

February 9, 2012

Mr. Bennett M. Weiner
Chief Operating Officer
BBB Wise Giving Alliance
4200 Wilson Boulevard
Suite 800
Arlington, Virginia 22203

Dear Mr. Weiner,

Thank you for your January 9, 2012, letter regarding the valuation of inkind medical donations. Direct Relief is a BBB-accredited charity and supportive of your organization's objectives, so I am pleased to assist in the review of this important matter.

Your letter inquired whether, during the year covered by the most recent audited financial statements, Direct Relief received and [or] distributed the deworming medications mebendazole or albendazole. Direct Relief's Fiscal Year 2011, which ended on June 30, 2011, is the year covered by our most recent audited financials. During this period, Direct Relief did not purchase, receive via donation, or distribute these or any other deworming medications.

Direct Relief's most recent experience with these particular deworming medications was during Fiscal Year 2009, during which Direct Relief received via donation and subsequently distributed over four million tabs of mebendazole. Because this previous experience seems directly related to the topic of your inquiry, this letter responds to your specific questions using information from our organization's FY 2009 financial statements regarding how the mebendazole donations were handled at that time.

1. Were the mentioned de-worming medications received as a donation, purchased, or both during this period?

The mebendazole product Direct Relief received in FY 2009 was received as a donation, without *any* payment or financial transfer of *any* type (such as a handling fee) to the organization that made the donation. I note the absence of any such payments or financial transfers because press reports indicate that some organizations have taken the position that a "handling fee" payment to another nonprofit organization in exchange for a product is a charitable donation of the product rather than a purchase.

Recent press stories also have reported that some groups have taken the position that a payment to a commercial company in exchange for goods or services can be considered a

charitable donation if the company is providing a below-market discount of the product and has “donative intent.”

When such situations have arisen in Direct Relief’s experience, the transactions are considered a sale of goods, not a donation, and the value of the items received via the transaction would be reflected in our financial statements as the price paid.

As I understand some of the recent controversies and the components of your question, addressed below, a threshold matter of whether a transaction is considered a charitable donation arises before the subsequent question of its value does. It becomes a matter of defining “donation” and “purchase.” If an item is purchased, its value is clear. When an item is donated, its value must be established.

I very much appreciate that your inquiry attempts to delineate these issues, which seem to have become conflated. However, I would offer that if one were to take the position that certain exchanges or transfers of money for product are donations, not purchases, this rationale would carry forward throughout your entire series of questions, i.e. if the pills were donated, they were not purchased.

(a) If the pills were donated, were they received directly from the manufacturer?

In 2009, Direct Relief received as a donation from another nonprofit organization a non-FDA-approved generic formulation of 500mg chewable tablets of mebendazole manufactured in India by MicroLabs Ltd. We were informed at the time that the donating nonprofit organization had contracted with the company to manufacture the pills. Prior to accepting the donation offer, Direct Relief requested and received detailed product information from the donating nonprofit organization. The information included such detail as the manufacturer, dates of manufacture and expiry, packaging and labeling of the product, certificates of authenticity, and batch numbers. It is Direct Relief’s standard practice to obtain such information, because it typically must be furnished before any product can be imported into a country for donation to partner organizations and use by patients.

In this case, the donating nonprofit organization transferred the title of the property to Direct Relief and also arranged and paid for the transportation costs of the product from India to the port of entry in the various countries in which Direct Relief subsequently arranged the provision and distribution of the product at no charge. Direct Relief had no direct contact with the manufacturer.

Direct Relief’s extensive, longstanding program model involves donations directly from the manufacturers that both make and donate the product. The case in 2009 described here, in which another nonprofit organization contracted for a product’s manufacture and then donated the product to Direct Relief, is exceedingly rare in our experience. Although it is not the subject of your inquiry, it is worth noting that quality of the product was good, that it was requested by Direct Relief-approved partner organizations, that it was approved for importation by the relevant authority in each country into which it was provided, and that the

need for deworming medication is chronically high. It was for those reasons that Direct Relief was very pleased to accept the donation.

(b) If the pills were purchased, did you assign a value beyond the purchase price as a type of donation? If so, please explain.

Direct Relief did not purchase the medications. I note again, however, that answering the question “were the pills purchased?” turns on how “purchase” is defined. So it is important to emphasize that Direct Relief provided no payment of any type, made no financial or in-kind donation, and did not otherwise engage in any financial transaction whatsoever with the nonprofit organization that donated the tablets. Had we done so, the transaction would have been considered and reflected on our financial statements as a purchase and the value of the products would have been the price paid.

This is an important distinction to emphasize, as Direct Relief has been approached by nonprofit organizations offering to provide contract-manufactured, non-FDA-approved generic medications in exchange for a “donation.” It seems self-evident that simply characterizing a purchase transaction as a charitable donation does not make it a charitable donation. However, as your question here illustrates, the effect of such a sleight-of-hand accounting rationale becomes clear. If one takes the position that such a transaction *is* a donation, then no purchase occurs. By extension, no assignment of value *beyond the purchase price* can occur because there was no purchase price.

2. Please identify the volume and recognized dollar amount for the pills distributed during the fiscal year covered by your most recent audit report.

In FY 2009, Direct Relief received and distributed 4,308 bottles of 1,000-tab bottles (or a total of 4,308,000 tablets) of mebendazole. Each tab was valued at 3.2 cents. The recognized value for the donation, which is reflected as revenue, and subsequent distribution, which is reflected as a programmatic expense, was \$137,856.

As noted in your letter, Direct Relief also is aware of press reports, notably in *The Chronicle of Philanthropy* and *Forbes*, citing that similar generic, non-FDA-approved formulations of mebendazole obtained via donation or purchase have been valued at \$10 per tab or higher by nonprofit organizations that received them.

In Direct Relief’s experience, it is inconceivable that the donation of mebendazole our organization received in 2009, which was valued and reported at \$137 thousand could reasonably be valued at over \$43 million simply by virtue of an alternative accounting methodology being used.

3. Please describe the methodology (accounting rationale) used in arriving at the claimed value of de-worming medication distributed during this period. Please be more specific than stating only that the fair market value was used. For example, how did your organization arrive at the fair market value used?

In FY 2009, the product that Direct Relief received via donation from the nonprofit that had contracted for its manufacture was produced by MicroLabs Ltd. That company is one of six UNICEF-approved vendors of that specific product. To determine the fair market value of the donation, Direct Relief consulted the pricing guide jointly published by UNICEF and the World Health Organization (WHO) for this particular formulation and used the median published price, which was 3.2 cents/tablet. The resulting financial value recorded and reported on Direct Relief's financial statements was \$137,856.

I note that, in this particular case, the process of determining the value of the donated product was neither time consuming nor complicated. The pricing information for 500mg mebendazole chewable tabs is printed on page 16 of the UNICEF/WHO pricing guide, which is published online here: http://www.unicef.org/aids/files/Sources_and_prices_of_selected_medicines2009.pdf.

Although Direct Relief's longstanding program model is based on encouraging donations from manufacturers to serve people who need but cannot afford to purchase the products, our organization also routinely purchases medications needed for our humanitarian programs that are unavailable through donation. In all such instances, irrespective of the character (nonprofit or commercial) or intention of the seller, the value reflected on our financial statements is the purchase price of the product, which we believe is in accordance with U.S. GAAP and common sense.

Your letter notes the concerns that have been raised in specific regard to deworming medications, but the underlying issues about valuation are not exclusive to those particular drugs.

In addition to providing donated medications internationally for several decades as part of our humanitarian programs, Direct Relief is the only U.S. nonprofit organization licensed to distribute prescription medications in each of the 50 U.S. states. The Direct Relief USA program is the largest nonprofit provider of free medications to uninsured, low-income persons at America's nonprofit clinics and community health centers. This program alone provided more than 5,000 shipments containing a wide variety of prescription, over-the-counter medications, and medical supplies to nonprofit clinics in calendar year 2011.

Direct Relief's unique standing and experience within the U.S. is particularly helpful to our understanding of the strict legal and regulatory compliance issues related to the handling of prescription medications. Moreover, our experience in the U.S. and internationally also makes us keenly aware of the significant pricing differences that exist between FDA-approved formulations—since only such approved drugs may be distributed in the U.S.—and non-FDA-approved generic formulations made and sold elsewhere.

These distinctions are important for many reasons, including for the purpose of determining the fair market value of a medication when it is donated to Direct Relief. Any published pricing guide for a drug in the U.S. market necessarily presumes the product is an FDA-approved formulation, since only FDA-approved drugs may be distributed in the U.S. market. Prices are generally higher in the U.S. than in other markets. Because of this dynamic, U.S. pricing guides are not relevant for products that cannot be sold in the U.S. market.

Direct Relief publishes on our public website our organization's detailed policy and rationale regarding the valuation of inkind resources. Your letter notes that the BBB's interest in this matter is tied to the potential impact on your charity evaluations. I certainly appreciate and share this concern and respectfully offer that the topic also is a matter of law, accounting principles, public-reporting requirements, and relates to the matter of public trust generally. Because of this, Direct Relief is committed to getting it right and fixing it if we get it wrong. We welcome and appreciate any feedback, comments, or suggestions about these matters generally and how Direct Relief handles them specifically.

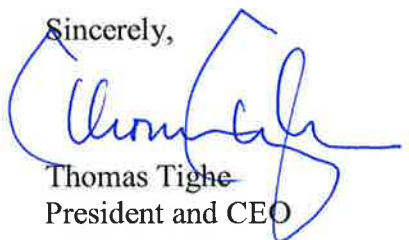
I am hopeful that Direct Relief's policies may provide more detail and be of additional benefit to your inquiry. The policy is published here:
<http://www.directrelief.org/OurFinances/Transparency/InKindValuation.aspx>.

As is noted in that policy, it may be helpful to consider the commodity of water in understanding and avoiding the confusion that has arisen with regard to valuing the commodity of drugs when they are donated. With water, the price (and therefore value if donated) that is paid for the same compound, H₂O, ranges from free in a public tap to several dollars for a "branded" bottled equivalent in a hotel room.

From a valuation perspective, if each type of water were to be donated to a nonprofit organization, the difference in its market price would be reflected accordingly in financial statements. Whatever tortured accounting logic might be applied, it would be absurd for the receiving nonprofit to conclude and reflect on its financial statements that a donation of tap water, which is usually available free, has the same fair market value as the "branded" water that sells for several dollars per bottle. Direct Relief's longstanding policy would prevent such an absurd result.

Thank you again, Mr. Weiner. Please do not hesitate to contact me if we can provide any additional information or clarification on this or any other matter.

Sincerely,



Thomas Tighe
President and CEO