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Unambiguous Identification of Obesity Trials

TO THE EDITOR: Colman et al. (Oct. 25 issue)[1] describe trial results underlying approval of two weight-management drugs by the Food and Drug Administration. However, their table included noninformative terms (e.g., "study 1") without citing publications or ClinicalTrials.gov records. The materials that were referenced[2,3] used only acronyms (e.g., BLOOM) and internal identifiers (e.g., OB-301) — neither of which could be linked to the terms in the table. Using ClinicalTrials.gov (www.clinicaltrials.gov), we identified six studies of lorcaserin for obesity[4] and nine studies of phentermine and topiramate for obesity[5] (as of October 15, 2012). Only Colman et al. could confirm the likely matches (Table 1).

This is an important example of why listing ClinicalTrials.gov identifiers (NCT numbers) would provide unambiguous access to trial-design infor-

Table 1. Different Identifiers for the Same Clinical Studies.*

Drug, Identifier Used by Colman et al., and Identifier Used in References Cited by Colman et al.	Probable ClinicalTrials.gov Identifier	Publication (PubMed Identifier) Associated with Probable ClinicalTrials.gov Identifier
Belviq		
Studies 1 and 2 combined		
BLOOM	NCT00395135	Smith et al. Multicenter, placebo-controlled trial of lorcaserin for weight management. N Engl J Med 2010; 363:245-56 (20647200)
BLOSSOM	NCT00603902	Fidler et al. A one-year randomized trial of lorcaserin for weight loss in obese and overweight adults: the BLOSSOM trial. J Clin Endocrinol Metab 2011; 96:3067-77 (21795446)
Study 3		
BLOOM-DM	NCT00603291	O'Neil et al. Randomized placebo-controlled clinical trial of lorcaserin for weight loss in type 2 diabetes mellitus: the BLOOM-DM study. Obesity (Silver Spring) 2012;20:1426-36 (22421927)
Qsymia		
Study 1		
OB-302	NCT00554216	NA
Study 2		
OB-303	NCT00553787	Gadde et al. Effects of low-dose, controlled-release, phentermine plus topiramate combination on weight and associated comorbidities in overweight and obese adults (CONQUER): a randomized, placebo-controlled, phase 3 trial. Lancet 2011;377:1341-52 (21481449)

* BLOOM denotes Behavioral Modification and Lorcaserin for Overweight and Obesity Management, BLOOM-DM Behavioral Modification and Lorcaserin for Obesity and Overweight Management in Diabetes Mellitus, BLOSSOM Behavioral Modification and Lorcaserin Second Study for Obesity Management, and NA not applicable.

mation as well as results entries and publication information. We think that trial-registration numbers should be used in all documentation for referencing clinical trials to mitigate potential confusion about the study under consideration.

Deborah A. Zarin, M.D.
Tony Tse, Ph.D.
National Library of Medicine
Bethesda, MD
dzarin@mail.nih.gov

Dr. Zarin reports being the director of and Dr. Tse reports being a program analyst at ClinicalTrials.gov of the National Library of Medicine, National Institutes of Health. No other potential conflict of interest relevant to this letter was reported.

Editor's note: Zarin and Tse are correct. It is our policy to refer to clinical trials by their registration number or to reference a publication in which they can be unequivocally identified, and we should have done so for the ones they mentioned in their letter.

1. Colman E, Golden J, Roberts M, Egan A, Weaver J, Rosebraugh C. The FDA's assessment of two drugs for chronic weight management. N Engl J Med 2012;367:1577-9.
2. FDA briefing document — lorcaserin hydrochloride tablets, 10 mg. Presented at the Endocrinologic and Metabolic Drugs Advisory Committee meeting, May 10, 2012 (http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM303198.pdf).
3. FDA briefing document: phentermine/topiramate. Presented at the Endocrinologic and Metabolic Drugs Advisory Committee meeting, February 22, 2012 (http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM292315.pdf).
4. Lorcaserin trials. ClinicalTrials.gov (http://clinicaltrials.gov/ct2/results?term=lorcaserin+%5BTREATMENT%5D+AND+obesity+%5BDISEASE%5D).
5. Phentermine/topiramate trials. ClinicalTrials.gov (http://clinicaltrials.gov/ct2/results?term=%28+Phentermine+AND+Topiramate+%29+%5BTREATMENT%5D+AND+Obesity+%5BDISEASE%5D).

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Priming with Whole-Cell versus Acellular Pertussis Vaccine

TO THE EDITOR: From January through August 2012, Oregon had its highest annual tally of reported pertussis cases since 1959. The incidence was highest among infants and children between 10 and 14 years of age. Increasing disease among school-aged children despite high vaccination coverage may be in part a consequence of using acellular pertussis vaccines (diphtheria–tetanus–acellular pertussis, or DTaP), which in 1997 were approved and recommended for all childhood series instead of whole-cell pertussis vaccines (diphtheria–tetanus–whole-cell pertussis, or DTwP).[1] We wanted to examine the effectiveness of first-dose DTwP priming in children fully immunized with DTaP beyond their first year of life and in those who subsequently received a tetanus–diphtheria–acellular pertussis (Tdap) booster.

Pertussis cases from statewide surveillance and immunization records from Oregon's population-based immunization information system, ALERT IIS, were reviewed for children born in Oregon in the years 1997 through 1999. Cases included all patients considered to have "confirmed" pertussis as defined by the Council of State and Territorial Epidemiologists.[2] The incidence of disease among children who initially received an acellular vaccine was compared with that among children who initially received a whole-cell vaccine in the context of a variety of pertussis vaccination scenarios.

ALERT IIS holds pertussis immunization records for 195,959 children born from 1997 through 1999. From April 1997 through July 2012, a total of 484 cases of pertussis were reported, of which 402 (83%) could be matched to ALERT IIS pertussis vaccination records; 346 of these children had been vaccinated 14 days or more before disease onset. In all scenarios, the reported rates of pertussis were significantly lower among children who had started the vaccination process with DTwP than among those who had started with DTaP (Table 1). This effect existed regardless of whether the pertussis vaccination series had been completed or a recent Tdap booster dose had been administered. The risk of pertussis in the cohorts diverged at 10 years of age.

Among children born during the 1997–1999 transition period, those who underwent priming with acellular rather than whole-cell pertussis vaccine had higher rates of reported pertussis. Our findings concur with those from Australia and are consistent with the recent epidemiologic reports on pertussis in the United States.[3,4] Although statewide surveillance data underestimate disease incidence, and population-based immu-