Blackstone

October 25, 2023

Vanessa A. Countryman
Secretary
Securities and Exchange Commission
100 F Street, NE
Washington, D.C. 20549-1090

Re: Request for Comment on Proposed Rule on Safeguarding Advisory Client Assets;
Rel. No. IA-6240; File No. S7-04-23

Dear Ms. Countryman:

We greatly appreciated the opportunity to speak with staff from the Division of Investment Management and Division of Economic and Risk Analysis of the Securities and Exchange Commission (the "**Commission**") on August 2nd about how the above-referenced proposed rule ("**Proposed Rule**") would apply to advisory clients' investments in the form of transferable contractual arrangements with biotechnology, pharmaceutical and medical technology companies ("**life sciences companies**"). We refer to these contractual arrangements throughout this letter as "**Contracts**" and we write today to memorialize and elaborate on information we provided to the staff at that meeting.

Contracts, which are not securities, provide an important source of capital to life sciences companies to develop drugs and devices during clinical trials through regulatory approval in exchange for the right to receive future milestone and/or royalty payments. This capital allows life sciences companies to develop drugs and devices for patients in diseases with high unmet needs. Blackstone strongly supports the Commission's goal to protect advisory clients' investments, but we have concerns that the Proposed Rule would effectively eliminate advisory clients' access to life sciences investment strategies involving Contracts.[1] As such, the effect of the Proposed Rule would run counter to the SEC's mission, which includes promoting capital formation and efficiency in the markets, as well as protecting investors. Indeed, we see the Proposed Rule as impeding capital formation by life sciences companies and reducing market

[1] We note that several commenters have objected to the Proposed Rule being adopted, citing a wide range of negative consequences across the U.S. financial markets. See, e.g., Joint Trades Letter, Re: Negative Impacts of the Safeguarding Proposal on Investors, Market Participants, and the Financial Markets (Sep. 12, 2023), available at https://www.sec.gov/comments/s7-04-23/s70423-258159-603042.pdf. See also Comment Letter from American Investment Council (May 8, 2023) (imploring the SEC to withdraw or repropose the Proposed Rule), available at https://www.sec.gov/comments/s7-04-23/s70423-185839-339964.pdf.

Blackstone
345 Park Avenue New York NY 10154
T +1 212 583 5000 F +1 212 583 5749
blackstone.com

efficiencies. This would be a particularly regrettable outcome because Contracts raise little, if any, risk of investor harm through misappropriation.[2]

We provide below a summary of our comments to the Proposed Rule, followed by a more detailed discussion.

Summary of Comments

1. Life sciences Contracts support vital medical research and development ("**R&D**"), and many advisory clients seek access to investments in life sciences Contracts.

2. The Proposed Rule risks effectively eliminating advisory clients' ability to invest in life sciences Contracts. Accordingly, the Commission should exclude Contracts from any final rule.

3. If the Commission does not exclude Contracts, it should at a minimum expand the exception for privately offered securities and physical assets to include Contracts.

4. In all cases, the Commission must include in any final rule a grandfathering or "legacy" exception for existing investments.

Discussion of Comments

1. Life sciences Contracts support vital medical R&D, and many advisory clients seek access to investments in life sciences Contracts.

Over the past two decades, life sciences companies have emerged as an engine of innovation and job growth, and a primary source of novel therapeutics for patients and their families in the United States and globally. Since 2010, for example, about two-thirds of drugs in development and more than half of Food and Drug Administration ("**FDA**") approvals have biotechnology origins.[3] The cost of innovative medicines and other pharmaceuticals is substantial, however, averaging approximately $2.6 billion to develop,[4] and most biotechnology companies developing new products do not generate any product revenues.[5] Large numbers of these companies, therefore, depend on external sources for financing. Even major pharmaceutical and medical technology companies depend on external sources of financing (e.g., stock issuances) to help develop their R&D pipeline due to competing demands and limited resources. This funding paradigm exposes the life sciences industry to the capital market's inherent volatility and is

---

[2] This letter focuses on Contracts in the life sciences context, but our comments are applicable to a wide variety of non-security contractual investments that are not subject to transfer restrictions in which advisory clients invest and that have similar characteristics. These contractual investments include ones involving music and film catalogues and rights, litigation settlements, life insurance contracts and accounts receivable. For purposes of this letter, the term "Contracts" should be read to refer to these other contractual investments, in addition to ones with life sciences companies. The Commission would need to include in its analysis the inability of investment advisers to comply with the Proposed Rule, as drafted, relative to all investment contracts in advisory clients' accounts, which burden would amount to an effective ban on those investments. Although beyond the scope of this letter, we also have significant concerns for the Proposed Rule's impact on other widely traded non-security instruments, including loans and swaps and other derivatives instruments We believe the Proposed Rule's "possession and control" requirements for qualified custodians will hamper the timely settlement for derivatives and disrupt investment advisers' ability to hedge client accounts through the use of derivatives.

[3] Iquvia Institute, "Global Trends in R&D 2023" (Feb. 2023), available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/global-trends-in-r-and-d-2023.

[4] See, e.g., Deloitte, "Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022" (Jan. 2022).

[5] According to Capital IQ, 84.7% of U.S. public biotech companies have negative earnings before adjustments associated with interest, tax, depreciation, and amortization over a trailing 12-month period.

inconsistent with the long-term nature of drug development. These tensions have played out dramatically over the past two years. The unprecedented declines in public biotechnology markets have left hundreds of biotechnology companies without adequate resources to advance their programs and many now face existential risks.[6]

Private sources of capital are an alternative for life sciences companies to being acquired by a larger pharmaceutical company or accessing the public markets, which can be costly or simply unavailable. Clients of investment advisers, including Blackstone Life Sciences ("**BXLS**"), serve as a vital lifeline to the medicines of tomorrow by helping companies continue to fund their programs when public markets become either less willing or able. Funds advised by BXLS enter into risk-sharing partnerships with life sciences companies where the client provides capital to develop drugs and devices during late-stage clinical trials through FDA or other regulatory approval in exchange for the right to receive future milestone and/or royalty payments if the drug or device is eventually approved and/or commercialized ("**Future Milestone Payments**" and this type of Contract entered into between parties, a "**Joint Development Agreement**"). Life sciences companies find these risk-sharing partnerships attractive because (i) there is a genuine sharing of risk on the development of a medicine or device between the life sciences company and fund, (ii) they tend not to dilute the companies' equity shareholders, (iii) the public equity market as a source of capital exposes life sciences companies to the market's inherent volatility, and (iv) these arrangements are consistent with the long-term capital needs of drug development, with discovery to marketing of a drug taking an average of 12 or more years.[7]

In our experience, life sciences companies value BXLS client investment not just as a source of funding but also because of its accompanying development, regulatory, commercial, and operational expertise. BXLS's investment professionals include medical doctors, PhDs with advanced scientific degrees and former CEOs and heads of R&D and clinical, regulatory and commercial operations of life sciences companies who have collectively helped steer twenty-seven drugs through the FDA approval process.[8] Beyond financings, BXLS routinely offers and delivers substantial assistance to the companies in which clients invest by, for example, designing clinical trials for the maximum chance of success, setting up joint steering committees to make other major decisions regarding the conduct of the clinical trials, reviewing the selection of the clinical research organization that conducts the clinical trial, and, in certain cases, being responsible for the day-to-day operations of the clinical trial.

Contracts, including Joint Development Agreements, often provide the ability for an advisory client to transfer its rights to receive Future Milestone Payments to third parties following regulatory approval, and such transfer does not require the life science company's prior consent. This important feature provides liquidity opportunities for the advisory client. For example, Future Milestone Payments may extend over the life of the patent, often a decade or two long, while the life of a fund client may be shorter. Therefore, BXLS will, in many cases, seek to monetize the economic interest in the Contract before the end of the term for the benefit of that fund's limited partners.

---

[6] The Wall Street Journal, "Layoffs and Shutdowns Hit Biotech Industry in U-Turn; After years of easy money and heady growth, funding is slim and stocks are down" (Feb. 10, 2023).

[7] DiMasi J.A., Feldman L., Seckler A., Wilson A. "Trends in risks associated with new drug development: success rates for investigational drugs," Clin Pharmacol Ther. 2010;87:272–277.

[8] As of September 1, 2023.

As discussed below, the Proposed Rule represents an existential threat to this funding. It likewise would deprive advisory clients of an investment opportunity they desire, as demonstrated by BXLS having raised more than $8 billion across several life sciences funds.

2. The Proposed Rule risks effectively eliminating advisory clients' ability to invest in Contracts. Accordingly, the Commission should exclude Contracts from any final rule.

Current Rule 206(4)-2 (the "**Custody Rule**") under the Investment Advisers Act of 1940 ("**Advisers Act**") requires an investment adviser to maintain clients' funds and securities with a qualified custodian. When a client receives a Future Milestone Payment pursuant to a Contract, the cash payment must be held with a qualified custodian, but the Contract itself is not maintained at a qualified custodian because it is not cash or a security.

The Proposed Rule would require the investment adviser to maintain the Contract with a qualified custodian, and the Contract must be subject to that custodian's possession and control. The proposing release accompanying the Proposed Rule (the "**Proposing Release**") defines "possession or control" as "holding assets such that the qualified custodian is required to **participate in any change in beneficial ownership** of those assets, the qualified custodian's participation would **effectuate the transaction** involving the change in beneficial ownership, and the qualified custodian's involvement is a condition precedent to the change in beneficial ownership."[9]

Given those requirements for holding and transfer, the Proposed Rule provides an impractical and unworkable framework for this asset class. It would require a fundamental change to Joint Development Agreements and other Contracts, which is unlikely to ever happen for the reasons set forth below. As a result, the Proposed Rule, if adopted as drafted, will deprive advisory clients of investments in an attractive asset class and also deprive life sciences companies of a vital source of capital.

We strongly encourage the Commission to exclude Contracts entirely from the scope of any final rule. We believe that the benefits of the Proposed Rule do not justify the harm to Contracts and advisory clients that would result.[10]

The Commission's stated goal of the Proposed Rule is to protect assets from loss, theft, misuse, and misappropriation. Accordingly, any assessment of the potential benefits of the Proposed Rule requires an evaluation of the potential risk of loss, theft, misuse, and misappropriation of the assets subject to the rule. If the risk of loss to an asset is low or nonexistent, so too are the benefits of applying the Proposed Rule to that asset. The Proposing Release, however, contains no evaluation of any risk of loss for Contracts. Indeed, although the Proposing Release discusses

---

[9] Safeguarding Advisory Client Assets, Release No. IA-6240 at 62 (Feb. 15, 2023), https://www.sec.gov/rules/proposed/2023/ia-6240.pdf (emphasis added).

[10] Because the Proposing Release did not address Contracts, the Commission did not fulfill its obligations under Section 202(c) of the Advisers Act, which Courts and the Commission staff have interpreted to require the Commission when engaging in rulemaking to consider the benefits and costs to investors and other market participants of the proposed rulemaking. See, e.g., Business Roundtable v. SEC, 647 F.3d 1144 (D.C. Cir. 2011) (addressing statutory provisions in the Securities Exchange Act of 1934 and the Investment Company Act of 1940 that are identical to Section 202(c)); Chamber of Commerce v. SEC, 412 F.3d 133, 143 (D.C. Cir. 2005); see also SEC staff, Current Guidance on Economic Analysis in SEC Rulemakings (Mar. 16, 2012), available at https://www.sec.gov/divisions/riskfin/rsfi_guidance_econ_analy_secrulemaking.pdf.

certain asset classes, such as real estate, artwork and physical commodities,[11] it does not even mention Contracts as an asset class.

In terms of potential benefits from applying the Proposed Rule to Contracts, the Proposing Release provides no example of misappropriation of a Contract, nor are we aware of any such instance. One reason is that counterparties to Joint Development Agreements and other Contracts have strong incentives to confirm that they are satisfying their own contractual obligations to pay the appropriate party pursuant to the Contract. We believe any indication of misappropriation would trigger immediate scrutiny, including if the Contract was transferred to an affiliate of the investment adviser. This "self-policing" by counterparties to a Contract would likely be triggered no later than a request by an investment adviser or third party for payment to be made to any party other than the one specified by the Contract. Moreover, a fund's annual audit would include review of a significant sampling of proceeds received by the investment adviser and distributions made to fund investors. Any misappropriation or discrepancies are highly likely to be detected by the auditor. As part of a fund's annual audit, for example, the auditor receives written verification from a significant sampling of the counterparties to the Joint Development Agreements that the fund is still entitled under such Joint Development Agreements to receive the Future Milestone Payments. Accordingly, the risk – and corresponding benefits – of the Proposed Rule are minimal and highly theoretical.

The burdens imposed by applying the Proposed Rule to Contracts, in contrast, are severe and highly predictable. The Proposed Rule would fundamentally change the ownership and transfer rights of Joint Development Agreements. Based on our reading of the Proposing Release, having a qualified custodian hold a copy of the Joint Development Agreement in safekeeping will not be sufficient to maintain "possession or control" (and, in our experience, we believe custodians will be unwilling to do even that). We see no way for a custodian to have "possession or control" in the way the Proposing Release indicates other than by seeking to have the qualified custodian become a party to the Joint Development Agreement with authority to prevent the transfer of contractual rights, including the rights to future cash payments. As discussed below, we question how this impediment could be executed.

We expect that custodians will not willingly agree to become parties to these highly technical agreements. Custodians do not have the technical expertise necessary to review and be bound by these agreements nor are they likely to agree to assume the additional risk given the heightened negligence standards required by the Proposed Rule. Some Joint Development Agreements, for example, only provide for transferability once highly technical milestones have been reached. It is not realistic to expect a qualified custodian with no experience in pharmaceutical and medical device development to agree to put itself in a position where it would need to independently evaluate whether any milestone has or has not been achieved such that the rights under the Joint Development Agreement would become transferable and subject itself to liability for breach if its determination is challenged.

Even if custodians were willing to become a party to a Joint Development Agreement, doing so would harm investors. The Proposed Rule would effectively require the qualified custodian's consent to any transaction involving the sale of rights under a Contract by an advisory client,

[11] Safeguarding Advisory Client Assets, Release No. IA-6240 at 28 (Feb. 15, 2023), https://www.sec.gov/rules/proposed/2023/ia-6240.pdf.

which consent might not be forthcoming out of potential liability or other concerns. Even if the custodian provides consent, the marketplace would become far less efficient because a transaction would be unable to occur until the qualified custodian clears internal processes to approve it. This could add weeks and months to a transaction involving a Contract and introduce very significant deal risk.

The proposed "possession and control" requirement would severely disadvantage advisory clients versus other sources of capital, such as major pharmaceutical companies, that are not investment advisers. We believe that life sciences companies would become reluctant to engage with investment advisers because of the requirement to negotiate with a qualified custodian, in addition to the investment adviser, over the terms of the Joint Development Agreement. In addition to the added time, expense and complexity to add qualified custodians as parties to Joint Development Agreements, we believe that life science companies would be extremely sensitive to qualified custodians having access to some of their most sensitive intellectual property and trade secrets and potentially having any input into how a drug or device is to be developed. The result would reduce investment opportunities for advisory clients and impede the efficient flow of capital to life sciences companies as an alternative to large pharmaceutical companies or other market participants unburdened by this possession and control requirement. Life sciences Contracts account for over 80% of investments managed by BXLS. In their absence, the investment strategies of advisory clients, including those existing funds in which investors have already committed significant capital, would not be viable.

More broadly, the Proposed Rule would disrupt the funding of innovation in the life sciences industry, potentially causing investment advisers not only to halt future investments into the industry but also to need to abruptly exit existing investments (assuming any final rule does not include grandfathering as discussed later in this letter). This could leave life sciences companies at risk of losing funds they counted on to sustain the years-long course of developing medicines and devices through to approval.

3. If the Commission does not exclude Contracts, it should at a minimum expand the exception for privately offered securities and physical assets to include Contracts.

The Proposed Rule provides a limited, conditional exception for privately offered securities and commodities and other physical assets that are not securities. The proposed exception is not available for Contracts as they would not satisfy the definition of "privately offered securities"[12] under the Proposed Rule and they are not physical assets. We believe an exclusion for Contracts from any final rule is objectively better for investors because that would avoid unnecessary costs for the proposed auditor verifications for transfers of an asset that is difficult for an adviser to misappropriate. If the Commission disagrees, it is critically important that it expand the exception to cover Contracts so that any final rule is proportionate to the limited risk of misappropriation of Contracts.[13]

---

[12] To qualify for the exemption under Proposed Rule 223-1(b)(2), the asset must be a "privately offered security" (or a physical asset). To qualify as a privately offered security, the asset must be a security, and also transferable only with the prior consent of the issuer or holders of the outstanding securities of the issuer. Contracts do not meet either condition, nor are they physical assets.

[13] We believe more broadly that the privately offered securities exemption should be expanded beyond securities to include loans, derivatives and other types of Contracts. As the Proposed Rule would expand the scope of the Custody Rule beyond securities to include all funds or other positions held in an advisory client's account, equal consideration should be given as to whether an exemption is appropriate for these additional asset classes subject to the safeguarding obligation in the Proposed Rule.

At our meeting in August, the Staff asked questions about extending the exception to Contracts because Contracts typically do not require any consent for a transfer of rights to receive Future Milestone Payments. In contrast, the exception for privately offered securities would require that those securities must not be transferable without the prior consent of the issuer (or holders of the outstanding securities of the issuer). The SEC adopted this restriction on transferability to provide some external safeguards against the kinds of abuse the rule seeks to prevent.[14] This same goal is accomplished in the context of Contracts, but in a manner different than transferability.

A party to a Joint Development Agreement risks liability if that party fails to satisfy its contractual payment obligations. Any indication of misappropriation is highly likely to trigger enhanced diligence, especially if the payment was requested to be made to any party other than the one specified by the contract. In other words, the policy goal is achieved through the self-interested vigilance required by parties to Joint Development Agreements and other Contracts to ensure they are paying the correct party.

To be clear, we do not believe that the other requirements under the revised "privately offered securities" exemption (e.g., annual verification by an auditor and the requirement to notify an auditor of any transfer of an asset) are necessary for the protection of, or in all cases workable with respect to, Contracts.[15] However, if retained, they would provide even further external safeguards to detect and prevent misappropriation.

Although the Commission might think that the parallel to the issuer's or holders' consent under the "privately offered securities" exception might be to require the affirmative consent of the counterparty to the Joint Development Agreement, we believe that introducing this requirement would substantially harm investors because the decision about if and when to monetize an investment would be shifted to a counterparty that owes no fiduciary duty to act in the best interests of the advisory client and has no incentive to provide its consent. We believe the right to transferability found in the Joint Development Agreements is in the best interest of advisory clients, who hire us and other investment advisers specifically to make that decision on their behalf. As a result, we believe Contracts should not be subject to the transfer restrictions prong of the proposed definition of "privately offered securities."[16]

---

[14] Custody of Funds or Securities of Clients by Investment Advisers, Advisers Act Rel. No. IA-2176, 68 Fed. Reg. 56,692 (Sept. 25, 2003), https://www.sec.gov/rules/final/ia-2176.htm.

[15] The Proposed Rule would require that (1) the investment adviser reasonably determines and documents in writing that ownership cannot be recorded and maintained in a manner in which a qualified custodian can maintain possession, or control transfers of beneficial ownership of such assets; (2) the investment adviser reasonably safeguards the assets from loss, theft, misuse, misappropriation, or the investment adviser's financial reserves, including the investment adviser's insolvency; (3) an independent public accountant, pursuant to a written agreement between the investment adviser and the accountant takes certain actions related to verification and notification; (4) the investment adviser notifies the independent public accountant engaged to perform the verification of any purchase, sale, or other transfer or beneficial ownership of such assets within one business day; and (5) the existence and ownership of each of the client's privately offered securities or physical assets that is not maintained with a qualified custodian are verified during an annual surprise examination or as part of a financial statement audit. Many aspects of these conditions present problematic burdens, as the AIC Comment Letter discussed. We share the AIC's concern that accountant verification and notification requirements (items 3 and 4 above) will impose undue costs for a low-risk asset class and will strain the operational capabilities of investment advisers and independent accountants alike.

[16] We reiterate our earlier point that other contractual investments should receive the same treatment as Contracts with life sciences companies. See footnote 1 of this letter.

4. The Commission must include a grandfathering or "legacy" exception for existing investments.

We urge the Commission in the strongest terms to provide, in any final rule, legacy treatment of existing contractual arrangements, similar to the Commission's legacy exception under the recently adopted Private Fund Adviser Rule for existing fund operational documents.[17]

Finding qualified custodians for, and amending, existing Joint Development Agreements as contemplated under the Proposed Rule may well be impossible. As explained above, we believe that custodians will not agree to become parties to these agreements and would be unable to custody them in compliance with the Proposed Rule. Even if they are willing to become a party to these contractual arrangements, it will take substantial time for investment advisers to negotiate and renegotiate agreements with each of their custodians and counterparties, respectively.

We similarly have no way to guarantee or require the cooperation of our life sciences counterparties as they would have no legal obligation or economic incentive to consent to these changes. Indeed, the amendments may increase their legal risk by introducing a new counterparty – the qualified custodian – not known to them and that has no expertise in life sciences and whose consent will now be necessary to give effect to contractual provisions in a pre-existing contractual arrangement.

Legacy treatment is required even if the Commission expands the exception for privately offered securities to include Contracts. Counterparties to existing contracts can, and very likely will, simply refuse to make the necessary amendments or will demand significant concessions in return for their consent. Given our expectation that we would need to renegotiate more than three dozen existing Contracts, most of which are with separate counterparties whom we expect to take varying positions on the renegotiation of the Contracts, it will not be possible to be compliant with the Proposed Rule within the currently proposed compliance period, if at all. If this is the case, our advisory clients who have invested in non-security contractual arrangements will be obligated to sell their interests in Contracts, likely at "fire sale" prices. No broad, liquid market for Contracts exists given the scientific expertise and experience required to diligence each investment, and therefore it may not be possible to complete any sale process within the currently proposed compliance period. For all of these reasons, we believe that the Commission must include a grandfathering provision in a final rule.

* * * * *

[17] Private Fund Advisers; Documentation of Registered Investment Adviser Compliance, Advisers Act Rel. No. IA- 6383, 88 FR 63,206 (Sept. 14, 2023), https://www.sec.gov/rules/final/ia-2176.htm.

Again, we appreciated the opportunity to meet with the staff of the Division of Investment Management and Division of Economic and Risk Analysis to discuss the foregoing, and we urge the Commission to consider our comments and recommendations to avoid the severely negative impact the Proposed Rule will have on Contracts if adopted as proposed. If you have any questions, please do not hesitate to contact the undersigned.

Sincerely,

/s/ John Finley
John Finley
Chief Legal Officer
Blackstone Inc.

cc: The Hon. Gary Gensler, Chairman

The Hon. Hester M. Peirce, Commissioner

The Hon. Caroline A. Crenshaw, Commissioner

The Hon. Jaime Lizárraga, Commissioner

The Hon. Mark T. Uyeda, Commissioner

Mr. William Birdthistle, Director, Division of Investment Management