



WHITE PAPER

TAXATION OF CLINICAL TRIAL PARTICIPANTS



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Payments received by clinical trial participants to cover non-medical costs- including costs associated with transportation to and from the clinical trial site, lodging, loss of wages, additional childcare, parking, and meals- are treated as taxable gross income in the United States.

As many clinical trials fail to reach target enrollment, taxing those that participate in clinical trials appears to fly in the face of common sense and deter participation, in particular for (i) recipients of low-income subsidies if the remuneration received from clinical trials causes their income to exceed the income threshold to qualify for subsidies; and (ii) undocumented immigrants who may be reluctant-out of fear of deportation- to complete required tax forms to obtain financial assistance.

The time is now to amend the Internal Revenue Code to provide a gross income exclusion for payments to clinical trial participants. Such an amendment would not merely remove the barrier to participation by undocumented immigrants and recipients of income-based subsidies but would also provide a positive incentive for participation in clinical trials by all members of our society.

I. Taxation of Payments to Clinical Trial Participants

The Internal Revenue Code (“Code”) defines “gross income” as “all income from whatever source derived,” specifically including compensation for services. The Internal Revenue Service (the “IRS”) and the courts have applied the definition broadly to include “income realized in any form”¹ and any “accessions to wealth, clearly realized.”² Specific to the biomedical context, the Tax Court has held that payments received by a blood donor for plasma and travel allowances is “clearly” income.³ The IRS has also treated as income payments an asthma sufferer received for participating as a subject in testing experimental asthma medications.⁴

¹ Treas. Reg. §1.61-1(a).

² *Comm’r v. Glenshaw Glass Co.*, 348 U.S. 426, 431 (1955).

³ See *Green v. Comm’r of Internal Revenue*, 74 T.C. 1229, 1233 (1980).

⁴ See Tech. Adv. Mem. 9106004 (August 2, 1990).



While clinical trial payments are included within the concept of gross income, participants may be able to offset the income with deductions for expenses incurred in connection with their participation in the trial. Such expenses are deductible if they qualify as “trade or business” expenses or as deductible medical expenses. As illustrated next, these deductions are difficult for most clinical trial participants to qualify for.

A. Trade or Business Expenses

If a taxpayer’s participation in a clinical trial constitutes a “trade or business,” the taxpayer may be able to deduct the travel and other ordinary and necessary expenses associated with that activity from gross income.⁵

The Code does not define the phrase “trade or business,” and no general conclusions can be drawn about whether participation in a clinical trial constitutes a trade or business. Rather, each case must be evaluated on its own. In general, however, the Supreme Court has stated that the trade or business concept generally requires that “the taxpayer must be involved in the activity with continuity and regularity and that the taxpayer’s primary purpose for engaging in the activity must be for income or profit.”⁶

Applying these general principles, the Tax Court has held that a taxpayer who sold a rare type of blood plasma was engaged in a trade or business where she sold her plasma continually for over seven years, was motivated primarily by the payments offered by the recipient blood lab, and where those payments were her main source of income during the year in question.⁷ By contrast, the IRS has held that a participant in an experimental asthma drug test was not engaged in a trade or business where the taxpayer had other full-time employment and was primarily motivated by a desire to receive treatment for his asthma.⁸

⁵ See Code §162.

⁶ *Comm’r v. Groetzinger*, 480 U.S. 23, 35 (1987).

⁷ See *Green*, 74 T.C. at 1235.

⁸ See Tech. Adv. Mem. 9106004.



While these disparate decisions reveal the case-by-case nature of the trade or business analysis, several factors suggest that it will be difficult for clinical trial participation to qualify as a trade or business. First, the remuneration offered is typically modest and intended to cover the costs of travel and inconvenience, not to provide a meaningful

source of income. Second, it may be difficult for the participant to show that earning the remuneration was the primary motivation. Finally, the limited life of a clinical trial will generally prevent the taxpayer's participation from being "regular and continuous" enough to constitute a trade or business.⁹

B. Deductible Medical Expenses

Deductible medical expenses are generally defined to include payments for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body, as well as transportation essential to obtain such care.¹⁰ For some clinical trial participants, participation in the trial may involve the receipt of medical care. However, because the clinical trial participant is not paying for the care, the medical expense deduction would be limited to transportation expenses.

More importantly, the medical expense deduction is limited to expenses in excess of 7.5% of the taxpayer's adjusted gross income.¹¹ As a result, even if a taxpayer's transportation expenses qualified as deductible medical care expenses, the deduction would only be available in very rare cases.

⁹ It should also be noted that if a participant was treated as engaged in a trade or business, any net income the participant derived from that trade or business would be treated as self-employment income subject to Social Security and Medicare taxes. *See* Code §1402.

¹⁰ *See* Code §213(d)(1).

¹¹ Code §213(a).

C. Treating Payments to Clinical Trial Participants as Taxable Income Imposes Barriers

i. Barriers to Recipients of Low-Income Subsidies



Participant remuneration made to offset the cost associated with participation in a clinical trial may create a barrier to participation if the payments threaten the participants' eligibility to qualify for income-based government benefit programs, such as Supplemental Security Income (SSI) and the Supplemental Nutrition Assistance Program (SNAP), as these benefits are in part based on an individual's

income and available resources.¹² To address this, Congress passed the *Improving Access to Clinical Trials Act of 2009*, which requires that the Social Security Administration (SSA) exclude up to \$2,000 annually in compensation received by individuals who participate in rare disease clinical trials when determining their SSI eligibility and benefits. Given the narrow application of this exclusion to rare disease clinical trials only, most payments to participants in clinical trials will be included in income for purposes of determining eligibility to qualify for income-based programs.

ii. Barriers to Undocumented Immigrants

Payments to clinical trial participants are reportable on tax form 1099. To issue a form 1099 to a clinical trial participant, the payor is required to obtain the clinical trial participant's taxpayer identification number ("TIN") by having the participant complete a form W-9.

¹² Since 1974, the SSI program, under Title XVI of the Social Security Act, as amended, has provided benefits to certain low-income aged, blind, and disabled persons—including adults and children—who meet the SSI program's eligibility requirements, including financial eligibility requirements. The SSI program was established by the Social Security Amendments of 1972 and became effective in 1974. Pub. L. No. 92-603, § 301, 86 Stat. 1329, 1465-78 (codified as amended at 42 U.S.C. § 1381-1383f).



The TIN for most taxpayers is their social security number. However, certain foreign nationals residing in the United States are not entitled to obtain a social security number. Instead, these individuals must request an Individual Taxpayer Identification Number (“ITIN”). Many foreign nationals present in the United States illegally are reluctant to obtain an ITIN, since this might lead to deportation or criminal proceedings. Treating clinical trial remuneration as taxable income thus has the practical effect of deterring undocumented immigrants from participating in clinical trials in the United States.

The Pew Hispanic Center, a non-partisan research organization based in Washington, DC, estimated that there were 11 million undocumented immigrants in the United States in 2019, representing 3.4% of the U.S. population. To ensure that the risk and benefits of a medical product are fully known, excluding undocumented immigrants from participating in clinical trials limits the scientific effectiveness of many clinical trials and present a public health risk to the population at large.

D. [A Better Approach](#)

The COVID-19 pandemic has highlighted many of the existing regulatory barriers that prevent or deter access to clinical trials. The time is now to amend the Internal Revenue Code to provide a gross income exclusion for payments to clinical trial participants. Such an amendment would not merely remove the barrier to participation by undocumented immigrants and recipients of income-based subsidies but would also provide a positive incentive for participation in clinical trials by all members of our society.

There is ample precedent for enacting such an exclusion. Congress has created gross income exclusions to incentivize or reward a variety of socially useful behaviors. For example, exclusions have been enacted to reward military service,¹³ to encourage education,¹⁴ to

¹³ See Code §§112 (excluding military pay during periods of service in a combat zone); 122 (excluding certain military retirement pay) and 134 (excluding certain military benefits).

¹⁴ See Code §§ 117 (excluding scholarships for tuition and related expenses) and 127 (excluding certain employer-provided educational assistance).



ameliorate the consequences of disasters and other misfortunes,¹⁵ to encourage family formation and child welfare,¹⁶ to encourage home ownership,¹⁷ and to protect the environment.¹⁸

Congress has also used exclusions specifically to promote positive healthcare outcomes. For instance, the Code currently excludes from gross income amounts received under employer-provided health plans,¹⁹ the value of employer-provided health insurance coverage,²⁰ benefits contributed to certain medical savings accounts,²¹ certain federal prescription drug subsidies²² and the value of certain health benefits received by Indian tribes and their members.²³ An exclusion for participants in clinical trials would provide an obvious benefit to the nation's public health and would be entirely consistent with these other health-related exclusions.

An exclusion for clinical trial payments would be unlikely to have any significant revenue impact for the government. Participation payments are generally modest, and Institutional Review Boards can be trusted to keep them so to prevent exploitation of vulnerable populations. If fiscal impact were a concern, the exclusion could be limited to payments below a given ceiling.

¹⁵ See Code §§ 101 (excluding certain death benefits), 104 (excluding payments received on account of certain injuries or sicknesses), 123 (excluding certain insurance-provided living expenses upon the loss of or damage to a home), 139 (excluding certain disaster relief payments) and 139F (excluding certain compensation for wrongful incarceration).

¹⁶ See Code §§ 129 (excluding employer-provided dependent care assistance), 131 (excluding amounts received by certain foster care providers) and 137 (excluding employer-provided adoption assistance).

¹⁷ See Code §121 (excluding certain gain from the sale of a principal residence).

¹⁸ See Code §§ 126 (excluding payments received under certain federal environmental conservation programs) and 136 (excluding payments received from utilities to purchase or install energy conservation property). In addition to these income exclusions, the IRS has recognized that certain payments should not be reportable as a matter of public policy. These include payments made to individuals for the benefit of the general welfare, such as certain job training awards (*see, e.g.*, PLR 201127007 (April 5, 2011)) and certain whistleblower awards (*see* Treas. Reg. §1.6041-1(l)).

¹⁹ See Code §105.

²⁰ See Code §106.

²¹ See Code §138.

²² See Code §139A.

²³ See Code §139D.



II. CONCLUSION

A gross income exclusion for clinical trial participant remuneration would provide an opportunity to dramatically change the narrative around clinical trials by removing regulatory barriers to participation. An exclusion would further promote and recognize the benefit of clinical trial participation to the advancement of medical knowledge.

