's actions).

[28] *See, e.g., Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

But "We Don't Take Insurance": Why Cash-Pay Digital Health Companies Still Face Kickback and Fee-Splitting Risk

By Andrea Linna (Partner), Tracy Shapiro (Partner, San Francisco), Nawa Lodin (Associate, Washington, D.C.), and Seamus Taylor (Associate, Washington, D.C.)

Executive Summary

- *Cash-pay healthcare models do not eliminate referral risk.* Even when a company does not bill Medicare, Medicaid, or commercial insurers, federal, state, and "all-payor" fraud and abuse laws may still apply to compensation arrangements involving patient referrals.
- *Certain arrangements carry heightened scrutiny.* Percentage-based compensation, referral fees, physician equity, and marketing arrangements tied to patient volume frequently trigger regulatory risk.
- *The risks extend beyond regulatory penalties.* Improper referral arrangements can create downstream issues for companies that go beyond possible civil and criminal liability, including issues arising when the company expands its business model to accept insurance, expands nationally, or undergoes investor diligence for future fundraising rounds, mergers and acquisitions, or IPO preparation. Improper arrangements can also invalidate contracts, harm the company's reputation with patients, and create reluctance among providers to participate in the company's platform due to fear of professional discipline.

Even when a company does not bill Medicare, Medicaid, or commercial insurers, federal, state, and "all-payor fraud and abuse laws may still apply to compensation arrangements involving patient referrals

Introduction

Cash-pay healthcare companies enjoy many regulatory freedoms that their insurance-accepting counterparts do not. However, cash-pay healthcare companies, their founders, operators, and investors, and the providers they work with, may still face meaningful kickback, self-referral, and fee-splitting risks under federal and state laws, including so-called "all-payor" laws. These risks often arise when companies structure compensation, partnerships, or other relationships with referral sources who may have the ability to steer patients to the company in exchange for payments, percentages of revenue, equity, or other forms of compensation.

Learn More

To learn more, please click here.

Andrea Linna
(650) 461-6556
alinna@wsgr.com

Tracy Shapiro
(415) 947-2042
tshapiro@wsgr.com

Nawa Lodin
(202) 920-8770
nlodin@wsgr.com

Seamus Taylor
seamus.taylor@wsgr.com
(202) 973-8961

Your First Legal Hire Is Not a Math Problem

Building the In-House Legal Function in Biotech, Digital Health, and Medical Devices Companies

By Alexander Nguyen (General Counsel in Residence, Palo Alto)

Most biotech, digital health, and medical devices CEOs decide to hire their first in-house lawyer when outside counsel costs exceed a set threshold. Shortly thereafter, a "Senior Counsel" or "Head of Legal" joins, and the contracts queue shortens. This approach is a procurement decision, not a strategic one. It is a missed opportunity. The first legal hire establishes the company's risk tolerance, shapes internal perception of legal for years, and influences the business model. Over time, these trajectories compound just like a golf ball hit slightly off target.

I have built and run legal functions from both sides: first as a lawyer spinning companies out of a hub-and-spoke biotech platform, then as Chief Legal Officer and Head of Operations at a public biotech company. The first in-house hire is not a substitute for outside counsel; it is a complement. Understanding this distinction can be what separates a strategic legal department that drives value from one that operates well below its potential.

Two Functions, One System

Outside counsel can be crucial partners throughout the company's life cycle, though their involvement can often be episodic. They can drive a key financing, a complex license or collaboration, a bet-the-company litigation, a savvy patent strategy, or a vital regulatory submission. Additionally, they are best when they bring sophisticated portfolio-level pattern recognition, specialist depth, and the capacity to run a complex transaction or defense.

In contrast, in-house counsel provides continuous support by spotting issues in real time—for example, monitoring a Slack thread when a CRO MSA becomes problematic, reviewing commercial claims before they appear on a slide, or participating in early business development conversations about a "standard" term in a term sheet. Additionally, in-house counsel are operators. For instance, in early-stage biotech, digital health, or medical devices companies, the volume of repeatable contracts is substantial, and reducing cycle time provides a competitive advantage. The right in-house lawyer treats this as an engineering problem, building systems that make the user experience both seamless and efficient.

Why Earlier? And How Biotech and Digital Health or Medical Devices Companies Differ?

Biotech companies should bring in their first in-house lawyer earlier because legal decisions here shape enterprise value from the beginning.

In biotech, because of the asset-centric nature of the business, decisions made early affect value over years. In-licensing terms, intellectual property (IP) strategy, and CRO and clinical agreements do not feel existential when they are signed, but they define value and how flexible a company can be later. Having in-house legal counsel who can consistently connect key decisions across time, influence strategy from a legal perspective, or coordinate diligence and compliance is extremely valuable. That is the gap an in-house legal leader fills.

In digital health and medical devices, the timeline compresses, and the need comes even earlier. Your company may be commercial, public-facing, and handling patient data almost immediately. Product and go-to-market decisions are regulatory decisions shaped by HIPAA, AKS, Stark, CPOM, FDA pathways, and a fragmented (and constantly shifting) state privacy regime. If those calls are made without the legal team in the room, companies can often end up reworking products or business models after the fact.

What to Filter for When You Hire

On substantive capabilities, there are a several archetypes to consider—IP/regulated-industry, corporate/securities, and commercial—and these skill sets rarely coexist in a single individual. Therefore, the dominant risk should guide the choice of archetype: an IP-focused professional for a platform company, a commercial General Counsel (GC) who can manage deals and enterprise contracts, or someone with go-public experience if an IPO is imminent. For very early companies, fractional in-house arrangements can be a great option to get access to senior, business-minded operators who can run formation, IP architecture, business development term sheets, deal structure, and board hygiene without committing to a full-time hire (yet).

In terms of traits that matter, over time I have seen the following traits can predict success.

- Risk tolerance—the ability to act on incomplete information without flinching.

Continued on page 6...

Your First Legal Hire Is Not a Math Problem *(Continued from page 5)*

- Clear, plain-English communication through bullets, takeaways, and action items.
- Willingness to own decisions rather than escalate them.
- Decision velocity—the right in-house counsel accelerates the business; the wrong one slows it down.
- A deep network of regulatory, IP, and transactional specialists, combined with the judgment to know when to involve others and when to resolve matters internally.
- A builder at heart, with the courage to push back thoughtfully, even when it is uncomfortable.

One structural mistake worth identifying: do not have your GC report to the chief financial officer. It signals that the company considers the legal function second-tier, and top talent will often go elsewhere.

The right first in-house lawyer, paired with the right outside counsel, pays back many times over what the spend-math model says they cost, and it is never too early to consider it.

Alexander Nguyen
(650) 858-7031
alexander.nguyen@wsgr.com

Sachin Kohli Joins Wilson Sonsini's Mergers and Acquisitions Team

On May 27, 2026, Wilson Sonsini announced that Sachin Kohli has joined the firm's Mergers and Acquisitions practice as a partner in its New York office. His arrival advances the firm's national M&A platform, expands the firm's New York presence, and deepens the team's capabilities in transformative transactions across life sciences, healthcare, and technology.

Widely regarded for his pragmatic, business-oriented mindset, Sachin combines significant experience in transactional execution with ongoing strategic counsel on governance, disclosure, shareholder activism, and defensive preparedness. His cross-sector experience spans life sciences, healthcare, technology, energy, gaming, consumer, and industrials, positioning him as a go-to practitioner for companies navigating an increasingly dynamic and competitive deal environment.

Sachin has worked on numerous high-profile transactions, including Sanofi's acquisitions of Blueprint Medicines, Dynavax Technologies, Provention Bio, and Bioverativ and The Dow Chemical Company's merger of equals with DuPont and its subsequent spin-off.

"I built my career at my prior firm, so this move was not made lightly," said Sachin. "What drew me to Wilson Sonsini was its focused and intentional approach to guiding innovative companies through their most complex, high-stakes transactions—along with its institutional strength, sophisticated client base, and proven ability to execute at scale. I was looking for a platform where I could make an immediate impact and help shape what comes next. I am excited to join and contribute to the continued growth of an already exceptional M&A practice."

To learn more, please see the firm's news release.

Life Sciences Venture Financings for Wilson Sonsini Clients

By Scott Murano (Partner, Palo Alto)

The table below includes data from life sciences transactions in which Wilson Sonsini clients participated across the first and second halves of 2025. Specifically, the table compares—by industry segment—the number of closings, the total amount raised, and the average amount raised per closing across the two six-month periods.

	1H 2025	1H 2025	1H 2025	2H 2025	2H 2025	2H 2025
Life Sciences Industry Segment	Number of Closings	Total Amount Raised ($M)	Average Amount Raised ($M)	Number of Closings	Total Amount Raised ($M)	Average Amount Raised ($M)
Biopharmaceuticals	61	$1,337.55	$21.93	60	$1,265.72	$21.10
Genomics	2	$2.01	$1.01	6	$27.81	$4.64
Diagnostics	12	$127.01	$10.58	15	$154.86	$10.32
Medical Devices & Equipment	43	$460.41	$10.71	45	$532.78	$11.84
Digital Health	28	$1,010.99	$36.11	27	$989.41	$36.64
Healthcare Services	16	$269.27	$16.83	22	$318.28	$14.47
Total	**162**	**$3,207.24**		**175**	**$3,288.86**	

The data demonstrates that venture financing activity increased marginally from the first half of 2025 to the second half of 2025 with respect to number of closings and total amount raised. Specifically, the number of closings across all industry segments increased by 8.0 percent, from 162 to 175 closings, and the total amount raised across all industry segments increased 2.5 percent, from $3,207.24 million to $3,288.86 million.

The industry segment with the largest number of closings during the second half of 2025—biopharmaceuticals—decreased in number of closings and in total amount raised from the first half of 2025 to the second half of 2025. Specifically, the number of closings in biopharmaceuticals decreased 1.6 percent, from 61 to 60, while the total amount raised decreased 5.4 percent, from $1,337.55 million to $1,265.72 million. Similarly, the industry segment with the third largest number of closings during the second half of 2025—digital health—experienced a decrease in both number of closings and total amount raised across these same periods, as the number of closings decreased 3.6 percent, from 28 to 27 closings, and the total amount raised decreased 2.1 percent, from $1,010.99 million to $989.41 million.

The data demonstrates that venture financing activity increased marginally from the first half of 2025 to the second half of 2025 with respect to number of closings and total amount raised.

All remaining industry segments experienced an increase in number of closings and total amount raised.

Specifically, the industry segment with the second-largest number of closings during the second half of 2025—medical devices and equipment—saw a 4.7 percent increase in number of closings, from 43 to 45, and a 15.7 percent increase in total amount raised, from $460.41 million to $532.78 million. Similarly, the industry segment with the fourth largest number of closings during the second half of 2025—healthcare services—also experienced an increase in both number of closings and total amount raised, as the number of closings increased 37.5 percent, from 16 to 22, while total amount raised increased 18.2 percent, from $269.27 million to $318.28 million. The industry segment with the fifth largest number of closings during the second half of 2025—diagnostics— also experienced an increase in both number of closings and total amount raised. Specifically, the number of closings increased 25 percent, from 12 to 15, while total amount raised increased 21.9 percent, from $127.01 million to $154.86 million. Finally, the industry

Continued on page 8...

Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 7)*

segment with the sixth largest number of closings during the second half of 2025—genomics—experienced a 200 percent increase in number of closings, from 2 to 6, and a 1283.6 percent increase in total amount raised, from $2.01 million to $27.81 million.

In addition, our data indicates that the amount of financing activity at any given stage of financing, as measured by number of closings, remained steady between the first and second halves of 2025. Specifically, Series Seed financing activity as a percentage of all financing activity increased from 22.2 percent to 25.5 percent, Series A financing activity as a percentage of all financing activity increased from 21.6 percent to 25.5 percent, Series B financing activity as a percentage of all financing activity increased from 16.8 percent to 17.4 percent, Series C and later-stage financing activity as a percentage of all financing activity increased from 11.4 percent to 12.4 percent, and bridge financing activity as a percentage of all financing activity increased from 14.4 to 15.5 percent. Offsetting those increases was a decrease in recap and other, non-traditional financing activity, which decreased from 13.8 percent to 3.7 percent.

Our data indicates that the amount of financing activity at any given stage of financing, as measured by number of closings, remained steady between the first and second halves of 2025.

Average pre-money valuations for life sciences companies closing Series Seed, Series A, Series B, and Series C and later-stage financings also remained constant between the first and second halves of 2025. Specifically, the average pre-money valuation for Series Seed financings decreased 0.3 percent, from $22.35 to $22.29 million; the average pre-money valuation for Series A financings decreased 2.3 percent, from $42.65 million to $41.69 million; the average pre-money valuation for Series B financings remained unchanged at $80.45 million; and the average pre-money valuation for Series C and later-stage financings decreased 0.9 percent, from $365.04 million to 361.89 million.

Overall, the data indicates that financing activity was consistent between the first and second halves of 2025 in number of closings and total amount raised. Similarly, the stages of financing at which those financing dollars were deployed and at what pre-money valuations also remained consistent between the two six-month periods. Companies in the medical devices and equipment, healthcare services, diagnostics, and genomics industry segments saw a slight increase in financing activity relative to their peer companies in the biopharmaceutical and diagnostic segments in terms of number of closings and total amount raised, but those declines in the biopharmaceutical and diagnostic segments were relatively small. These results are not surprising, given the market uncertainty with the ongoing geopolitical conflict. We anticipate the venture financing activity reported in our next edition, covering the first half of 2026, to differ significantly from that of the second half of 2025.

Average pre-money valuations for life sciences companies closing Series Seed, Series A, Series B, and Series C and later-stage financings also remained constant between the first and second halves of 2025.

Scott Murano
(650) 849-3316
smurano@wsgr.com

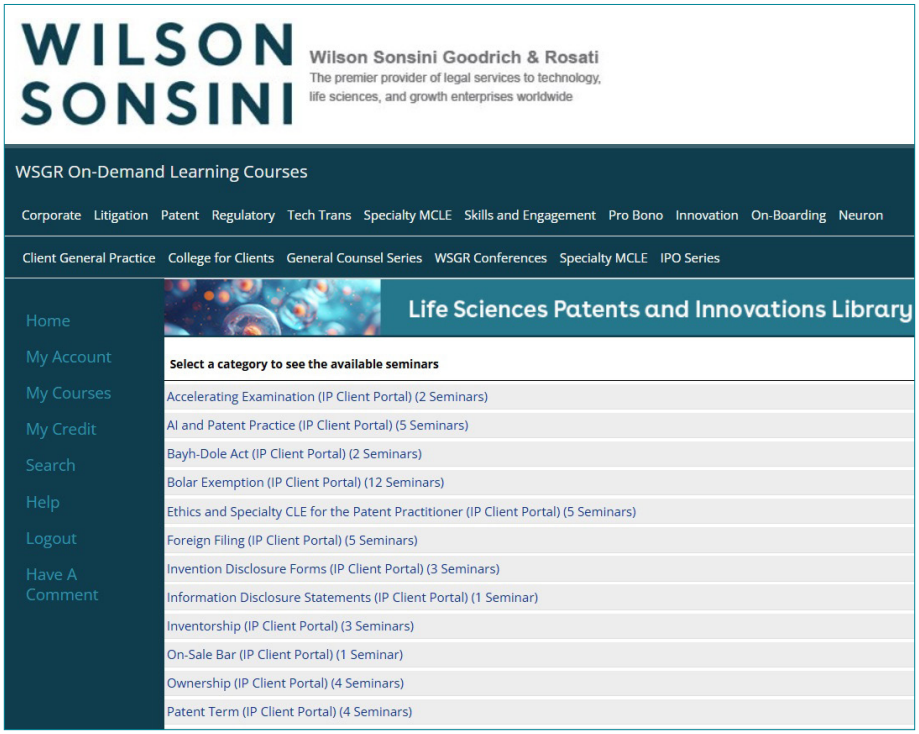
Life Sciences Patents and Innovations Library for In-House IP Counsel: New Courses on Obviousness and Pre-Appeals Now Available

We are pleased to present new courses in Wilson Sonsini's Patents and Innovations Library. Available in the On-Demand Learning section of our firm's website, this curated collection of legal courses is produced by our patent attorneys and designed to empower in-house IP counsel in the life sciences sectors with the knowledge and insights needed to navigate the complex world of patent law.

Obviousness Mini-Series

A new set of courses in the **Obviousness Mini-Series** provides practical guidance for addressing USPTO obviousness rejections, covering key strategies such as arguing lack of motivation to combine references and challenging the examiner's showing of a reasonable expectation of success. It also explores the effective use of secondary considerations as objective evidence and offers examples involving claim ranges, small molecule inventions, and dosing regimens derived from clinical studies.

- The Obviousness Mini-Series - Motivation to Combine – *Presented by Lu Perla*
- The Obviousness Mini-Series - Reasonable Expectation of Success – *Presented by Seth Lee*
- The Obviousness Mini-Series - Secondary Considerations – *Presented by Carey Cling*
- The Obviousness Mini-Series - Examples re Ranges – *Presented by Lucas Batties*



- The Obviousness Mini-Series - Small Molecules – *Presented by Christina Hoong*
- The Obviousness Mini-Series - Dosing Claims – *Presented by Nick Tiee*

Pre-Appeal Conference Requests

In addition, the series introduces Pre-Appeal Conference Requests, explaining how they can be used strategically after a final rejection and before pursuing a formal appeal. An effective strategy for using such requests can significantly expedite your case review before you proceed with a full appeal. Don't miss the opportunity for an early resolution!

- Pre-Appeal Conference Requests, Part 1 (Background) – *Presented by Jean Witz*

The firm distributes quarterly updates highlighting the library's latest additions.

To access the **Patents and Innovations Library**, please log into Wilson Sonsini's On-Demand Learning portal here. For instructions to create an account, click here.

Disclaimer: *The Patents and Innovation Learning Library is provided as a service to our clients and friends and is for informational purposes only. These videos are not intended to create an attorney-client relationship or constitute an advertisement, a solicitation, or professional advice as to any particular situation.*

Latest NextGen VC Podcast Episodes Share Insights on Life Sciences Investing

The NextGen VC Podcast is the premier podcast for forward-thinking venture capitalists to sharpen their skills and learn from industry leaders. Hosted by Wilson Sonsini partners Michael Hostetler and Jennifer Fang, the podcast unpacks the opportunities, challenges, and breakthroughs shaping life sciences investing today. Each episode features interviews with seasoned venture capitalists, successful entrepreneurs, and industry leaders. Gain an understanding of how the pros have navigated challenges, made strategic decisions, and achieved remarkable success by tuning in wherever you listen to podcasts. The podcast is produced in partnership with Wilson Sonsini and LaunchBio.

For a full listing of all previous episodes, visit https://launchbio.org/nextgen-vc-podcast/. Please see below for details on the latest podcast episodes.

Aimee Raleigh
Principal, Atlas Venture
Episode (May 2026)

Aimee Raleigh, Ph.D., Principal at Atlas Venture, joins Mike and Jen as she walks through how companies get built before they're even companies. From evaluating early science to forming a real point of view, Aimee shares how investors build conviction at the earliest stages. We get into the pace of early-stage venture, how to juggle multiple opportunities, make decisions with imperfect data, figure out what's worth leaning into, and more. Aimee discusses her path into venture and what she's learned along the way in an industry that doesn't slow down. Listen and be prepared to walk away seeing early-stage ventures a little differently.

Rich Gaster
Managing Partner, venBio
Episode (April 2026)

Rich Gaster, M.D., Ph.D., discusses what it takes to go from performing reconstructive plastic surgeries at Harvard to becoming a managing partner at one of biotech's most focused venture firms. He traces a career path that includes Stanford M.D.-Ph.D. training, two grad school start-ups, the company-building engine at Third Rock Ventures, and the founding team of Pliant Therapeutics before he landed at venBio, where he helped engineer three back-to-back acquisitions in a single quarter. Rich also breaks down what makes venBio's small-team, high-conviction model so effective, how asset-focused investing differs from platform company builds, and what he looks for when deciding to pull the trigger on a deal.

Dr. Anna French
Managing Partner, Qiming Venture Partners USA
Episode (March 2026)

Dr. Anna French traces her non-linear path from an Oxford D.Phil. and Boston Consulting Group boardrooms to becoming employee No. 1 at one of biotech's most globally connected venture firms. Anna shares what it's really like to build a fund from the ground up, why she championed Umoja Biopharma's bold bet on in vivo CAR-T and in-house manufacturing, and how a global perspective—forged in UK labs, Korean hospitals, and Parisian roundtables—shapes the way she looks for innovation. She also discusses LP fundraising, the U.S.-China biotech opportunity, and what work-life balance actually looks like when both you and your spouse are running full speed.

Suen Tuang
Associate, TCG Crossover
Episode (February 2026)

Suan Tuang, M.D., Ph.D., didn't take a traditional path into biotech investing, and this journey shapes how he evaluates risk today. Now at TCG Crossover, with prior experience at Foresite and Eventide, Suan brings a clinician-scientist lens to investing across private and public markets. In this episode, he shares how his immigrant journey and academic challenges at MIT and Harvard have shaped his unique approach to risk and resilience. Suan also discusses how he leverages clinical data over hype and balances scientific rigor with market realities, and offers practical advice for aspiring investors and entrepreneurs.

Continued on page 11...

Latest NextGen VC Podcast Episodes Share Insights . . . *(Continued from page 10)*

"The [NextGen VC Podcast] is a great resource to those who are early in their [VC] careers or who are considering this career path."

- Katie Spielberg, 5AM Ventures

To subscribe to the NextGen VC Podcast, visit https://launchbio.org/nextgen-vc-podcast/. Scan the code to learn more:

Available on:
Amazon Music
Apple Podcasts
iHeart Radio
Spotify

Disclaimer: *These episodes may feature current or former clients of Wilson Sonsini. This podcast is for general informational purposes and is not intended to provide and should not be relied on as legal advice. The information in this podcast is not tailored to a particularized situation or jurisdiction, may not reflect the current state of the law, and should not be considered a substitute for the advice of your own legal counsel. You should not consider this podcast an invitation to form an attorney-client relationship, and no attorney-client relationship is created by your use of this podcast. Wilson Sonsini disclaims all liability in respect to any actions taken or not taken based on the content of this podcast and notes that prior results do not guarantee a similar outcome. This podcast may be considered attorney advertising in certain jurisdictions.*

Wilson Sonsini Hosts Biotech's New Playbook: Spinouts & Optionality

On May 14, 2026, Wilson Sonsini hosted *Biotech's New Playbook: Spinouts & Optionality* in San Diego. Organized by attorneys across multiple practice areas, the event convened 40 biotech executives, VC investors, and pharmaceutical business development leaders based in Southern California. The program explored the strategic and operational complexities of structuring biotech spinouts, multi-asset transactions, and efficiently separating company assets.

Through two dynamic panel discussions, speakers provided practical insights on various spinout structures, the key drivers behind these transactions, and the critical importance of early planning around tax, intellectual property, governance, financing, and operational issues. Robust audience engagement reflected the life sciences community's recognition of spinouts as a vital strategic tool to maximize value, preserve innovation, and unlock future growth opportunities.

Wilson Sonsini looks forward to continuing to host events that foster innovation in the life sciences sector.

Select Recent Life Sciences Client Highlights

- Advised **Whitehawk Therapeutics** on its PIPE financing (May 2026)
- Advised **Odyssey Therapeutics** on patent matters related to its IPO (May 2026)
- Advised **BioOrbit** on its Seed round financing (May 2026)
- Advised **Investors** in Winward Bio's crossover financing (May 2026)
- Advised **Candid Therapeutics** on patent matters related to its acquisition by UCB (May 2026)
- Advised **Arcellx** on its merger with Gilead Sciences (April 2026)
- Advised **Nervonik** on its Series B (April 2026)
- Advised **Novo Holdings, Norwest,** and **Platanus** on Ray Therapeutics' Series B (April 2026)
- Advised **Novo Holdings** on Route 92 Medical's growth financing (April 2026)
- Advised **Neurona Therapeutics** on its acquisition by UCB (April 2026)
- Advised **Terremoto** on IP matters related to its Series C (April 2026)
- Advised **Ultralight** on its Seed funding (April 2026)
- Advised **Forte Biosciences** on its public offering (April 2026)
- Advised **HexemBio** on its Seed round (April 2026)
- Advised **Renovare Therapeutics** on its company launch and collaboration with CU Boulder (April 2026)
- Advised **Sidewinder Therapeutics** on its Series B (April 2026)
- Advised **Soleno Therapeutics** on its acquisition by Neurocrine (April 2026)
- Advised **Frazier Life Sciences** on IP matters related to Immutrin's Series A (April 2026)
- Advised **View Point Medical** on its acquisition by Merit Medical (April 2026)
- Advised **Ambrosia Biosciences** on its Series B (April 2026)
- Advised **Centessa** on IP matters related to its acquisition by Lilly (March 2026)
- Advised **Insilico** on its global R&D collaboration with Lilly (March 2026)
- Advised **NexCure** on its Series A (March 2026)
- Advised **Pinnacle Medicines** on corporate and IP matters related to its Series B (March 2026)
- Advised **Excellergy** on its acquisition by Novartis (March 2026)
- Advised **OnKure Therapeutics** on its private placement (March 2026)
- Advised **Nosis Bio** on its strategic collaboration and license agreement with Johnson & Johnson (March 2026)
- Advised **Dimer Health** on its Series A financing (March 2026)
- Advised **R1 Therapeutics** on its Series A financing (March 2026)
- Advised **Enodia Therapeutics** on its purchase agreement with Kezar Life Sciences (March 2026)
- Advised **Day One** on IP matters related to its acquisition by Servier (March 2026)
- Advised **lead investors** on SHINE's equity funding (March 2026)
- Advised **Cognito Therapeutics** on its Series C (March 2026)
- Advised **Sinopia Biosciences** on its target discovery collaboration with Ono Pharmaceutical (March 2026)
- Advised **Candid Therapeutics** on its patent matters related to acquisition by Rallybio (March 2026)
- Advised **Arcellx** on its acquisition by Gilead (February 2026)
- Advised **PacBio** on its sale of short-read DNA sequencing assets (February 2026)
- Advised **SpyGlass Pharma** on its IPO (February 2026)
- Advised **Ekso Bionics** on its contribution and exchange agreement with Applied Digital (February 2026)
- Advised **ALX Oncology** on its public offering (February 2026)
- Advised **vTv** on its expanded license agreement with Newsoara (February 2026)
- Advised **Think Bioscience** on patent matters related to its Series A (January 2026)
- Advised **Genyro** on its license agreement with Caltech for "Sidewinder" Technology (January 2026)
- Advised investor **SR One** on Corxel Pharmaceuticals' Series D (January 2026)

Continued on page 13...

Select Recent Life Sciences Client Highlights *(Continued from page 12)*

- Advised **Janux Therapeutics** on patent matters related to its license agreement with Bristol Myers Squibb (January 2026)
- Advised **Pacira BioSciences** on its agreements with LG Chem (January 2026)
- Advised **Proxima** on its Seed financing (January 2026)
- Advised **Mirador** on its patent matters related to its Series B (January 2026)
- Advised **SR One** on AirNexis Therapeutics' Series A (January 2026)
- Advised **Crinetics** on patent matters related to its public offering (January 2026)
- Advised **Juvena Therapeutics** on IP matters related to its Series B (January 2026)
- Advised **Frazier Life Sciences** on patent matters related to AirNexis Therapeutics' Series A financing (January 2026)
- Advised **Link Cell Therapies** on its strategic collaboration with Johnson & Johnson (January 2026)
- Advised **InduPro** on its strategic investment and research collaboration with Sanofi (January 2026)
- Advised **IndpuPro** on its strategic collaboration with Eli Lilly (January 2026)
- Advised **Soley Therapeutics** on its Series C financing (January 2026)
- Advised **Ventyx Biosciences** on its acquisition by Eli Lilly (January 2026)

Upcoming Life Sciences Events

Wilson Sonsini's Medical Device & Digital Health Conference
June 4-5, 2026
InterContinental San Francisco
San Francisco, CA
https://mdc.wsgrevents.com/

Wilson Sonsini's 33rd Annual Medical Device & Digital Health Conference will feature engaging panel sessions and keynote addresses, a Partnering Hall connecting attendees with start-ups and investors from around the globe, the MedTech Innovator pitch event, and a lively wine tasting reception where venture capitalists serve as sommeliers.

Phoenix 2026: The Medical Device and Diagnostic Conference for CEOs and Medtech Executives
October 7-9, 2026
Grand Hyatt Scottsdale Resort
Scottsdale, AZ
https://phoenix.wsgrevents.com/

The 2026 Phoenix Conference is an exclusive, invitation-only gathering that brings together leading medical device executives, entrepreneurs, investors, and stakeholders. Designed to foster meaningful connections among industry leaders, the conference encourages candid dialogue on pressing issues, cultivates lasting relationships, and delivers actionable insights to drive business growth and innovation.

Wilson Sonsini's Biotech Summit
October 21-22, 2026
The Newbury Boston
Boston, MA
https://biotech.wsgrevents.com/

Wilson Sonsini's third Annual Biotech Summit will address topics of critical importance to biotech and biopharmaceutical companies, including early and late-stage venture financing, partnering strategies, current and future AI trends in healthcare, and developments in M&A. This unique event will bring together leaders from across the biotech industry, including CEOs, prominent investors, esteemed researchers, and policymakers.

Elton Satusky and Scott Murano have editorial oversight of *The Life Sciences Report*. They would like to take this opportunity to thank all of the contributors to the report, which is published on a semi-annual basis.

Elton Satusky
(650) 565-3588
esatusky@wsgr.com

Scott Murano
(650) 849-3316
smurano@wsgr.com

WILSON SONSINI

650 Page Mill Road, Palo Alto, California 94304-1050 | Phone 650-493-9300 | Fax 650-493-6811 | www.wsgr.com

Wilson Sonsini has 17 offices in technology and business hubs worldwide. For more information, visit wsgr.com/offices.