Written Testimony Submitted by

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House Financial Services Subcommittee Hearing:

The Future of American Capital: Strengthening Public and Private Markets by Increasing Investor Access and Facilitating Capital Formation

February 26, 2025

Chairwoman Wagner, Ranking Member Sherman, members of the Subcommittee, thank you for inviting me to testify today. As a native of St. Louis and the CEO of Geneoscopy, a life-sciences start-up headquartered in St. Louis, I am especially proud to be here today before our member of Congress, Chairwoman Wagner. At Geneoscopy, we are developing innovative diagnostic tests for gastrointestinal health. We are in the process of bringing our innovative product, ColoSense, to the U.S. market so more individuals can access live-saving screening options for colorectal cancer.

I am here today to share my experience with respect to raising capital for our company; a journey that began in 2015, when my sister, Erica, called to inform me she had developed a technology that could save countless lives and that we would be founding a company together to do just that. At the time, I was an MBA student at The Wharton School and my sister was an MD/PhD student at the Washington University School of Medicine in St. Louis. I jumped at the opportunity; as it was a logical extension of my coursework in business and healthcare and my early professional career in the financial services industry. 10 years ago, we started as two students with an idea, and since then we have cultivated that idea into a company with over 50 employees, raised over $150M of venture capital, and are poised to bring a novel solution to market to address the second deadliest – yet most preventable - cancer in our country.

Today, I have three topics to highlight; the importance of start-ups to our economy, the challenges that exist for start-ups when raising capital, and how good policy can help facilitate access to capital.

Start-ups are critical economic growth drivers in the United States. In 2023, over 5 million businesses were started in the U.S.[1] Small businesses, defined as having fewer than 500 employees, have accounted for 71% of total job creation in the current business cycle, with new start-ups alone

[1] Melhorn, Stephanie Ferguson, and Lindsay Cates. "New Business Applications Are Booming. Track Them by State." U.S. Chamber of Commerce. February 2, 2024. Accessed February 24, 2025. https://www.uschamber.com/small-business/new-business-applications-a-state-by-state-view

accounting for 26% of total job creation.[2] Serving for centuries as the global epicenter of innovation has made America's economy the strongest in the world. Looking forward, as we move into new phases of disruptive change, it is critical for our country to continue to support startups through a strong workforce, supportive infrastructure, good government policy, and a culture of entrepreneurship and risk-taking.

Approximately 90% of startups fail.[3] In one study of failed startups, the top reason cited for failure was running out of cash or failing to raise new capital.[4] Startups need capital to cover the initial costs of launching and operating their business, supporting expenses such as product development, marketing, hiring, office space, inventory, and research. Fundraising is a constant challenge for founders. It is estimated that venture capitalists fund fewer than 1% of the pitches they receive.[5,6] At Geneoscopy, we have navigated the full spectrum of capital raises; friends, family, angel, and institutional VC, and have seen the challenges first-hand. But we also count ourselves as fortunate – having the backgrounds to overcome being young, first-time founders, and starting a business outside of Silicon Valley.

Given the importance of start-ups to our economy and the challenges that exist for start-ups with fundraising, it is critical that governmental policy facilitates, and does not stifle, access to capital. Our experience highlights the importance of the legislation under consideration by this subcommittee. Early-stage investors like to deploy capital locally, and the Midwest sees significantly less venture capital investment per capita than other areas, such as the West Coast.[7] Lessening the burden for angel investors, lowering the barriers for venture fund formation, and making crowdfunding more pervasive would all help start-ups access vital growth capital. Geneoscopy will require additional capital to grow and is preparing to access the public markets. However, disclosure requirements and the regulatory burden can be daunting – alleviating these barriers for emerging growth companies makes sense.

Lastly, included here, appended to my written submission, is a copy of written testimony that I submitted to your colleagues on the Ways & Means Committee last October describing the "valley of death" that life-sciences start-ups often face after FDA approval because of the federal government's policies, bureaucracy, and inaction. Beyond the topic of access to capital I have highlighted today, improved federal policies that streamline Medicare coverage and payment, and

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[2] Van Nostrand, Eric. "Small Business and Entrepreneurship in the Post-COVID Expansion." U.S. Department of the Treasury. September 3, 2024. Accessed February 24, 2025. https://home.treasury.gov/news/featured-stories/small-business-and-entrepreneurship-in-the-post-covid-expansion

[3] Szathmári, E., Varga, Z., Molnár, A., Németh, G., Szabó, Z. P., & Kiss, O. E. "Why do startups fail? A core competency deficit model." Frontiers in Psychology, 15, 1299135. https://doi.org/10.3389/fpsyg.2024.1299135

[4] "The Top 12 Reasons Startups Fail". CB Insights. August 3, 2021. Accessed February 24, 2025. https://www.cbinsights.com/research/report/startup-failure-reasons-top

[5] Doncheva, Tzvete. "How to Cold Pitch a VC and Get a Response." Startups Magazine. Accessed February 24, 2025. https://startupsmagazine.co.uk/article-how-cold-pitch-vc-and-get-response

[6] Schlopsna, Niclas. "How to Raise Venture Capital Funds: Guide for Startups". spectup. November 2, 2023. Accessed February 24, 2025. https://www.spectup.com/resource-hub/how-to-raise-venture-capital

[7] Dowd, Kevin. "Examining the geographic divide of VC activity in 4 key industries". Carta. July 24, 2024. Accessed February 24, 2025. https://carta.com/data/vc-industry-geography-2024

more nimble federal agencies that embrace innovation are the key ingredients that life-sciences start-ups like Geneoscopy require to cross the valley of death and, in turn, boost the economy, increase job growth, and save lives. I thank you all for your attention to these issues and for the important work you are doing on this Subcommittee to ensure access to capital.

Thank you again for the opportunity to provide testimony and for your consideration of my recommendations. I stand ready to serve as a resource to you and your colleagues and welcome your questions.

Investing in a Healthier America: Chronic Disease Prevention and Treatment

Written Testimony Submitted to

U.S. House Committee on Ways & Means Subcommittee on Health

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Thank you for the opportunity to provide written testimony in response to the Subcommittee's hearing on chronic disease prevention and treatment. As discussed at the hearing, diet, nutrition, food, and disease screening and detection are all intertwined. We would like to discuss these items further below, specifically, how Geneoscopy is innovating in detection and screening.

Evidence shows a significant association between a diet high in ultra-processed food and an increased risk of cancer and specifically colorectal cancer.[1] Colorectal cancer is the second deadliest cancer in the U.S., causing more than 50,000 deaths annually. Of particular concern is the significant increase in the incidence of colorectal cancer among younger Americans. Since 1994, cases of early-onset colorectal cancer (i.e., colorectal cancer diagnosed before the age of 50) have increased by 51%, and since 2004, there has been a rapid shift in mortality patterns, with colorectal cancer moving from being the fourth leading cause of cancer-related deaths among young men and women to now being the leading cause in men and the second leading cause in women.[2]

Fortunately, routine colorectal cancer screenings for Americans aged 45 years and older are an effective intervention to detect precancerous polyps so that they can be removed before they develop into cancer, thereby preventing colorectal cancer.[3] Despite this, one in four adults aged 45 to 75 are not getting screened as recommended. In 2021, only 19.7%, or fewer than 4 million out of 19 million eligible adults aged 45-49 were up to date with their colorectal cancer screening.[4] As such, it is essential that more colorectal cancer screening options be available to people aged 45 and older and that such tests be accessible and affordable for all who are eligible for screening.

Colon cancer is the most preventable cancer if people get screened for it regularly. Colorectal cancer almost always develops from precancerous polyps (abnormal growths, also called adenomas) in the colon or rectum. If you can find and remove the precancerous polyps through screening, you can head off cancer before it develops. A New England Journal of Medicine study concluded that the more adenomas found during screening, the less cancer is subsequently

[1] Isaksen, I. M., & Dankel, S. N. (2023). Ultra-processed food consumption and cancer risk: A systematic review and meta-analysis. *Clinical nutrition (Edinburgh, Scotland)*, *42*(6), 919–928. https://doi.org/10.1016/j.clnu.2023.03.018.

[2] https://www.nbcnews.com/health/health-news/colon-cancer-deaths-younger-men-women-report-rcna134084

[3] https://www.cdc.gov/chronicdisease/programs-impact/pop/colorectal-cancer.htm

[4] https://www.cdc.gov/pcd/issues/2023/23_0071.htm

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diagnosed.[5] Screening can also identify early-stage cancer. When colorectal cancer is found at an early stage, before it has spread, it is more treatable, and the five-year relative survival rate is about 90%. The percentage of individuals diagnosed with advanced-stage colorectal cancer has increased from 52% in the mid-2000s to 60% in 2019.[6] Survival rates are lower when cancer has spread outside the colon or rectum.[7] Unfortunately, many patients avoid screening, and so their cancer is diagnosed at later stages. Approximately 40% of patients fail to get screened in part because they do not want to have a colonoscopy, which is the gold standard for colorectal cancer screening in the U.S. Colonoscopies are frequently met with patient aversion due to the required bowel preparation, sedation, and potential time away from work.[8]

An alternative to colonoscopy for average-risk patients is noninvasive screening tests, like Geneoscopy's ColoSense, which can be used at home. ColoSense can play a critical role in addressing access to care challenges by reducing barriers to early detection, particularly among underserved populations. Traditional screening methods, like colonoscopies, can be inaccessible due to cost, geographic location, or the need for specialized facilities – challenges that disproportionately affect low-income, rural, and minority communities. A noninvasive test such as ColoSense offers a more affordable, convenient, and less intimidating option, increasing the likelihood that patients will seek regular screenings given their potential to detect precancerous polyps and cancer at earlier stages when it is most treatable.

Everyone is at some risk for developing colorectal cancer, though some groups are at elevated risk. Of particular concern, in the U.S. African Americans have the highest colorectal cancer incidence and mortality rates of all racial groups. African Americans are approximately 20% more likely to develop colorectal cancer and an estimated 40% more likely to die from it than most other populations.[9] Moreover, as noted earlier, colorectal cancer incidence and mortality rates among people ages 45-54 have increased in recent years. The percentage of individuals diagnosed with colorectal cancer who are under the age of 55 doubled from 11% in 1995 to 20% in 2019.[10] In 2021, the U.S. Preventive Services Task Force (USPSTF) lowered the recommended age for people to begin colorectal cancer screening from 50 to 45.[11] With that change, 17 million more people entered the recommended screening cohort. Clearly, there is an urgent need to increase screening efforts.

As technological innovations in the field of preventive screening and diagnostics advance for the country's deadliest diseases, more effective screening modalities become available. For example, ColoSense uses mRNA technology that has demonstrated the potential to improve the

[5] https://www.nejm.org/doi/full/10.1056/NEJMoa1309086
[6] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772
[7] https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/detection.html
[8] https://www.sciencedirect.com/science/article/pii/S2211335519300750
[9] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772
[10] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772
[11] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations

detection of colorectal cancer and advanced adenomas (AA) above and beyond other tests on the market. Top-line data from the CRC-PREVENT clinical study for Geneoscopy's test demonstrated 93% sensitivity for colorectal cancer and 45% sensitivity for AA.[12] In addition, ColoSense's ability to detect AA does not materially erode for the youngest screening bracket of 45-49-year-olds as occurs in other screening methods.[13] This finding may lead physicians to choose different screening modalities for different patient demographics. When it comes to screening, more choice is better, and the best colorectal cancer screening test for a given patient is the one that physicians will use. Geneoscopy's clinical trial showed that the new technology worked successfully for people across demographic groups all over the country and has the real promise to advance the vital goal of increasing access to health care innovation for historically underserved populations. In Geneoscopy's trial, 30% of participants had an income below $50,000 annually, 9% were on Medicaid, and 5% were from rural areas[14].

There are a few key hurdles to bringing life-saving cancer screening tests to patients. First, getting approval by the Food and Drug Administration (FDA); second, qualifying for coverage and payment by the Centers for Medicare and Medicaid Services (CMS); and third, inclusion in the USPSTF screening recommendations given that commercial insurers generally will not cover a test until it is included in USPSTF guidelines. Start-up companies like Geneoscopy take risks when developing new technologies and face the "valley of death" when coverage and guidelines inclusion do not come quickly after FDA approval. To keep pace with biotech innovation and provide access to these innovations, we propose that:

(1) There should be automatic, temporary Medicare coverage for a four year transitional period of all medical devices – including screening tests and diagnostics – that are approved under the FDA Breakthrough Devices Program. To that end, we support H.R. 1691, the Ensuring Patient Access to Critical Breakthrough Products Act of 2023, and H.R. 5389, the National Coverage Determination Transparency Act. These bills would provide the predictable pathway innovators seek for coverage and payment and expedite patient access to novel cancer screening tests like ours. It is imperative that once the FDA approves a test, CMS updates its coverage and payment policies in a timely manner. For example, ColoSense was approved by FDA in May 2024, and we promptly requested that CMS update its National Coverage Determination for colorectal cancer so Medicare beneficiaries and dually-eligible individuals could have access to it. Given feedback we have received from CMS, Medicare coverage for ColoSense likely will not be granted until the end of CY2025 or the first quarter of CY2026 – an estimated full year and a half to two years after receiving FDA approval. This means that Medicare beneficiaries and dually-eligible individuals will face a significant delay in accessing ColoSense and if not otherwise screened could develop colorectal cancer during that timeframe.

[12] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001
[13] https://doi.org/10.1158/1940-6207.CAPR-20-0294
[14] https://pubmed.ncbi.nlm.nih.gov/37870871/

(2) We recommend temporary inclusion in the USPSTF screening guidelines when devices are approved under the FDA Breakthrough Devices Program. This would allow patients to have access to FDA breakthrough designated and approved devices until USPSTF completes the next update of its guidelines for the particular disease or condition, which could take up to six years depending on the particular review cycle.

The USPSTF plays an integral role in colorectal cancer prevention and early detection because its recommendations are used by commercial insurers to determine coverage of colorectal cancer screening tests. Further, any colorectal cancer screening modalities that receive an A or B rating from the USPSTF are fully covered by insurance thus eliminating patient cost-sharing, which facilitates access and utilization. Many commercial insurers will decline to cover a preventive screening test until it is included in the USPSTF guidelines, regardless of strong data supporting the test, endorsement by other guidelines such as from the American Cancer Society, or a positive coverage decision by CMS. The USPSTF typically updates its recommendations every five years, although it often takes longer. Once the USPSTF begins the process to update guidelines, it usually takes more than two years. Based on the standard five-year timeframe, the USPSTF should have commenced the two-year process in January 2024 to update the colorectal cancer screening guidelines, but the agency has taken no such action, despite patient advocacy groups this summer making a formal request for an update; it remains unclear when USPSTF will begin the update process.

(3) We believe it is appropriate and good policy for Medicare quality metrics to align with Medicare coverage and payment policy; if Medicare deems something worthy of payment, then it follows that providers should receive credit for using the test. Currently, the Partnership for Quality Measurement (PQM), which establishes Stars quality metrics, relies on the measure steward, the National Committee for Quality Assurance (NCQA) to set quality measures for Medicare and commercial insurance. However, NCQA will not add a new cancer screening test to its measures – even if Medicare provides coverage and payment – until it is included in the USPSTF guidelines. As such, USPSTF guidelines dictate commercial coverage and quality metrics for prescribing clinicians, including those serving Medicare beneficiaries and dually-eligible individuals. Payment drives practice and therefore, until USPSTF includes a new test, health plans typically will not cover a test, and clinicians will not prescribe it for commercial or Medicare patients. Without quality metric credit, too many providers likely will opt to use older, less effective tests because they are already in the quality measurement system.

To address this issue, we recommend that CMS establish a new process to ensure that the latest cancer screening tests covered under Medicare are automatically considered for inclusion in the PQM Stars quality metrics. Instead of relying only on the arduous process for inclusion in USPSTF guidelines, this new process should be a dynamic collaboration between CMS, NCQA, and USPSTF to expedite the evaluation and integration of new tests into quality metrics once Medicare coverage is established. Additionally, CMS should

consider incentivizing health plans and clinicians to adopt newly covered tests in quality measurement programs, which may lead to faster alignment between coverage and payment, and ultimately facilitate providers and patients in utilizing the most effective screening tests.

Individually and together, these three factors create a significant barrier to innovative, FDA-approved tests reaching patients in the U.S. health care system.

Thank you again for the opportunity to share our work on chronic disease prevention as it pertains to colorectal cancer; we urge you to take steps to address the "valley of death" that companies like ours face. These barriers not only slow access to ColoSense but will thwart access to other much-needed tests in the Geneoscopy pipeline, as well as those in development by other companies. We hope we can work together to facilitate access to innovative tests to screen, diagnose, and prevent myriad serious and life-threatening diseases for patients of all ages.

About Geneoscopy

Geneoscopy was founded in 2015 with a vision to improve how gastrointestinal diseases are prevented, detected, and treated. My sister, Dr. Erica Barnell, and I co-founded Geneoscopy after Erica developed a groundbreaking technology to isolate and interrogate mRNA while she was pursuing her MD/PhD at Washington University School of Medicine in St. Louis, Missouri. Geneoscopy's initial product is a noninvasive colorectal cancer screening test, ColoSense, that detects colorectal cancer and high-risk precancerous polyps—advanced adenomas.[14] Designated a Breakthrough Device by FDA, ColoSense received FDA approval on May 6, 2024.[15]

[14] https://pubmed.ncbi.nlm.nih.gov/11916153/
[15] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001

Government Processes Delay Access and Slow Adoption of Screening Innovations

Requirements for Medicare & Commercial Coverage and Steps to Secure Provider Utilization of Innovative Technologies for CRC Screening

Task 1: Breakthrough Device Designation Grants 18 Month Accelerated FDA Approval
Task 2: CMS NCD Reconsideration Delay Due to "Internal Capacity Restraints" (9–12+ month process)
Task 3: USPSTF Updates About Every 6 years ACA Refers to USPSTF for Payor Coverage Mandate CRC Review Cycle *Estimated* to Begin 2025
Task 4: NCQA (Medicare & Commercial) Quality Metrics Rely on USPSTF Guideline Inclusion
Task 5: Coverage by Commercial Payors and Provider Utilization/Adoption Following USPSTF & NCQA