

AMERICAN COLLEGE of CARDIOLOGY



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June 4, 2001

VIA UPS

Dockets Management Branch
Food and Drug Administration
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Re: Comments on Citizen Petition Docket No. 01P-0010

The American College of Cardiology (ACC) submits these comments to the Citizen Petition filed by Milberg, Weiss, Bershad, Hynes, and Lcrach LLP on behalf of Lawrence Bernhardt and Arnold Liebman (Docket No. 01P-0010). The Citizen Petition requests the Food and Drug Administration (FDA) to require notice to the medical community and users of Cardura® for the treatment of hypertension of the findings of the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attacks Trial (ALLHAT). The ACC would like to clarify information submitted in this Citizen Petition to the FDA, which was discussed in a public meeting by the Cardiovascular and Renal Drugs Advisory Committee on May 24, 2001.

The petition inaccurately describes the ACC's issuance of its "Clinical Alert On The Use of Alpha Blockers For Hypertension," dated March 15, 2000 (the original news release about the Clinical Alert attached as Exhibit 1, and the corrected news release attached as Exhibit 2). The news release outlined the recommendations contained in the ACC's Clinical Alert, which addressed the findings of the ALLHAT study.

To clarify, on March 15, 2000, the final day of the ACC's 49th Annual Scientific Session, at which the findings of the ALLHAT study were presented, the ACC issued a Clinical Alert to guide physicians and the public on how to interpret the findings of this study. The Clinical Alert was posted on the ACC's Web site (Exhibit 3). In addition, ACC issued a news release to the media with the heading that stated "AMERICAN COLLEGE OF CARDIOLOGY ISSUES CLINICAL ALERT ON THE USE OF ALPHA BLOCKERS FOR HYPERTENSION—ACC Recommends that Physicians Reassess Use Based on New Findings." (Exhibit 1). This heading and the text of the news release outlined the content of the ACC's Clinical Alert, which stated that physicians should reassess use of the alpha blocker, doxazosin (Cardura®). However, the news release contained a clerical error in the first sentence that stated

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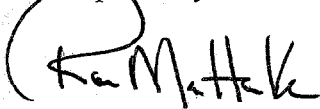
“The American College of Cardiology (ACC) recommends that physicians discontinue use of a widely prescribed drug, an alpha-adrenergic blocker, for the treatment of hypertension.” (Id. (emphasis added)). Almost immediately after issuing the news release, the error was noticed. It was the ACC’s intent to use “reassess” (and not “discontinue”) in both the headline and the first sentence in the news release. Therefore, that same day, the ACC quickly issued a second news release (Exhibit 2) that in the first sentence noted that “The American College of Cardiology (ACC) recommends that physicians reassess use of a widely prescribed drug. . . .” (Id. (emphasis added)). The two statements are identical except for the correction of the word “discontinue” to read “reassess” in the first sentence. The change in the language was not due to pressure from any third party outside of the ACC; it was simply a correction of a clerical error made in preparing the news release on that day.

On March 22, 2000, Pfizer Inc., (Pfizer) the manufacturer of Cardura®, contacted the ACC and brought to the ACC’s attention that the original, incorrect news release (Exhibit 1) had reached some physicians and that physicians had been confused by the difference between this news release and the actual Clinical Alert posted on the ACC Web site (Exhibit 3). Due to this confusion, on March 23, 2000, the ACC decided to issue a clarification explaining that its position on March 15 had always been that “physicians should carefully reassess the use of alpha blocker doxazosin (Cardura®), rather than automatically discontinuing its use. . . .” (March 23, 2000, statement attached as Exhibit 4). The March 23 statement was intended only to address any lingering confusion and to reiterate that the ACC’s position had not changed from its corrected version of the March 15, 2000, news release.

The Citizens Petition included the first March 15, 2000, news release (Exhibit 1) and the March 23, 2000, statement (Exhibit 4). It did not include the second March 15, 2000, news release (Exhibit 2)—the version with the correction in the first sentence—or the Clinical Alert itself (Exhibit 3). The ACC believes it is important for the FDA record in this matter to accurately reflect the releases made by it and the reasons therefor.

The ACC appreciates this opportunity to set the record straight and respectfully asks the FDA to note this letter as an addendum to the Citizen Petition. The ACC stands behind its Clinical Alert released on March 15, 2000, for physicians to “reassess use of the drug doxazosin.”

Respectfully submitted,



Ron Mattocks
Executive, Marketing and Communications

Exhibits 1–4 attached



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FOR IMMEDIATE RELEASE
March 15, 2000

Contact: Beth Cassady or Melanie Caudron
March 15, 714-765-2419
After March 15, 301-897-2628 or
Kathleen McGraw at 202-835-8807

AMERICAN COLLEGE OF CARDIOLOGY ISSUES CLINICAL ALERT ON THE USE OF ALPHA BLOCKERS FOR HYPERTENSION

ACC Recommends that Physicians Reassess Use Based on New Findings

(ANAHEIM, CALIF.)—The American College of Cardiology (ACC) recommends that physicians discontinue use of a widely prescribed drug, an alpha-adrenergic blocker, for the treatment of hypertension. This recommendation follows announcement of the results of a large high blood pressure study today at the ACC 49th Annual Scientific Session in Anaheim, Calif. Approximately 50 million Americans have hypertension, or high blood pressure.

The study was halted last week by the study sponsor, the National Heart, Lung, and Blood Institute (NHLBI), due to data showing that the alpha blocker, doxazosin (Cardura[®]), is less effective than the more traditional diuretic in reducing some forms of cardiovascular disease, such as congestive heart failure. The study, Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), showed that users of doxazosin had 25 percent more cardiovascular events and were twice as likely to be hospitalized for heart failure than users of the diuretic chlorthalidone.

According to the NHLBI, of the 24 million Americans who take medication to treat their hypertension, about one million use an alpha blocker.

“The ACC encourages physicians who treat hypertensive patients to review the new data with their colleagues to ensure the rapid dissemination of this important information,” said Dr. Robert J. Cody, chair of the ACC Hypertensive Diseases Committee and associate chief of the Cardiovascular Division at the University of Michigan Medical School in Ann Arbor. “At the same time, hypertensive patients taking an alpha blocker should first see their physicians before discontinuing its use. This is important because the treatment of hypertension and the choice of medication should be individualized for each patient.”

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NEWS RELEASE

The results were presented at the ACC meeting by Dr. Curt Furberg, of the Wake Forest University School of Medicine in Winston-Salem, N.C., and Dr. Barry Davis, of the University of Texas School of Public Health in Houston. For more information about the ALLHAT study, go to www.nhlbi.nih.gov and go to “news” and “press releases.”

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Alpha Blockers for Hypertension

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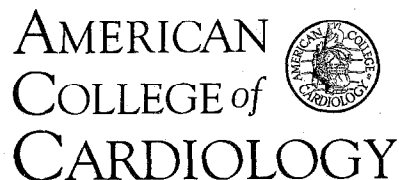
"The ACC encourages physicians who treat hypertensive patients to review the new data with their colleagues to ensure the rapid dissemination of this important information," said Dr. Robert J. Cody, chair of the ACC Hypertensive Diseases Committee and associate chief of the Cardiovascular Division at the University of Michigan Medical School in Ann Arbor. "At the same time, hypertensive patients taking an alpha blocker should first see their physicians before discontinuing its use. This is important because the treatment of hypertension and the choice of medication should be individualized for each patient."

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FOR IMMEDIATE RELEASE
March 23, 2000

Contact: Beth Cassady or Melanie Caudron
301-897-2628

ACC CLARIFIES CLINICAL ALERT ON ALPHA BLOCKERS FOR HYPERTENSION TREATMENT

(BETHESDA, MD)—The American College of Cardiology (ACC) is clarifying its previously released information on alpha-adrenergic blockers for the treatment of hypertension to emphasize the intent of its March 15, 2000, statement. The ACC Clinical Alert on Alpha Blockers for Hypertension stated that physicians should carefully reassess the use of alpha blocker doxazosin (Cardura[®]), rather than automatically discontinuing its use, based on the findings of a study sponsored by the National Heart, Lung, and Blood Institute (NHLBI). The ACC strongly encourages physicians to review the NHLBI data and statement for clarity and guidance in treating hypertensive patients.

The ACC clinical alert followed announcement of the results of a large study on the treatment of hypertension on March 15 at the ACC 49th Annual Scientific Session in Anaheim, Calif.

In its official statement, which follows, the ACC Hypertensive Diseases Committee urged patients taking an alpha blocker to see their physicians for reassessment. "This is important because the treatment of hypertension and the choice of medication should be individualized for each patient," stated Committee Chair Dr. Robert J. Cody.

The ACC clinical alert can also be found at www.acc.org.

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NEWS RELEASE

**ACC Clinical Alert on Alpha Blockers for Hypertension
(released March 15, 2000)**

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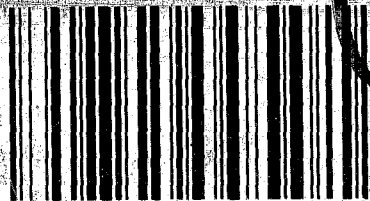


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Eugene Swift - A 1996 Olympian representing the United States in the 110-meter hurdles, Swift is training in the same event for the 2000 Olympic Games in Sydney, Australia. He has worked at UPS for 14 years and is currently in the human resources department in Oakland, California. He is a member of the global UPS Athlete Training Assistance Program (ATAP), which provides employee-athletes with the support they need to pursue their Olympic dreams.