ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

ACRO Remarks as Prepared for Testimony – IRS and Treasury Public Hearing on Base Erosion and Anti-Abuse Tax (BEAT) Proposed Regulation

JOHN BENOIT: Thank you for allowing us to testify. I'll start by introducing ACRO and describe how the clinical research organization (CRO) industry works. The Association of CROs (ACRO) member companies are CROs themselves, with 130,000 employees around the world. Candice Whitehurst and I work for competitor CROs, but stand here together as part of ACRO because the BEAT rules are creating existential issues for our industry.

CROs provide a wide range of services to pharma, biotech, and the medical device industry, the bulk of which are clinical trials that help obtain FDA or foreign regulatory approval for a drug. A trial is performed in stages and is basically performed by administering an experimental therapy on patients versus a placebo and/or a similar therapy to test two elements: safety and effectiveness.

It is so challenging to find and recruit a patient—and thus also their doctor—to a specific clinical trial that in order to recruit enough patients to meet the study protocol within timelines, you often need to cover 50+ countries. The ongoing trial process requires boots on the ground in those 50 countries to manage and monitor the trial according to regulatory guidelines. This manpower burden is too large for pharma companies to perform if they only have a few drugs in their pipeline because the hours are heavily weighted at the beginning and end of the project. Therefore, they outsource to CROs who can run many trials and keep staff chargeable throughout the year. In the service industry, CROs are considered low margin and high volume, and pricing is commodity based. CROs are effectively the middlemen between these pharma or biotech customers, who we call "Sponsors," and the doctors ("Investigators") who are performing the real clinical check-up work with their patients in the trial.

In addition to our own direct work for the sponsors, we administer the *contracts with* and *payments to* those investigators, patients, pharmacies, and other *third parties* on behalf of the sponsors. These indirect, or "pass-through," costs are charged on to sponsors with zero markup, with the sponsors owning the data having responsibility to patients for the drug itself.

Importantly, because our sponsors demand one point of contact, we are frequently obligated to operate under a hub and spoke model, whereby a given sponsor contracts with one CRO entity (referred to as "Prime"), which in turn subcontracts to 50 different foreign subsidiaries for the local work performed, and those subs in turn contract locally with third party investigators and pay those pass-through costs. Even in cases where sponsors allow contracting with two or more CRO legal entities for the same trial, they typically require that all billing be administered via one entity.

This leads us to the impact of BEAT on our industry. Our comment letter addressed four main concerns: pass-through payments, revenue sharing payments, netting, and bifurcated year. I will hand it over to Candice to address these concerns.

CANDICE WHITEHURST: Thanks, John. As John mentioned, CROs enter into contracts with sponsors for certain clinical trial services. Generally, these contracts include a direct and indirect fees portion. Let's focus on the indirect fees first.

Indirect fees are for reimbursable costs also referred to as pass-through costs that the CRO incurs on behalf of the sponsor. The indirect fees completely offset the pass-through costs, resulting in zero margin for the CRO. For example, investigator payments are a significant component of pass-through costs. Investigator payments are fees paid to compensate doctors and hospitals for administering the trials. CROs provide clinical trial project management services, but do not provide the medical expertise to oversee the trial. The contracts with the sponsor require reimbursement of these investigator pass-through expenses without any markup. Furthermore, the CRO's foreign affiliates incur come of the pass-through expenses based on the location of the clinical trial. As mentioned earlier, the sponsor wants to administer billing with one entity, in this example the US entity, and as such the reimbursement of the pass-through costs comes in through the US and then the US remits to the foreign affiliate (with no markup) their share of the indirect fees to cover their pass-through costs.

The proposed regulations do not contain any specific provisions with respect to the treatment of payments made by a US taxpayer to reimburse a foreign related party without a markup for these pass-through payments. ACRO recommends that the final regulations acknowledge that pass-through payments to foreign affiliates are not base erosion payments, and provide factors and/or safe harbors that state reimbursements for third party cost costs without markup are not base eroding. ACROs recommendation is consistent with general tax principles where an entity that is just facilitating a payment would be treated as a mere conduit. The CRO does not experience an accession to wealth when they receive indirect fees, since they have an obligation to repay a 3rd party. CROs have no claim of right to, and receive no benefit from, amounts received from sponsors that are required to be transmitted to foreign related parties to cover pass-through costs.

Additionally, while we recognize the government's intent based on the language in the preamble for general tax principles to apply in determining the treatment of pass-through payments, ACRO feels this clarification is necessary given the significance of the amounts at issue to the industry. For example, if a CRO remitted $50M of pass-through payments related to indirect to fees to its foreign affiliates, and if subject to BEAT, it would result in $5M of tax at the 10% rate for which there was zero margin on those indirect fees. Further, depending on the size and operating model of the CRO, those pass-through payments may be upwards of $200M.

Now, let's look at the direct fees. Direct fees are simply fees for services that the sponsor pays the CRO for clinical trial management and monitoring services. In accordance with the sponsor contract, the services may be performed by the CRO or its foreign affiliates depending on the location of the clinical trial. In the CRO structure mentioned earlier, generally the US entity and foreign affiliates will share in the direct fee revenue based on the location of the clinical trial.

The proposed regulations do not contain any specific rules regarding direct fees but merely note in the preamble that general tax principles should apply in determining the beneficial owner of income. The CRO generally does not have a claim of right to direct fees received when it has a requirement to transmit the amount to a foreign affiliate in a valid agency or revenue sharing agreement. Furthermore, under agency principles, in order to support a position that the US entity is an agent for the foreign related parties, the US entity generally must be disclosed as an agent with respect to any services performed by a foreign related party. If a US entity is an agent, then amounts collected from the customer for direct fees and transmitted to foreign related parties would not be treated as income or deductions of the US entity.

Similarly, under revenue sharing principles, a US entity arguably would not have income for direct fees it receives from a customer related to an arrangement to share revenue where each of the parties has the rights and obligations with respect to their performance using their assets and their employees. If the US entity and the foreign related parties have a valid revenue sharing arrangement, then amounts collected from the customer for direct fees and transmitted to foreign related parties would not be treated as income or deductions of the US entity.

Given the CRO operating model, it is critical that revenue sharing payments be received pursuant to a valid agency or revenue sharing arrangement. A different result would substantially change the economics of the transactions. As such, many CROs are faced with the need to restructure their operations and/or contracting models to ensure their agreements are considered valid agency or revenue sharing arrangements.

Due to the significance of the issue to the CRO industry, ACRO recommends that the final regulations acknowledge that revenue sharing payments are not base erosion payments to the extent they are paid pursuant to a valid agency or revenue sharing agreement, and provide factors or safe harbors to determine whether the agency or revenue sharing agreement is valid.

We hope we have provided insight on why the CRO's industry specific facts on structure and contracting make clear that indirect fees for pass-through costs and direct fees under revenue sharing agreements are not eroding the US tax base and should not be considered base eroding payments. In addition to providing clarification in the final regulations on these payments, we would like to recommend that gross payments made and received by a taxpayer be netted to the extent the payments are connected with the same business activity, product or service as outlined in our comment later. Lastly, we would recommend that the proposed regulations be modified to provide that section 15 does not apply to taxable years beginning in calendar year 2018, and align with the statutory language that a rate of 5% shall apply to taxable years beginning in 2018. Thank you for time and consideration.