From: OC GCP Questions

To: Subject:

Financial Disclosure Question on Annuities and Mutual Funds

Date: Monday, May 05, 2014 8:32:28 AM

Good morning -

I have consulted a few of my colleagues here at FDA.

If the annuity is issued by a company that isn't related to the sponsor (e.g., an insurance company), and the investigator has no control over the investments that fund the annuity, then I would say it isn't reportable

Regarding whether equity in a mutual fund, 401(k), or annuity is reportable, the guidance does say that control over stocks is what matters. The investigator has to have control over the stocks *and* actually hold some equity interests in the sponsor within the retirement account for the funds to be reported. If the investigator has control over her 401(k) and invests in energy companies, those stocks would not be reportable.

I hope this information is helpful. Please contact us again at gcp.question@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN Senior Health Policy Analyst Office of Good Clinical Practice Office of the Commissioner, FDA

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From: [Redacted]

Sent: Wednesday, April 30, 2014 2:33 PM

To: OC GCP Questions

Subject: Financial Disclosure Question on Annuities and Mutual Funds

I've got a question about financial disclosure concerning annuities.

There is no mention of them in the guidance.

Would the guidance concerning mutual funds and 401Ks apply to financial instruments like annuities?

The guidance says that they would not be reportable "in most cases" and then goes on to note that the investigator having control over the buying and selling of stocks within the mutual fund (or annuity?) then it's reportable. And if it's over \$50,000 AND the investigator has control over whether to buy or sell, it's reportable.

Would it be accurate to say that the control over buying and selling stocks within the financial instrument is the determining factor in whether or not the financial instrument is reportable?

Even a mutual fund or annuity that focuses on the healthcare/pharmaceutical industry wouldn't need to be reported if the investigator had no control over buying and selling decisions?

Could you provide an instance where an annuity or mutual fund would be reportable when the investigator does NOT have control over the buying and selling of stocks/investments within the fund?

Thanks [Redacted]