



September 9, 2014

Congressional Committees

Clinical Trials: Little is Known about Participation by Supplemental Security Income Recipients

Clinical trials can help to generate the evidence base for decision-making about the use of new treatments or drugs, and can be especially important for patients with serious or life-threatening health conditions who have limited treatment options. However, because trials are dependent upon voluntary participation from individuals who meet trial-specific criteria, successfully conducting a clinical trial can be challenging if there is a small pool of potential participants, such as individuals with rare diseases. Rare diseases generally include those affecting less than 200,000 individuals, though some such as amyotrophic lateral sclerosis (ALS) and cystic fibrosis affect far fewer individuals. As of March 2014, there were over 4,800 rare disease clinical trials in the United States seeking participants from a relatively small pool of individuals who may each choose to participate or not to participate in these trials for a variety of reasons. For example, Supplemental Security Income (SSI) recipients may be discouraged from participating if the clinical trial offers compensation that could affect their SSI eligibility and benefits, as these are, in part, based on an individual's income and available resources.¹

Finding that advances in medicine depend on clinical trial research, that researchers may face challenges enrolling participants in rare disease clinical trials, and that offering payment to participants may pose a barrier to enrollment if the payments threaten participants' eligibility for SSI, Congress passed the Improving Access to Clinical Trials Act of 2009 (the act).² The act required 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.³ The act also mandated that GAO review the impact of this change on SSI recipients' participation in rare disease clinical trials.⁴ We assessed: (1) what is known about SSI recipients' participation in clinical trials for rare diseases,

¹Since 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).

²Pub. L. No. 111-255, 124 Stat. 2640 (2010).

³SSA modified its Program Operations Manual System, effective April 3, 2011, to describe its policy and procedures for implementing the act. While this report focuses on SSI, the act also created a \$2,000 exclusion for rare disease clinical trial compensation when determining an individual's income eligibility for Medicaid. Under a sunset provision in the act, the amendments that established these exclusions will be repealed on October 5, 2015.

⁴§ 4, 124 Stat. at 2642.

including compensation received for their participation; and (2) what is known about the factors that affect SSI recipients' decisions to participate in clinical trials.

To answer our research questions, we collected and analyzed information through several methods. We reviewed relevant federal laws and regulations, as well as SSA policies related to rare disease clinical trial compensation received by SSI recipients. We also interviewed SSA officials and reviewed the agency's data on the exclusion of compensation for such trials from SSI eligibility and benefit determinations from April 2011, when SSA implemented the statutory exclusion, through April 2014. We determined these data were sufficiently reliable for the purposes of this report based on interviews with SSA officials about the agency's procedures to ensure the quality of these data and a review of related documentation. Because the National Institutes of Health (NIH) is the key federal agency involved in sponsoring and conducting biomedical research, including clinical trials, we interviewed NIH officials about factors that affect participation in clinical trials. As NIH also maintains the world's largest registry of publicly and privately supported clinical trials—ClinicalTrials.gov—we also reviewed national data on rare disease clinical trials available from this registry. Because we aimed to assess the impact of the changes made by the act, we reviewed data on rare disease clinical trials from calendar year 2008 through March 2014, a period covering the years immediately preceding and following its enactment. We determined these data were sufficiently reliable for the purposes of this report based on interviews with NIH officials about the procedures in place to ensure the quality and completeness of these data. In addition, we identified rare disease professional organizations, such as the National Organization of Rare Diseases (NORD), and interviewed organization officials about the impact that excluding trial compensation from SSI eligibility and benefit determinations has had on participation in clinical trials for their respective diseases, as well as factors that generally affect participation in clinical trials. We also worked with NORD to collect this information from its over 200 member organizations. Further, we conducted a literature search that identified 53 studies on the topic of participation in clinical trials published since 2000—a time period we chose to ensure we obtained a comprehensive view of factors that affect individuals' decisions to participate in trials. We performed an initial review of these studies to identify those that focused on factors that affect individuals' decisions to participate in clinical trials, including those for rare diseases. Based on this criterion, we selected 10 studies for inclusion in this report.⁵ As part of our review, we assessed the methodologies and findings of each of these studies and determined that they were sufficiently reliable for the purposes of this report.

We conducted this performance audit from February 2014 to August 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

Some SSI recipients have participated in clinical trials for rare diseases and received compensation for their participation in recent years. Since April 2011, when it implemented the statutory exclusion, the SSA has excluded this type of compensation for 36 SSI recipients when determining their eligibility and benefit amounts. The amount of compensation that SSA excluded for each recipient generally ranged from \$50 to \$2,000 each year.

⁵Two of these studies looked at participation in clinical trials for two separate rare diseases, Lymphangioleiomyomatosis (LAM) and Pulmonary Arterial Hypertension (PAH).

Little is known about factors that affect SSI recipients' decisions to participate in rare disease clinical trials, as they have not been specifically studied. However, time, travel requirements, and other factors have been found to affect participation in clinical trials in general, including those for rare diseases. In particular, the amount of time involved in trial participation, including time away from school and work, as well as travel requirements, are factors that affect individuals' decisions to participate in trials, according to both literature we reviewed and rare disease organization officials we interviewed.

Background

Rare Diseases and Clinical Trials

There are approximately 7,000 rare diseases afflicting individuals in the United States, according to a recent Institute of Medicine report.^{6, 7} Some diseases are so rare that the number of reported cases is in the single or low double digits, while others afflict hundreds, thousands, or tens of thousands. This same report found that because the number of people afflicted with any particular rare disease is relatively small and the total number of rare diseases is relatively large, a range of challenges complicate the development of safe and effective drugs, biologics,⁸ and medical devices to prevent, diagnose, treat, or cure them. These challenges include difficulties in recruiting sufficient numbers of research participants for clinical trials, which are conducted to investigate the safety and effectiveness of new drugs or medical devices. Clinical trials are distinguished by phases and require different levels of participation. For example, phase I trials typically may only involve a small group of 20 to 80 people, while phase III trials may involve large groups of 1,000 or more people.⁹ Participants in clinical trials may receive compensation for their time and effort or reimbursement to cover out-of-pocket expenses they incur while participating, such as travel expenses.

Information about some clinical trials is available at ClinicalTrials.gov, a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world, which is maintained by NIH.¹⁰ Information available at ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Trial

⁶The Orphan Drug Act, as amended, defines a rare disease or condition as one which affects less than 200,000 persons in the United States, or which affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available a drug for such disease or condition will be recovered from sales in the United States of such drug. 21 U.S.C. § 360bb(a)(2)

⁷Institute of Medicine, *Rare Diseases and Orphan Products, Accelerating Research and Development* (Washington, D.C.: National Academies Press, 2010).

⁸Biologics include a wide range of products such as vaccines, blood, and blood components.

⁹According to NIH officials, clinical trials typically include fewer people when studying rare diseases. For example, the median numbers of people participating in rare disease trials registered in ClinicalTrials.gov were 30 and 240 in phase I and phase III, respectively.

¹⁰ClinicalTrials.gov was created in response to the Food and Drug Administration Modernization Act of 1997, which required the Department of Health and Human Services, through NIH, to establish a registry of clinical trials information for both federally and privately funded trials of experimental drugs for serious or life-threatening diseases or conditions. Pub. L. No. 105-115, § 113, 111 Stat. 2296, 2310-12 (codified as amended at 42 U.S.C. § 282(i)). The Food and Drug Administration Amendments Act of 2007 expanded the scope of trials required to be registered and added a requirement for summary results to be submitted for some registered trials. Pub. L. No 110-85, § 801, 121 Stat. 823, 904-22 (codified as amended at 42 U.S.C. § 282(j)). The site, which was made available to the public in February 2000, included registration information for more than 170,000 clinical studies and results of more than 13,000 of those studies as of July 9, 2014.

information is generally submitted when the trial begins and includes information such as the description and design of the study; the medical product, behavior, or procedure being studied; eligibility criteria for participation; locations where the study is being conducted; and contact information. In some cases, results of the study are also submitted. Federal law requires information about clinical trials that meet specified criteria to be submitted to the registry.¹¹ Other trials that have been approved by a human subjects review board and conform to the regulations of the appropriate national or international health authority may also be submitted. In part, to improve the amount of information available to the public, the International Committee of Medical Journal Editors (ICMJE) requires registration of clinical trials in public trial registries, such as ClinicalTrials.gov, in order for the results to be accepted for publication.¹²

Supplemental Security Income (SSI) Program

SSI provides cash benefits to low-income aged, blind, and disabled persons—including adults and children—who meet the SSI program’s eligibility requirements. SSA administers the SSI program through over 1,200 field offices around the country where staff process applications for benefits, verify financial eligibility, and compute benefit amounts. Following SSA’s review, state disability determination services offices assess applicants’ medical eligibility for SSI. In order to be eligible for SSI benefits based on a disability, an individual must have a medically determinable physical or mental impairment that (1) prevents the individual from engaging in any substantial gainful activity, and (2) has lasted or is expected to last at least 1 year or result in death.^{13, 14}

To be financially eligible for SSI, individuals must meet certain resource and income requirements.¹⁵ Specifically, an individual can have resources worth no more than \$2,000.¹⁶ However, some resources such as an individual’s home, a car used for necessary transportation, and household goods and personal effects, are not counted when determining eligibility for SSI benefits.¹⁷ Concerning income requirements, for 2014 the maximum SSI benefit amount was \$721 per month for an individual living in his or her own household and

¹¹See 42 U.S.C. § 282(i)-(j).

¹²The ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. The purposes of clinical trial registration are to prevent selective publication and selective reporting of research outcomes, to prevent unnecessary duplication of research effort, to help patients and the public know what trials are planned or ongoing, and to help give ethics review boards considering approval of new studies a view of similar work.

¹³The impairment must be of such severity that the individual is not only unable to do his or her previous work, but also cannot engage in any other kind of substantial gainful work which exists in the national economy. 42 U.S.C. § 1382c(a)(3)(A)-(B). Substantial gainful activity is generally work activity involving significant physical or mental activities that are done for pay or profit, whether or not a profit is realized. 20 C.F.R. § 416.972. A person who is earning more than a certain monthly amount is ordinarily considered by SSA to be engaging in substantial gainful activity. For 2014, the substantial gainful activity threshold is \$1,800 per month for blind recipients and \$1,070 per month for individuals with other disabilities.

¹⁴A child under the age of 18 may qualify as disabled if he or she has an impairment that results in “marked and severe” functional limitations. 42 U.S.C. § 1382c(a)(3)(C). Different considerations also apply when determining whether individuals are blind for SSI eligibility purposes. Adults aged 65 or older may qualify for SSI benefits without being disabled.

¹⁵See generally 42 U.S.C. §§ 1382(a), 1382a, 1382b.

¹⁶The resource limit for a couple is \$3,000.

¹⁷42 U.S.C. § 1382b(a).

having no other countable income.¹⁸ The benefit is reduced if the individual has countable income, and if such income exceeds the maximum benefit amount, he or she is ineligible for SSI benefits. However, some types of income are not counted when determining SSI eligibility and benefit amounts. For example, nutrition, housing, and home energy assistance benefits are types of unearned income that are excluded for SSI purposes.¹⁹ Further, the act requires that SSA exclude the first \$2,000 in compensation that participants in eligible rare disease clinical trials receive in a calendar year for purposes of determining their SSI eligibility and benefits.²⁰ SSA's operations manual classifies this income as unearned and establishes procedures for its exclusion.

Some SSI Recipients Have Participated in Clinical Trials for Rare Diseases and Received Compensation for Participation in Recent Years

In recent years, a small number of SSI recipients have participated in clinical trials for rare diseases and received compensation for their participation, according to SSA data. Specifically, since April 2011, when SSA began implementing the act by excluding participants' rare disease trial compensation from SSI eligibility and benefit calculations, 36 SSI recipients have reported receiving such compensation.²¹ Further, some of these recipients reported receiving trial compensation in multiple years. During this same period, however, recipients who had compensation excluded represented a very small proportion of the over 8 million SSI recipients yearly. Rare disease trial compensation excluded for each recipient generally ranged from \$50 to \$2,000 each year, with an average amount of \$804 since the exclusion provision went into effect. (See table 1.) Further, six of these recipients received over \$2,000 in trial compensation in a year, ranging from a total of \$2,850 to \$8,300.²² Under SSA policy, this type of income was not required to be specified as rare disease trial compensation in SSA's data before SSA began excluding it in 2011. Therefore, it is unknown how these data compare to the number of recipients who had rare disease clinical trial compensation before 2011 and the amount of compensation they received. Further, although SSA's data provide some information, they may not include information on all SSI recipients who were compensated for participating in a rare disease clinical trial since the statutory exclusion was implemented for reasons related to the recording of this type of income. For example, SSA guidance directs staff to record this type of compensation as "other" unearned income and then document that it is income from a rare disease clinical trial in a narrative field using the phrase "clinical trials act." Because this is a manual process, SSA officials acknowledged that if this information is not recorded as directed,

¹⁸For 2014, the maximum benefit amount was \$1,082 for eligible couples.

¹⁹Certain types of income are excluded under the SSI program by the Social Security Act. 42 U.S.C. § 1382a(b). For a list of types of income excluded under the SSI program as provided by federal laws other than the Social Security Act, see the appendix to 20 C.F.R. part 416, subpart K.

²⁰42 U.S.C. § 1382a(b)(26).

²¹These recipients had a variety of primary diagnoses, with the most common being schizophrenic, paranoid and other psychotic disorders; cystic fibrosis; and chronic pulmonary insufficiency. The rare disease clinical trials that these individuals participated in may not be related to these specific diagnoses.

²²For one SSI recipient, SSA excluded \$3,700 in rare disease trial compensation during a year, which exceeds the \$2,000 maximum. An SSA official told us that this was a processing error and not consistent with SSI policy. The maximum amount excluded for this recipient should have been \$2,000. SSA excluded \$2,000 of compensation for the other five SSI recipients who received more than \$2,000 in compensation in a year. Further, for these five SSI recipients the amount of clinical trial compensation they received made them ineligible for SSI benefits for at least one month.

SSA's data may underreport the number of recipients with rare disease clinical trial compensation.

Table 1: Supplemental Security Income (SSI) Recipients with Excluded Rare Disease Clinical Trial Compensation, 2011 through 2014

Calendar year	2011	2012	2013	2014
SSI recipients at end of year	8,112,773	8,262,877	8,363,477	8,414,517 ^a
Annual number of SSI recipients with excluded rare disease clinical trial compensation ^b	11 ^c	14	22	7 ^d
Average amount of trial compensation excluded	\$773 ^c	\$799	\$898	\$568 ^d

Source: GAO analysis of SSA data. | GAO-14-734R.

^aThis number is as of April 2014.

^bThe numbers of recipients in this row do not add to 36, as some SSI recipients received this type of compensation during multiple years.

^cThis amount is for the period April through December 31, 2011, as SSA began implementing the exclusion provision in April 2011.

^dThis amount is for the period January 1, 2014 through April 26, 2014.

Information on clinical trials that include U.S. participants is maintained in the federal ClinicalTrials.gov registry; however, the registry does not include information on individual participants, such as whether they are SSI recipients, or if they received trial compensation. Concerning clinical trials for rare diseases, each year from 2008 through 2013, between 1,500 and just over 1,700 rare disease clinical trials with at least one study location in the U.S. were added to ClinicalTrials.gov for a total of over 9,400 registered rare disease clinical trials over the 6-year period.²³ Further, the proportion of all clinical trials registered with ClinicalTrials.gov that address rare diseases was relatively constant over this time period, at about 25 percent in each year. The registry information also generally indicates the extent of the need for trial participants with rare diseases. As of March 19, 2014, there were over 4,800 registered rare disease clinical trials open for recruitment—trials that have not yet started recruiting or are currently recruiting participants—with anticipated enrollment of over 800,000.²⁴

Officials from most rare disease advocacy organizations we contacted did not have information about the extent to which SSI recipients with rare diseases participated in clinical trials before or after SSA implemented the statutory exclusion. Specifically, neither officials from NORD nor officials from its over 200 member organizations recalled any situations in which compensation provided to SSI recipients for participating in rare disease clinical trials affected trial participation before or after the exclusion. However, officials from the Cystic Fibrosis Foundation (CFF), which represents the estimated 30,000 individuals in the United States living with cystic fibrosis, told us that they began receiving calls from individuals concerned about the effect of trial compensation on their SSI benefits starting in 2006.²⁵ In response to a recent query by CFF,

²³These are interventional studies (or clinical trials), in which participants are assigned to receive one or more interventions—processes or actions that can include drugs, medical devices, procedures, vaccines, and other products—that are either investigational or already available so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. Interventions can also include noninvasive approaches, such as surveys, education, and interviews.

²⁴As previously noted, these open trials are those that had at least one study location in the United States. The proportion of the anticipated enrollment that would be drawn from the U.S. population is unknown.

²⁵According to May 2014 SSA data, there are over 8,000 SSI recipients with this disease, and as of March 2014, there were 46 open cystic fibrosis clinical trials with an anticipated total enrollment of just over 3,300 participants.

some officials associated with cystic fibrosis care centers indicated that SSI recipients had been unwilling to participate in trials at their centers prior to the exclusion of compensation because of these concerns, but more SSI recipients have been participating in clinical trials at their centers since SSA implemented the exclusion provision.²⁶ However, beyond these examples, data were not provided that could be used to quantify how many cystic fibrosis patients who receive SSI declined to participate in trials prior to the exclusion or chose to participate after the statutory exclusion was implemented.

Little Is Known About Factors That Affect SSI Recipients' Trial Participation

The factors that may specifically affect SSI recipients' decisions to participate in rare disease clinical trials have not been studied. However, time, travel requirements, and other factors have been found to affect participation in clinical trials in general, including those for rare diseases. In particular, the amount of time involved in trial participation, including time away from school and work, as well as travel requirements, are factors that affect individuals' decisions to participate in trials, according to both literature we reviewed and rare disease organization officials we interviewed. For example, according to officials from a rare disease organization, one recent clinical trial required participants to be available on site at the trial location one day, every other week, for eight months. These types of trial requirements can be particularly challenging for participants who do not live nearby, as noted by an individual who works at a Colorado medical center that conducts rare disease trials with participants who travel from as far away as Montana, Kansas, and Wyoming. Another rare disease organization official, who is also a parent of a child with a rare disease, noted that for one trial, the parent and child drove seven hours so the child could participate. These types of situations can be difficult both because of the travel time and the time away from work for the parent and school for the child. According to studies we reviewed, additional factors that affect individuals' decisions to participate in clinical trials include child care needs, a lack of awareness of the availability of relevant trials or the benefits of participating, and various medical factors, such as concerns about trial procedures and the risk of side effects of experimental drugs. Further, some factors that may positively influence individuals' decisions to participate in clinical trials include a desire to help future patients, the potential for improved health status, and compensation.

As previously mentioned, although some stakeholders noted that compensation decreased participation in clinical trials in the past because individuals were concerned about its impact on their SSI eligibility and benefits, financial incentives to participate in clinical trials have generally been found to encourage participation in trials. This is likely because of the time, inconvenience, and expense that may be involved. Specifically, some studies offer reimbursement to trial participants for certain types of expenses incurred, such as for travel, or compensation for the time and inconvenience of participating. According to the Food and Drug Administration (FDA), it is not uncommon for clinical trial sponsors to pay individuals for their participation in research, in part as a recruitment incentive, and this is often used when the health benefits to subjects are remote or non-existent. Clinical trials conducted by NIH compensate participants for their time and, in some instances, for the inconvenience of a procedure. For these trials, NIH has established standard compensation rates for participants' time, and each study's principal

²⁶CFF queried officials at 80 cystic fibrosis care centers where clinical trials are conducted to obtain this information. Twenty-six officials responded that SSI recipients were unable or unwilling to participate in clinical trials at their centers due to the effect of trial compensation on SSI benefits prior to the exclusion, and 13 responded that they had not encountered this situation at their center. Twenty-three of the 26 officials responded that more SSI recipients are participating in clinical trials at their centers due to the exclusion of trial compensation from SSI eligibility and benefit determinations. However, these officials did not report having data on the numbers of SSI recipients participating in trials at their centers. Officials representing the remaining 41 centers did not respond to the query.

investigator determines the amount of compensation for inconvenience. According to an official at the NIH Clinical Center, healthy volunteers are more likely to ask questions about payment for participation than individuals with the medical condition being studied. One study we reviewed on participation in clinical trials for a rare disease noted that patients identified financial considerations as relevant to their decisions to participate; however, these patients seemed to be interested primarily in receiving reimbursement for their incurred expenses.²⁷ Further, in this study, some patients downplayed the importance of compensation for trial participation, as one patient noted that compensation is a relevant issue, but the lack of it would not prevent him from participating in a trial.

Agency Comments

We provided a draft of this report to SSA and the Department of Health and Human Services (HHS). In its written comments, SSA agreed with our report as written. We have reprinted SSA's comments in their entirety in enclosure I. HHS provided technical comments, which we incorporated as appropriate.

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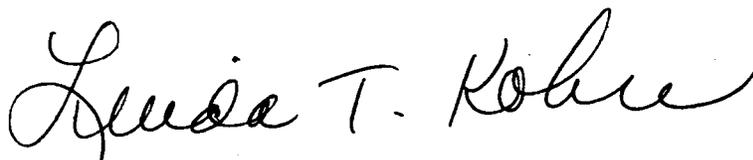
We are sending copies of this report to the Commissioner of Social Security, the Secretary of Health and Human Services, the Director of the National Institutes of Health, appropriate congressional committees, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

²⁷Carroll, Ricki et al., "Motivations of Patients With Pulmonary Arterial Hypertension to Participate in Randomized Clinical Trials," *Clinical Trials* June 2012.

If you and your staff have any questions, please contact Daniel Bertoni at (202) 512-7215 or bertonid@gao.gov or Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report were Rachel Frisk (Assistant Director), Natalie Herzog (Analyst in Charge), Sarah Cornetto, Jyoti Gupta, Kirsten Lauber, Ashley McCall, Martin Scire, and Jennifer Whitworth.



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Enclosure I: Comments from the Social Security Administration



SOCIAL SECURITY
Office of the Commissioner

August 18, 2014

Mr. Daniel Bertoni
Director, Education, Workforce,
and Income Security Issues
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Bertoni:

Thank you for the opportunity to review the draft report, "Clinical Trials: Little is Known about Participation by Supplemental Security Income Beneficiaries" (GAO-14-734R). We agree with the report.

If you have any questions, please contact me at (410) 966-9014. Your staff may contact Gary S. Hatcher, Senior Advisor for Records Management and Audit Liaison Staff, at (410) 965-0680.

Sincerely,

Katherine Thornton
Deputy Chief of Staff

Enclosure

SOCIAL SECURITY ADMINISTRATION BALTIMORE, MD 21235-0001

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