

# FOIA Marker

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## Domestic Policy Council

Gilbert, Alan

Stack:	Row:	Sect.:	Shelf:	Pos.:	FRC ID:	Location or Hollinger ID:	NARA Number:	OA Number:
W	8	17	11	3	6635	19570	8740	8813

Folder Title:

FDA 3: Steroids/Androstenedione [1] - [3]

# Withdrawn/Redacted Material

## The George W. Bush Library

DOCUMENT NO.	FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTIONS(S)
001	Memorandum	Proposed FDA and DEA Actions on Steroids - To: POTUS - From: Alan Gilbert	2	03/07/2004	P5;
002	Memorandum	Administration Action on the Improper Use of Steroids - To: POTUS - From: John P. Walters	3	03/06/2004	P5;
003	Memorandum	Proposed FDA and DEA Actions on Steroids - To: POTUS - From: Alan Gilbert	2	03/05/2004	P5;
004	Memorandum	Proposed FDA and DEA Actions on Steroids - To: POTUS - From: Alan Gilbert	2	03/05/2004	P5;
005	Email	Memorandum: Proposed FDA and DEA Actions on Steroids - To: Taylor Hughes, et al. - From: Lauren Vestewig	1	03/06/2004	P5;

**COLLECTION TITLE:**

Domestic Policy Council

**SERIES:**

Gilbert, Alan - Subject Files

**FOLDER TITLE:**

FDA 3: Steroids/Androstenedione [1]

**FRC ID:**

6635

### RESTRICTION CODES

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- P1 National Security Classified Information [(a)(1) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

**Deed of Gift Restrictions**

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007	Report	[HHS Proposed Actions]	1	03/01/2004	P5;
008	Agenda	Administration Action on Androstenedione [with attachment]	2	03/02/2004	P5;
009	Memorandum	For Your Meeting at the White House Today - To: Amit Sachdev - From: Nancy Yanish	1	03/02/2004	P5;
010	Memorandum	Proposed FDA and DEA Actions on Steroids - To: POTUS - From: Alan Gilbert	2	03/05/2004	P5;
011	Email	Andro and FDA Action - To: Alan Gilbert - From: Philo Hall	1	02/20/2004	P5;

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FDA -  
STEROID  
STAFF MEMO

FDA - STEROIDS/ANDRO

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**WHITE HOUSE STAFFING MEMORANDUM**

Date: 3/6/04 1:15 PM ACTION / CONCURRENCE / COMMENT DUE BY: 3/7/04 NOON

MEMO FOR THE PRESIDENT ON ADMINISTRATION ACTION ON THE IMPROPER  
 Subject: USE OF STEROIDS

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MANKIW	<input type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MCCLELLAN	<input type="checkbox"/>	<input type="checkbox"/>
BENNETT	<input type="checkbox"/>	<input type="checkbox"/>	MIERS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MONTGOMERY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input type="checkbox"/>	<input type="checkbox"/>	POWELL	<input type="checkbox"/>	<input type="checkbox"/>
FRIEDMAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input type="checkbox"/>	<input type="checkbox"/>
GAMBATESA	<input type="checkbox"/>	<input type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	SPELLINGS →	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input type="checkbox"/>
GORDON	<input type="checkbox"/>	<input type="checkbox"/>	<u>Walters</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HOBBS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
KAVANAUGH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

PLEASE FORWARD COMMENTS TO CHRIS MARSTON, EXTENSION 57286/FAX 56708, BY NOON ON SUNDAY, MARCH 7, 2004, WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

RESPONSE:

*ICS*  
*- Alan*  
*Allison*

Brett Kavanaugh  
 Assistant to the President  
 and Staff Secretary  
 Ext. 62702  
 FAX Ext. 62215

# Withdrawal Marker

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Memorandum	Administration Action on the Improper Use of Steroids - To: POTUS - From: John P. Walters	3	03/06/2004	P5;

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### COLLECTION:

Domestic Policy Council

### SERIES:

Gilbert, Alan - Subject Files

### FOLDER TITLE:

FDA 3: Steroids/Androstenedione [1]

### FRC ID:

6635

### OA Num.:

8813

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#### Records Not Subject to FOIA

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## Gilbert, Alan

---

**From:** McClellan, Mark, M.D. [MMcClellan@OC.FDA.GOV]  
**Sent:** Saturday, March 06, 2004 4:27 PM  
**To:** Gilbert, Alan  
**Subject:** Re: Briefing Materials for White House--Sending Again

Rarely. Might be useful in certain adrenal cortex defects that lead to hormone deficiencies. But there are generally better treatments.

-----Original Message-----

**From:** Gilbert, Alan <Alan\_Gilbert@opd.eop.gov>  
**To:** Sachdev, Amit <ASachdev@OC.FDA.GOV>; McClellan, Mark, M.D. <MMcClellan@OC.FDA.GOV>  
**Sent:** Sat Mar 06 16:18:32 2004  
**Subject:** RE: Briefing Materials for White House--Sending Again

Is there any redeeming quality of andro---under what circumstances would a doctor ever prescribe andro?

-----Original Message-----

**From:** Sachdev, Amit [mailto:ASachdev@OC.FDA.GOV]  
**Sent:** Saturday, March 06, 2004 3:59 PM  
**To:** Gilbert, Alan  
**Subject:** Fw: Briefing Materials for White House--Sending Again

Argh, sorry, try this one it should have all the docs

-----Original Message-----

**From:** Yanish, Nancy <NYanish@OC.FDA.GOV>  
**To:** Sachdev, Amit <ASachdev@OC.FDA.GOV>; Anderson, Donna <Donna.Anderson@FDA.GOV>  
**CC:** Barrett, Kari <Kari.Barrett@FDA.GOV>; Mital, Michele <MMITAL@OC.FDA.GOV>  
**Sent:** Tue Mar 02 11:57:12 2004  
**Subject:** Briefing Materials for White House--Sending Again

Sorry, I will try this again.

Nancy Foster Yanish  
Office of Legislation  
(301) 827-5708 phone  
(301) 827-1960 fax

**WHITE HOUSE STAFFING MEMORANDUM**

Date: 03-05-04 8:20 PM ACTION / CONCURRENCE / COMMENT DUE BY: 03-06-04 NOON

MEMORANDUM FOR THE PRESIDENT ON PROPOSED FDA AND DEA ACTIONS  
 Subject: ON STEROIDS

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CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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REMARKS:

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RESPONSE:

*ICS  
 Alisa  
 - Alan*

**Brett Kavanaugh**  
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

##### Deed of Gift Restrictions

- A. Closed by Executive Order 13526 governing access to national security information.
- B. Closed by statute or by the agency which originated the document.
- C. Closed in accordance with restrictions contained in donor's deed of gift.

##### Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

##### Records Not Subject to FOIA

Court Sealed - The document is withheld under a court seal and is not subject to the Freedom of Information Act.

108TH CONGRESS  
1ST SESSION

# S. 1780

To amend the Controlled Substances Act to clarify the definition of anabolic steroids and to provide for research and education activities relating to steroids and steroid precursors.

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## IN THE SENATE OF THE UNITED STATES

OCTOBER 23, 2003

Mr. BIDEN (for himself, Mr. HATCH, Mr. GRASSLEY, and Mr. HARKIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## A BILL

To amend the Controlled Substances Act to clarify the definition of anabolic steroids and to provide for research and education activities relating to steroids and steroid precursors.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Anabolic Steroid Con-  
5 trol Act of 2003”.

1 **SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES**2 **ACT.**

3 (a) DEFINITIONS.—Section 102 of the Controlled  
4 Substances Act (21 U.S.C. 802) is amended—

5 (1) in paragraph (41)—

6 (A) by realigning the margin so as to align  
7 with paragraph (40);

8 (B) by striking subparagraph (A) and in-  
9 serting the following:

10 “(A) The term ‘anabolic steroid’ means any drug or  
11 hormonal substance, chemically and pharmacologically re-  
12 lated to testosterone (other than estrogens, progestins,  
13 corticosteroids, and dehydroepiandrosterone), and in-  
14 cludes—

15 “(i) androstanediol—

16 “(I)  $3\beta,17\beta$ -dihydroxy- $5\alpha$ -androstane; and

17 “(II)  $3\alpha,17\beta$ -dihydroxy- $5\alpha$ -androstane;

18 “(ii) androstanedione ( $5\alpha$ -androstan-3,17-  
19 dione);

20 “(iii) androstenediol—

21 “(I) 1-androstenediol ( $3\beta,17\beta$ -dihydroxy-  
22  $5\alpha$ -androst-1-ene);

23 “(II) 1-androstenediol ( $3\alpha,17\beta$ -dihydroxy-  
24  $5\alpha$ -androst-1-ene);

25 “(III) 4-androstenediol ( $3\beta,17\beta$ -dihydroxy-  
26 androst-4-ene); and

- 1           “(IV) 5-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-  
2           androst-5-ene);  
3           “(iv) androstenedione—  
4           “(I) 1-androstenedione ([5 $\alpha$ ]-androst-1-en-  
5           3,17-dione);  
6           “(II) 4-androstenedione (androst-4-en-  
7           3,17-dione); and  
8           “(III) 5-androstenedione (androst-5-en-  
9           3,17-dione);  
10          “(v) bolasterone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -  
11          hydroxyandrost-4-en-3-one);  
12          “(vi) boldenone (17 $\beta$ -hydroxyandrost-1,4,-diene-  
13          3-one);  
14          “(vii) calusterone (7 $\beta$ ,17 $\alpha$ -dimethyl-17 $\beta$ -  
15          hydroxyandrost-4-en-3-one);  
16          “(viii) clostebol (4-chloro-17 $\beta$ -hydroxyandrost-4-  
17          en-3-one);  
18          “(ix) dehydrochlormethyltestosterone (4-chloro-  
19          17 $\beta$ -hydroxy-17 $\alpha$ -methyl-androst-1,4-dien-3-one);  
20          “(x) 4-dihydrotestosterone (17 $\beta$ -hydroxy-  
21          androstan-3-one);  
22          “(xi) drostanolone (17 $\beta$ -hydroxy-2 $\alpha$ -methyl-5 $\alpha$ -  
23          androstan-3-one);  
24          “(xii) ethylestrenol (17 $\alpha$ -ethyl-17 $\beta$ -hydroxyestr-  
25          4-ene);

- 1           “(xiii) fluoxymesterone (9-fluoro-17 $\alpha$ -methyl-  
2           11 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-en-3-one);
- 3           “(xiv) formebolone (2-formyl-17 $\alpha$ -methyl-  
4           11 $\alpha$ ,17 $\beta$ -dihydroxyandrost-1,4-dien-3-one);
- 5           “(xv) furazabol (17 $\alpha$ -methyl-17 $\beta$ -  
6           hydroxyandrostano[2,3-c]-furazan);
- 7           “(xvi) 18 $\alpha$ -homo-17 $\beta$ -hydroxyestr-4-en-3-one  
8           (13 $\beta$ -ethyl-17 $\beta$ -hydroxygon-4-en-3-one);
- 9           “(xvii) 4-hydroxytestosterone (4,17 $\beta$ -dihydroxy-  
10           androst-4-en-3-one);
- 11           “(xviii) 4-hydroxy-19-nortestosterone (4,17 $\beta$ -  
12           dihydroxy-estr-4-en-3-one);
- 13           “(xix) mestanolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
14           5 $\alpha$ -androstan-3-one);
- 15           “(xx) mesterolone (1 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
16           [5 $\alpha$ ]-androstan-3-one);
- 17           “(xxi) methandienone (17 $\alpha$ -methyl-17 $\beta$ -  
18           hydroxyandrost-1,4-dien-3-one);
- 19           “(xxii) methandriol (17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -  
20           dihydroxyandrost-5-ene);
- 21           “(xxiii) methenolone (1-methyl-17 $\beta$ -hydroxy-5 $\alpha$ -  
22           androst-1-en-3-one);
- 23           “(xxiv) methyltestosterone (17 $\alpha$ -methyl-17 $\beta$ -  
24           hydroxyandrost-4-en-3-one);

- 1           “(xxv) mibolerone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -  
2 hydroxyestr-4-en-3-one);
- 3           “(xxvi) nandrolone (17 $\beta$ -hydroxyestr-4-en-3-  
4 one);
- 5           “(xxvii) norandrostenediol—
- 6           “(I) 19-nor-4-androstenediol (3 $\beta$ , 17 $\beta$ -  
7 dihydroxyestr-4-ene);
- 8           “(II) 19-nor-4-androstenediol (3 $\alpha$ , 17 $\beta$ -  
9 dihydroxyestr-4-ene);
- 10           “(III) 19-nor-5-androstenediol (3 $\beta$ , 17 $\beta$ -  
11 dihydroxyestr-5-ene); and
- 12           “(IV) 19-nor-5-androstenediol (3 $\alpha$ , 17 $\beta$ -  
13 dihydroxyestr-5-ene);
- 14           “(xxviii) norandrostenedione—
- 15           “(I) 19-nor-4-androstenedione (estr-4-en-  
16 3,17-dione); and
- 17           “(II) 19-nor-5-androstenedione (estr-5-en-  
18 3,17-dione);
- 19           “(xxix) norbolethone (18 $\alpha$ -homo-17 $\beta$ -  
20 hydroxypregna-4-en-3-one);
- 21           “(xxx) norelostebol (4-chloro-17 $\beta$ -hydroxyestr-4-  
22 en-3-one);
- 23           “(xxxi) norethandrolone (17 $\alpha$ -ethyl-17 $\beta$ -  
24 hydroxyestr-4-en-3-one);

1           “(xxxii) oxandrolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
2 2-oxa-[5 $\alpha$ ]-androstan-3-one);

3           “(xxxiii) oxymesterone (17 $\alpha$ -methyl-4,17 $\beta$ -  
4 dihydroxyandrost-4-en-3-one);

5           “(xxxiv) oxymetholone (17 $\alpha$ -methyl-2-  
6 hydroxymethylene-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androstan-3-  
7 one);

8           “(xxxv) stanozolol (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
9 [5 $\alpha$ ]-androst-2-eno[3,2-c]-pyrazole);

10          “(xxxvi) stenbolone (17 $\beta$ -hydroxy-2-methyl-  
11 [5 $\alpha$ ]-androst-1-en-3-one);

12          “(xxxvii) testolactone (13-hydroxy-3-oxo-13,17-  
13 secoandrosta-1,4-dien-17-oic acid lactone);

14          “(xxxviii) 1-testosterone (17 $\beta$ -hydroxy-5 $\alpha$ -  
15 androst-1-en-3-one);

16          “(xxxix) testosterone (17 $\beta$ -hydroxyandrost-4-en-  
17 3-one);

18          “(xl) tetrahydrogestrinone (13 $\beta$ ,17 $\alpha$ -diethyl-  
19 17 $\beta$ -hydroxygon-4,9,11-trien-3-one);

20          “(xli) trenbolone (17 $\beta$ -hydroxyestr-4,9,11-trien-  
21 3-one); and

22          “(xlii) any salt, ester, or ether of a drug or sub-  
23 stance described in this paragraph.”; and

24                 (C) by adding at the end the following:

1       “(C) Notwithstanding subparagraph (A), the Attor-  
2 ney General may not schedule Androstenedione as a con-  
3 trolled substance in accordance with this Act until the At-  
4 torney General receives a finding from the Commissioner  
5 of Food and Drugs relating to whether Androstenedione  
6 is lawfully marketed under the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 321 et seq.)”; and

8           (2) in paragraph (44), by inserting “anabolic  
9 steroids,” after “marihuana,”

10       (b) AUTHORITY AND CRITERIA FOR CLASSIFICA-  
11 TION.—Section 201(g) of the Controlled Substances Act  
12 (21 U.S.C. 811(g)) is amended—

13           (1) in paragraph (1), by striking “substance  
14 from a schedule if such substance” and inserting  
15 “drug which contains a controlled substance from  
16 the application of titles II and III of the Comprehen-  
17 sive Drug Abuse Prevention and Control Act (21  
18 U.S.C. 802 et seq.) if such drug”; and

19           (2) in paragraph (3), by adding at the end the  
20 following:

21           “(C) Upon the recommendation of the Sec-  
22 retary of Health and Human Services, a compound,  
23 mixture, or preparation which contains any anabolic  
24 steroid, which is intended for administration to a  
25 human being or an animal, and which, because of its

1 concentration, preparation, formulation or delivery  
2 system, does not present any significant potential for  
3 abuse.”.

4 (c) ANABOLIC STEROIDS CONTROL ACT.—Section  
5 1903 of the Anabolic Steroids Control Act of 1990 (Public  
6 Law 101-647) is amended—

7 (1) by striking subsection (a); and

8 (2) by redesignating subsections (b) and (c) as  
9 subsections (a) and (b), respectively.

10 **SEC. 3. SENTENCING COMMISSION GUIDELINES.**

11 The United States Sentencing Commission shall—

12 (1) review the Federal sentencing guidelines  
13 with respect to offenses involving anabolic steroids;

14 (2) consider amending the Federal sentencing  
15 guidelines to provide for increased penalties with re-  
16 spect to offenses involving anabolic steroids in a  
17 manner that reflects the seriousness of such offenses  
18 and the need to deter anabolic steroid use; and

19 (3) take such other action that the Commission  
20 considers necessary to carry out this section.

21 **SEC. 4. PREVENTION AND EDUCATION PROGRAMS.**

22 (a) IN GENERAL.—The Secretary of Health and  
23 Human Services (referred to in this Act as the “Sec-  
24 retary”) shall award grants to public and nonprofit private  
25 entities to enable such entities to carry out science-based

1 education programs in elementary and secondary schools  
2 to highlight the harmful effects of anabolic steroids.

3 (b) ELIGIBILITY.—

4 (1) APPLICATION.—To be eligible for grants  
5 under subsection (a), an entity shall prepare and  
6 submit to the Secretary an application at such time,  
7 in such manner, and containing such information as  
8 the Secretary may require.

9 (2) PREFERENCE.—In awarding grants under  
10 subsection (a), the Secretary shall give preference to  
11 applicants that intend to use grant funds to carry  
12 out programs based on—

13 (A) the Athletes Training and Learning to  
14 Avoid Steroids program;

15 (B) the Athletes Targeting Healthy Exer-  
16 cise and Nutrition Alternatives program; and

17 (C) other programs determined to be effec-  
18 tive by the National Institute on Drug Abuse.

19 (c) USE OF FUNDS.—Amounts received under a  
20 grant under subsection (a) shall be used primarily for edu-  
21 cation programs that will directly communicate with  
22 teachers, principals, coaches, as well as elementary and  
23 secondary school children concerning the harmful effects  
24 of anabolic steroids.

1 (d) AUTHORIZATION OF APPROPRIATIONS.—There is  
2 authorized to be appropriated to carry out this section,  
3 \$15,000,000 for each of fiscal years 2004 through 2009.

4 **SEC. 5. NATIONAL SURVEY ON DRUG USE AND HEALTH.**

5 (a) IN GENERAL.—The Secretary of Health and  
6 Human Services shall ensure that the National Survey on  
7 Drug Use and Health includes questions concerning the  
8 use of anabolic steroids.

9 (b) AUTHORIZATION OF APPROPRIATIONS.—There is  
10 authorized to be appropriated to carry out this section,  
11 \$1,000,000 for each of fiscal years 2004 through 2009.

○

(Original Signature of Member)

108TH CONGRESS  
2D SESSION

**H. R.** 3866

MARCH 1, 2004

IN THE HOUSE OF REPRESENTATIVES

Mr. SENSENBRENNER (for himself, Mr. CONYERS, Mr. SWEENEY, Mr. OSBORNE, and Mr. BERMAN) introduced the following bill; which was referred to the Committee on \_\_\_\_\_

**A BILL**

To amend the Controlled Substances Act to provide increased penalties for anabolic steroid offenses near sports facilities, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Anabolic Steroid Con-  
5 trol Act of 2004".



1 **SEC. 2. INCREASED PENALTIES FOR ANABOLIC STEROID**  
2 **OFFENSES NEAR SPORTS FACILITIES.**

3 (a) IN GENERAL.—Part D of the Controlled Sub-  
4 stances Act is amended by adding at the end the following:  
5 ANABOLIC STEROID OFFENSES NEAR SPORTS FACILITIES

6 “Sec. 424. (a) Whoever violates section 401(a)(1) or  
7 section 416 by manufacturing, distributing, or possessing  
8 with intent to distribute, an anabolic steroid near or at  
9 a sports facility is subject to twice the maximum term of  
10 imprisonment, maximum fine, and maximum term of su-  
11 pervised release otherwise provided by section 401 for that  
12 offense.

13 “(b) As used in this section—

14 “(1) the term ‘sports facility’ means real prop-  
15 erty where athletic sports or athletic training takes  
16 place, if such property is privately owned for com-  
17 mercial purposes or if such property is publicly  
18 owned, but does not include any real property de-  
19 scribed in section 419;

20 “(2) the term ‘near or at’ means in or on, or  
21 within 1000 feet of; and

22 “(3) the term ‘possessing with intent to dis-  
23 tribute’ means possessing with the intent to dis-  
24 tribute near or at a sports facility.”

25 (b) TABLE OF CONTENTS AMENDMENT.—The table  
26 of contents for Comprehensive Drug Abuse Prevention



1 and Control Act of 1970 is amended by inserting after  
2 the item relating to section 423 the following new item:

“424. Increased Penalties for Anabolic Steroid Offenses Near Sports Facilities.”

3 **SEC. 3. SENTENCING COMMISSION GUIDELINES.**

4 The United States Sentencing Commission shall—

5 (1) review the Federal sentencing guidelines  
6 with respect to offenses involving anabolic steroids;

7 (2) consider amending the Federal sentencing  
8 guidelines to provide for increased penalties with re-  
9 spect to offenses involving anabolic steroids in a  
10 manner that reflects the seriousness of such offenses  
11 and the need to deter anabolic steroid use; and

12 (3) take such other action that the Commission  
13 considers necessary to carry out this section.

14 **SEC. 4. AMENDMENTS TO THE CONTROLLED SUBSTANCES**

15 **ACT.**

16 (a) DEFINITIONS.—Section 102 of the Controlled  
17 Substances Act (21 U.S.C. 802) is amended—

18 (1) in paragraph (41)—

19 (A) by realigning the margin so as to align  
20 with paragraph (40); and

21 (B) by striking subparagraph (A) and in-  
22 serting the following:

23 “(A) The term ‘anabolic steroid’ means any drug or  
24 hormonal substance, chemically and pharmacologically re-



1 lated to testosterone (other than estrogens, progestins,  
2 corticosteroids, and dehydroepiandrosterone), and  
3 includes—

4 “(i) androstenediol—

5 “(I)  $3\beta,17\beta$ -dihydroxy- $5\alpha$ -androstane; and

6 “(II)  $3\alpha,17\beta$ -dihydroxy- $5\alpha$ -androstane;

7 “(ii) androstenedione ( $5\alpha$ -androst-3,17-  
8 dione);

9 “(iii) androstenediol—

10 “(I) 1-androstenediol ( $3\beta,17\beta$ -dihydroxy-  
11  $5\alpha$ -androst-1-ene);

12 “(II) 1-androstenediol ( $3\alpha,17\beta$ -dihydroxy-  
13  $5\alpha$ -androst-1-ene);

14 “(III) 4-androstenediol ( $3\beta,17\beta$ -dihydroxy-  
15 androst-4-ene); and

16 “(IV) 5-androstenediol ( $3\beta,17\beta$ -dihydroxy-  
17 androst-5-ene);

18 “(iv) androstenedione—

19 “(I) 1-androstenedione ( $5\alpha$ -androst-1-en-  
20 3,17-dione);

21 “(II) 4-androstenedione (androst-4-en-  
22 3,17-dione); and

23 “(III) 5-androstenedione (androst-5-en-  
24 3,17-dione);



- 1           “(v)     bolasterone     (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -  
2     hydroxyandrost-4-en-3-one);
- 3           “(vi) boldenone (17 $\beta$ -hydroxyandrost-1,4,-diene-  
4     3-one);
- 5           “(vii)    calusterone     (7 $\beta$ ,17 $\alpha$ -dimethyl-17 $\beta$ -  
6     hydroxyandrost-4-en-3-one);
- 7           “(viii) clostebol (4-chloro-17 $\beta$ -hydroxyandrost-4-  
8     en-3-one);
- 9           “(ix) dehydrochlormethyltestosterone (4-chloro-  
10    17 $\beta$ -hydroxy-17 $\alpha$ -methyl-androst-1,4-dien-3-one);
- 11          “(x)     4-dihydrotestosterone     (17 $\beta$ -hydroxy-  
12    androstan-3-one);
- 13          “(xi) drostanolone (17 $\beta$ -hydroxy-2 $\alpha$ -methyl-5 $\alpha$ -  
14    androstan-3-one);
- 15          “(xii) ethylestrenol (17 $\alpha$ -ethyl-17 $\beta$ -hydroxyestr-  
16    4-ene);
- 17          “(xiii) fluoxymesterone (9-fluoro-17 $\alpha$ -methyl-  
18    11 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-en-3-one);
- 19          “(xiv)    formebolone     (2-formyl-17 $\alpha$ -methyl-  
20    11 $\alpha$ ,17 $\beta$ -dihydroxyandrost-1,4-dien-3-one);
- 21          “(xv)     firazabol         (17 $\alpha$ -methyl-17 $\beta$ -  
22    hydroxyandrostano[2,3-*c*]-fuzazan);
- 23          “(xvi)    18 $\alpha$ -homo-17 $\beta$ -hydroxyestr-4-en-3-one  
24    (13 $\beta$ -ethyl-17 $\beta$ -hydroxygon-4-en-3-one);



- 1           “(xvii) 4-hydroxytestosterone (4,17 $\beta$ -dihydroxy-  
2           androst-4-en-3-one);
- 3           “(xviii) 4-hydroxy-19-nortestosterone (4,17 $\beta$ -  
4           dihydroxy-estr-4-en-3-one);
- 5           “(xix) mestanolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
6           5 $\alpha$ -androst-3-one);
- 7           “(xx) mesterolone (1 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
8           [5 $\alpha$ ]-androst-3-one);
- 9           “(xxi) methandienone (17 $\alpha$ -methyl-17 $\beta$ -  
10           hydroxyandrost-1,4-dien-3-one);
- 11           “(xxii) methandriol (17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -  
12           dihydroxyandrost-5-ene);
- 13           “(xxiii) methenolone (1-methyl-17 $\beta$ -hydroxy-5 $\alpha$ -  
14           androst-1-en-3-one);
- 15           “(xxiv) methyltestosterone (17 $\alpha$ -methyl-17 $\beta$ -  
16           hydroxyandrost-4-en-3-one);
- 17           “(xxv) nibolerone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -  
18           hydroxyestr-4-en-3-one);
- 19           “(xxvi) nandrolone (17 $\beta$ -hydroxyestr-4-en-3-  
20           one);
- 21           “(xxvii) norandrostenediol—
- 22           “(I) 19-nor-4-androstenediol (3 $\beta$ , 17 $\beta$ -  
23           dihydroxyestr-4-ene);
- 24           “(II) 19-nor-4-androstenediol (3 $\alpha$ , 17 $\beta$ -  
25           dihydroxyestr-4-ene);



- 1           “(III) 19-nor-5-androstenediol (3 $\beta$ , 17 $\beta$ -  
2           dihydroxyestr-5-ene); and  
3           “(IV) 19-nor-5-androstenediol (3 $\alpha$ , 17 $\beta$ -  
4           dihydroxyestr-5-ene);  
5           “(xxviii) norandrostenedione—  
6           “(I) 19-nor-4-androstenedione (estr-4-en-  
7           3,17-dione); and  
8           “(II) 19-nor-5-androstenedione (estr-5-en-  
9           3,17-dione);  
10          “(xxix)       norbolethone       (18 $\alpha$ -homo-17 $\beta$ -  
11          hydroxypregna-4-en-3-one);  
12          “(xxx) norelostebol (4-chloro-17 $\beta$ -hydroxyestr-4-  
13          en-3-one);  
14          “(xxxi)       norethandrolone       (17 $\alpha$ -ethyl-17 $\beta$ -  
15          hydroxyestr-4-en-3-one);  
16          “(xxxii) oxandrolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
17          2-oxa-[5 $\alpha$ ]-androstan-3-one);  
18          “(xxxiii) oxymesterone (17 $\alpha$ -methyl-4,17 $\beta$ -  
19          dihydroxyandrost-4-en-3-one);  
20          “(xxxiv)       oxymetholone       (17 $\alpha$ -methyl-2-  
21          hydroxymethylene-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androstan-3-  
22          one);  
23          “(xxxv)       stanozolol       (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-  
24          [5 $\alpha$ ]-androst-2-eno[3,2-c]-pyrazole);



1           “(xxxvi) stenbolone (17 $\beta$ -hydroxy-2-methyl-  
2 [5 $\alpha$ ]-androst-1-en-3-one);

3           “(xxxvii) testolactone (13-hydroxy-3-oxo-13,17-  
4 secoandrosta-1,4-dien-17-oic acid lactone);

5           “(xxxviii) 1-testosterone (17 $\beta$ -hydroxy-5 $\alpha$ -  
6 androst-1-en-3-one);

7           “(xxxix) testosterone (17 $\beta$ -hydroxyandrost-4-en-  
8 3-one);

9           “(xl) tetrahydrogestrinone (13 $\beta$ ,17 $\alpha$ -diethyl-  
10 17 $\beta$ -hydroxygon-4,9,11-trien-3-one);

11           “(xli) trenbolone (17 $\beta$ -hydroxyestr-4,9,11-trien-  
12 3-one); and

13           “(xlii) any salt, ester, or ether of a drug or sub-  
14 stance described in this paragraph.”; and

15           (2) in paragraph (44), by inserting “anabolic  
16 steroids,” after “marihuana.”.

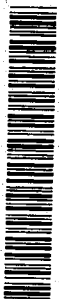
17           (b) AUTHORITY AND CRITERIA FOR CLASSIFICA-  
18 TION.—Section 201(g) of the Controlled Substances Act  
19 (21 U.S.C. 811(g)) is amended—

20           (1) in paragraph (1), by striking “substance  
21 from a schedule if such substance” and inserting  
22 “drug which contains a controlled substance from  
23 the application of titles II and III of the Comprehen-  
24 sive Drug Abuse Prevention and Control Act (21  
25 U.S.C. 802 et seq.) if such drug”; and



1           (2) in paragraph (3), by adding at the end the  
2 following:

3           “(C) Upon the recommendation of the Sec-  
4 retary of Health and Human Services, a compound,  
5 mixture, or preparation which contains any anabolic  
6 steroid, which is intended for administration to a  
7 human being or an animal, and which, because of its  
8 concentration, preparation, formulation or delivery  
9 system, does not present any significant potential for  
10 abuse.”.



**Lonick, Sandra Jo**

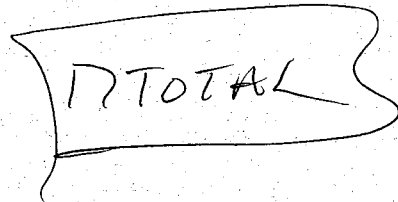
---

**Subject:** Andro  
**Location:** 472  
**Start:** Tue 3/2/2004 4:00 PM  
**End:** Tue 3/2/2004 5:00 PM  
**Recurrence:** (none)

There will be a meeting re: the FDA proposed ban on Androstenedione (Andro) on Tuesday, March 2 at 4:00 pm in EEOB Room 472. The purpose of this meeting is to hear from HHS about their proposed actions. Please respond to this e-mail to confirm your attendance. Also, if you need to be cleared into the building, please include your clearance information (DOB, SSN) with your response.

Participants include:

- Paula Stannard, HHS
- Ladd Wiley, HHS
- Mark McClellan, FDA (Will be about 20 minutes late)
- Amit Sachdev, FDA
- Chris Marston, Office of COS
- Diana Schacht, DPC
- Jonathan Burks, Office of COS
- Eric Pelletier, LEG
- Amy Jensen, LEG
- Ginger Loper, LEG
- Alan Gilbert, DPC
- Philo Hall, DPC
- Tom Capretta, OMB
- Harry Jackson, Office of Senior Advisor
- Suzy DeFrancis, COMM
- Ted Ulyot, Counsel's
- Jennifer Newstead, Counsel's
- Rex Cowdry (for Doug Badger), NEC
- Kelly Spearman, Cab. Aff.
- Abel Guerra, OPL
- Chris Doneso, DEA
- Paul Noe, OIRA
- Fumie Yokota, OIRA



17 TOTAL

Not attending:  
Kristin Silverberg, DPC

# Withdrawal Marker

## The George W. Bush Library

FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Report	[HHS Proposed Actions]	1	03/01/2004	P5;

**This marker identifies the original location of the withdrawn item listed above.  
For a complete list of items withdrawn from this folder, see the  
Withdrawal/Redaction Sheet at the front of the folder.**

**COLLECTION:**

Domestic Policy Council

**SERIES:**

Gilbert, Alan - Subject Files

**FOLDER TITLE:**

FDA 3: Steroids/Androstenedione [1]

**FRC ID:**

6635

**OA Num.:**

8813

**NARA Num.:**

8740

**FOIA IDs and Segments:**

2014-0126-F

**RESTRICTION CODES**

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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- P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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Freedom of Information Act - [5 U.S.C. 552(b)]

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**Records Not Subject to FOIA****Court Sealed - The document is withheld under a court seal and is not subject to the Freedom of Information Act.**

**Gilbert, Alan**

**From:** Besanceney, Brian R.  
**Sent:** Sunday, February 29, 2004 2:08 PM  
**To:** Gilbert, Alan; Marston, Christopher M.; Guerra, Abel  
**Subject:** Steroids/Pro-Sports League meeting

Wondering if you guys have any insight into what we should be saying in response to the press inquiry below.  
-----Original Message-----

**From:** Besanceney, Brian R.  
**Sent:** Sunday, February 29, 2004 12:39 PM  
**To:** Bartlett, Daniel J.; McClellan, Scott ; Silverberg, Kristen  
**Subject:** non-Haiti press inquiry today

AP is looking for comment on this story - specifically the status of discussions toward a White House meeting on steroids.

Any suggestions?

**MLB Players' Union Balks At Steroids Summit (WPost)**

Bush Administration's Proposed Meeting Would Include Representatives From All Four Major Sports and USOC

By Steve Fainaru and Mike Allen

The Washington Post, February 29, 2004

A White House effort to organize a summit of the major sports leagues to examine the use of steroids by athletes has run into resistance from the Major League Baseball Players Association, one of several defensive positions the union has staked out recently on performance-enhancing drugs.

Commissioners from the NFL, NBA, NHL and Major League Baseball, along with representatives from the United States Olympic Committee, have tentatively agreed to attend the meeting, officials from those organizations said. Bush administration officials described the proposed summit as an attempt by the president to hold direct discussions with the sports and their athletes and raise awareness of the issue.

However, the administration's efforts to arrange the summit have been complicated by the Major League Baseball Players Association (MLBPA), which has told the administration that baseball's steroids policy is a matter of collective bargaining and not the responsibility of the federal government, according to administration officials.

Bush's interest in the steroids issue arose, as aides tell it, from his personal interest in sports and his continuing ties, as a former owner of the Texas Rangers, to coaches, players and owners. The topic was quickly embraced by White House officials, who see steroids as another avenue for the president to promote a discussion of values in an election year.

The resistance from the baseball players' union to a steroids event was apparently a byproduct of what a senior administration official called the "acrimonious relationship between the players' union and management" on performance-enhancing drugs. "That's why you're seeing this disagreement," said the official, who refused to be identified by name because of the sensitivity of the negotiations. "There are issues in baseball that you're not seeing in the other sports."

The baseball union's stance could dissuade other organizations from participating. The NFL Players Association has signaled that it will not attend unless other sports, particularly Major League Baseball, also agree. Gene Upshaw, the NFLPA's executive director, said: "None of us wants to be used in a political way. What we want is to talk about what we've done in our sport and why we're proud of it.

We're not going alone."

Gene Orza, who oversees drug matters for the MLBPA, suggested in an e-mail that the union is open to discussions but left it unclear whether it would be willing to attend a summit. "I cannot imagine the circumstances which would generate the rumor that we are telling a president of the United States that, if he wants to talk to us, we are unwilling to do so," Orza said. "It is true we are steadfast in our commitment to both the collective bargaining process generally, and the principle that people are innocent until others who are duly charged with attempting to do so prove them guilty."

The White House initially told the leagues that the summit would take place Feb. 23 or Feb. 24, according to Joe Browne, the NFL's executive vice president. Browne and others in contact with the White House said they had since been told that the White House is making preparations for late March. The NFL and the NFLPA are particularly sensitive about being isolated on the issue. League and union officials said they believe the NFL was unfairly singled out by President Bush's surprising reference to steroids in his Jan. 20 State of the Union address. Cameras focused on New England Patriots quarterback Tom Brady as the president said "the use of performance-enhancing drugs like steroids in baseball, football and other sports is dangerous and sends the wrong message." He urged owners, union representatives, coaches and players to "get rid of steroids now." Administration officials said Brady was invited because of his mentoring efforts and were dismayed that the television cameras came to him during Bush's steroids passage.

Steroids help athletes build muscle mass and speed recovery, and numerous studies have shown that they may also contribute to a number of disorders.

On the afternoon of the speech, National Security Adviser Condoleezza Rice placed a heads-up call to NFL Commissioner Paul Tagliabue, with whom she has a personal relationship, as well as Olympic and NCAA officials. White House Chief of Staff Andrew H. Card Jr. notified NBA Commissioner David Stern and MLB Commissioner Bud Selig. Representatives of the NHL also were informed, the league said.

The NFL has the most aggressive drug policy of the four major professional sports leagues. League officials said they believed the NFL sent Brady to be held up as a role model and were surprised when he became linked to the steroid passage. Administration officials later said that the president was most concerned about Major League Baseball, whose drug policy has been widely criticized. That policy, which took effect last season, was significantly weakened during collective bargaining, and Orza has said the final agreement was essentially designed by the players' union.

The absence of the MLBPA from a White House summit would undoubtedly affect preparations. Baseball has come under intensifying scrutiny since a federal grand jury in San Francisco indicted four men -- including the personal weight trainer for San Francisco Giants left fielder Barry Bonds -- on Feb. 12 for allegedly distributing steroids to elite athletes. The indictments were announced in Washington by Attorney General John D. Ashcroft, a reflection of the administration's efforts to embrace the issue. John P. Walters, director of the White House Office of National Drug Control Policy, said in an interview that Major League Baseball needs more rigorous drug testing "to protect people from the consequences of steroids and the sport as a whole from the consequences of being increasingly viewed as corrupt."

The MLBPA has consistently said it views drug testing as a violation of players' privacy rights. "The debate is not about the end, which is the elimination of steroids. Everyone is committed to that," Orza wrote in his e-mail. "It is about what are appropriate means for achieving that end." The proposed summit is the latest issue on which the baseball players' union has resisted taking action on performance-enhancing drugs. Those positions have placed the union in conflict not only with the Bush administration but also with members of Congress, the NFLPA and even, in some instances, its own members.

The union, for example, has ignored appeals by the baseball commissioner's office to add the dietary supplement ephedra to baseball's banned-substances list, according to sources familiar with the discussions. Baseball's request followed the Food and Drug Administration's Dec. 30 announcement that it intended to remove ephedra from the market.

An ephedra-based supplement, Xenadrine RFA-1, played a "significant factor" in the death last spring of Steve Bechler, a 23-year-old Baltimore Orioles pitcher, a coroner concluded.

The late pitcher's father, Ernie Bechler, said in an interview that he was baffled by the union's reluctance to ban the drug. "My goodness, it took my son's life, just as plain as day," he said. "I just don't understand it. I cannot understand it. Aren't their players valuable to them? Don't you think they would want to protect their players? That's their bread and butter, man."

Orza wrote that baseball will ban ephedra when the government officially defines it a controlled substance. The union, he said, has urged players not to use dietary supplements that contain it. The union has also declined to support a Senate bill that would define steroid precursors as Schedule III controlled substances, like steroids, meaning they would be illegal to use without a prescription. The bill includes a prohibition on androstenedione, or andro, a dietary supplement that metabolizes into the steroid testosterone once inside the body. Retired St. Louis Cardinals slugger Mark McGwire has admitted that he used andro while chasing Roger Maris's single-season home run record in 1998. The bill, which is sponsored by Sen. Orrin Hatch (R-Utah) and Sen. Joseph Biden (D-Del.), among others, is endorsed by the NBA, NFL, Major League Baseball, the National High School Athletic Coaches Association, the American Medical Association and the American Academy of Family Physicians. Orza wrote that the union had "no objections" to the bill's passage. A Democratic aide familiar with the legislation said the union has told sponsors that the players would neither oppose nor support the bill.

"What's telling is that Major League Baseball itself, the NFL and the NBA are sort of falling all over themselves to move the bill forward," said the staffer, who spoke on condition of anonymity because the aide was not authorized to speak on policy matters. "And there's been a resounding silence from the players association." Aides to Hatch and Biden met this week with representatives of the Justice Department and the Drug Enforcement Administration to discuss the legislation with the expectation that President Bush would soon endorse it.

The Bush administration has sought to push steroids onto the national agenda since the State of the Union. Administration officials said the decision to place the steroid passage in the speech came from president himself -- "straight from the Oval" as one aide put it.

White House communications director Dan Bartlett said Bush became focused on the issue after a conversation at a White House Christmas party with a women's college track coach "who raised this issue with him and said how much she was concerned about women taking steroids in college athletics, and obviously in those who were performing professionally in track."

Walters said he and the president first discussed the issue about a week later, at a Dec. 19 meeting in the Oval Office.

Speaking out on steroids is "a bully-pulpit issue -- using the power of the presidency to bring attention to an issue that was not the most pressing in the consciousness of a lot of Americans," Bartlett said. "But a lot of athletes and a lot of family members -- particularly those parents out there who have teens in high school programs and junior high programs are struggling with this issue."

The steroids passage led to criticism that the White House was seeking to exploit a relatively frivolous issue and to divert attention from weightier matters such as the economy and Iraq. A House Republican leadership aide, who refused to be identified by name because he did not want to be seen as criticizing the White House, said the steroids passage became known to some on Capitol Hill as "the crazy two sentences."

A Republican adviser close to the White House said the administration also was looking for "a cluster of issues" that resonate with conservatives but also appeal to broader constituencies that could tilt the November election, such as suburban women.

"Steroids meets that test," said the adviser, who refused to be quoted by name because the White House did not want the initiative to be viewed as political. "This is the kind of thing that gets folks in swing states nodding their heads -- that New York and D.C. and California scoff at, but that middle America understands and responds to. . . . This is going to have more longevity than the rhetoric around the moon and Mars."

However, administration officials said the president has embraced an issue that touches upon the integrity of American institutions and other agencies have taken their cues. A Justice Department official described the decision to have Ashcroft announce the indictments in the steroid conspiracy case as "a no-brainer. The president had mentioned it in the State of the Union, and this is something that Americans deeply care about. It deserves a national stage, and it got it."

# Withdrawal Marker

## The George W. Bush Library

FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Agenda	Administration Action on Androstenedione [with attachment]	2	03/02/2004	P5;

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For a complete list of items withdrawn from this folder, see the  
Withdrawal/Redaction Sheet at the front of the folder.**

**COLLECTION:**

Domestic Policy Council

**SERIES:**

Gilbert, Alan - Subject Files

**FOLDER TITLE:**

FDA 3: Steroids/Androstenedione [1]

**FRC ID:**

6635

**OA Num.:**

8813

**NARA Num.:**

8740

**FOIA IDs and Segments:**

2014-0126-F

**RESTRICTION CODES**

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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Freedom of Information Act - [5 U.S.C. 552(b)]

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**Records Not Subject to FOIA**

Court Sealed - The document is withheld under a court seal and is not subject to the Freedom of Information Act.

## Organizations Endorsing S. 1780, The Anabolic Steroid Control Act

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Obstetricians and Gynecologists
- American College for Sports Medicine
- American Council on Exercise
- American Medical Association
- Association of Tennis Professionals
- Blue Cross Blue Shield Association
- Boys and Girls Clubs
- Community Anti-Drug Coalitions of America
- Consumer Healthcare Products Association
- Council for Responsible Nutrition
- The Endocrine Society
- The Hormone Foundation
- Little League
- Major League Baseball
- National Athletic Trainers Association
- National Basketball Association
- The National Center on Addiction and Substance Abuse at Columbia University
- National Collegiate Athletic Association
- National Federation of State High Schools Association
- National Football League
- National High School Athletic Coaches Association
- National Junior College Athletic Association
- National Nutritional Foods Association
- Pharmacists Planning Services, Inc.
- United States Anti-Doping Agency
- U.S. Olympic Committee
- U.S. Biathlon Association
- U.S. Soccer Federation
- USA Cycling
- USA Luge
- USA Swimming
- USA Track and Field
- Utah Natural Products Alliance
- Women's National Basketball Association

# Withdrawal Marker

## The George W. Bush Library

FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Memorandum	For Your Meeting at the White House Today - To: Amit Sachdev - From: Nancy Yanish	1	03/02/2004	P5;

**This marker identifies the original location of the withdrawn item listed above.  
For a complete list of items withdrawn from this folder, see the  
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**COLLECTION:**

Domestic Policy Council

**SERIES:**

Gilbert, Alan - Subject Files

**FOLDER TITLE:**

FDA 3: Steroids/Androstenedione [1]

**FRC ID:**

6635

**OA Num.:**

8813

**NARA Num.:**

8740

**FOIA IDs and Segments:**

2014-0126-F

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JUN 20 2002

The Honorable Orrin G. Hatch  
United States Senate  
Washington, D.C. 20510-4402

Dear Senator Hatch:

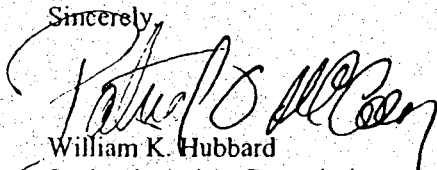
Thank you for your letters of October 11, 2001, and February 8, 2002, addressed to Dr. Bernard Schwetz, then Acting Commissioner of Food and Drugs, regarding the marketing of products as dietary supplements that contain the steroid hormone androstenedione. You asked the Food and Drug Administration (FDA or the Agency) to inform you as to whether androstenedione may be lawfully marketed as a dietary supplement. We regret the delay of this response.

In your letters, you expressed concerns about the marketing of dietary supplements containing androstenedione because of allegations that they may be potentially harmful to consumers. You asked the Agency to provide you with an explanation of the legal status of such products under the Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA).

We appreciate your concerns about this matter and, moreover, regret that we have not been able to respond to you within the time period you requested. However, in order to provide you with an accurate and informed answer to your questions about the legal status of androstenedione-containing products, a number of novel and complex legal and scientific issues need to be considered. I want to assure you that, in response to your request, we are diligently pursuing an evaluation of the legal and scientific issues that bear on androstenedione's status under the Act and intend to provide answers to your questions as soon as our evaluation is complete.

Thank you again for contacting us concerning this matter. A similar response has been sent to Senator Harkin. Please contact us if you have further questions concerning this matter.

Sincerely,

  
William K. Hubbard  
Senior Associate Commissioner  
for Policy, Planning, and Legislation

Page 2 - The Honorable Orrin G. Hatch

bcc: HFW-10  
HFW-1  
HFW-12  
HFW-14  
HF-22 (Hubbard)  
HF-1  
HF-40  
HFA-224  
HFC-1  
HFC-200  
HFD-1  
HFD-300  
HFS-1  
HFS-22, Salsbury, CCO  
HFS-800  
HFS-811 (Moore)  
GCF-1 (Troy, Nickerson)

Received by: HRubino: 2/11/02 (CFSAN received simultaneously)

R/D: HFS-811: RMoore: 6/5/02

reviewed: HFS-810: JForet: 6/6/02

reviewed: HFS-800: VWilkening for CTaylor: 6/7/02

Reviewed: P. Salsbury: HFS-22: 6/13/02

Reviewed/cleared: J. Levitt: HFS-1: 6/13/02

Revised: P. Salsbury: 6/14/02

Draft received by: NYanish: 6/14/02

Edits: HRubino: 6/17/02

Sent to type: 6/17/02

Returned to LC: 6/17/02

F/T: alb: 6/17/02 G:\WP\Yanish\Dietary Supplements\02-776Hatch.doc

Control No. 02-776

**United States Senate**  
WASHINGTON, DC 20510

February 8, 2002

Dr. Bernard Schwetz  
Acting Commissioner  
of Food and Drugs  
Rockville, Maryland 20852

Dear Dr. Schwetz:

We were very disappointed to be advised today by your legislative and legal staff that you had not received our October 11, 2001, letter with respect to whether androstenedione may be lawfully marketed as a dietary supplement under the Federal Food, Drug and Cosmetic Act. This is somewhat disturbing, since the letter was not only telefaxed to your office, but mailed to you, with separate copies to Mr. Leavitt and Secretary Thompson. We had asked to have a reply by October 23, and wished to have your decision prior to commencement of the winter Olympic Games.

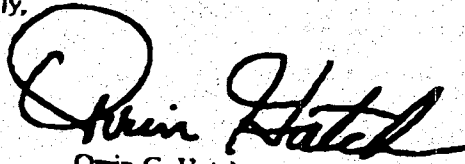
As you may be aware, there have been numerous credible reports that young athletes are taking this product with possible long-term, detrimental health effects. Our interest in the well-being of these athletes comes in the context of our growing concern that the agency is not devoting adequate resources to enforcement of the Dietary Supplement Health and Education Act (DSHEA) of 1994.

As this matter is of personal concern to us, we would appreciate your immediate reply as to whether androstenedione may be marketed lawfully as a dietary supplement. We have attached another copy of our letter.

Sincerely,



Tom Harkin  
United States Senator



Orrin G. Hatch  
United States Senator

02-776

United States Senate  
WASHINGTON, DC 20510

October 11, 2001

Dr. Bernard P. Schwetz,  
Acting Commissioner  
of Food and Drugs  
5600 Fishers Lane  
Rockville, Maryland 20852

Dear Dr. Schwetz:

There have been numerous press accounts implicating the safety and alleging abuses of the product androstenedione, marketed as a dietary supplement. Almost invariably, these news reports portray a range of adverse health consequences suffered by susceptible young athletes and state that the Food and Drug Administration's "hands are tied" because dietary supplements are "unregulated."

While we vigorously contest the false allegation that dietary supplement products are unregulated, we are extremely concerned about the potentially harmful effects of androstenedione and its use, particularly by young people. As you know, if a product is unsafe, be it a dietary supplement or other food, a drug, or medical device, the FDA possesses a broad range of authorities to take appropriate enforcement actions to safeguard the public health. It is our strong contention that, with respect to dietary supplements, this authority was enhanced - not diminished - by passage of the Dietary Supplement Health and Education Act (DSHEA), the law we authored with then-Representative Bill Richardson and which passed the Congress unanimously in 1994.

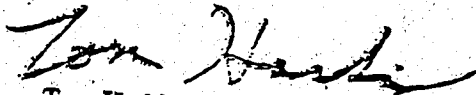
As a threshold matter, it is important to ascertain the regulatory status of androstenedione. Therefore, we request that you provide a simple response to the following two questions:

1) Is androstenedione a product that may be lawfully marketed as a dietary supplement under the "grandfather" provisions of DSHEA (section 413(c) of the Federal Food, Drug and Cosmetic Act)?

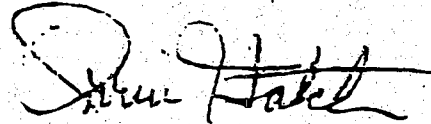
2) If the answer to question number one is "no," has the agency received a new dietary ingredient petition with respect to androstenedione and acted upon that submission under section 413(b) of the FDC Act?

We would appreciate receiving your response no later than October 23, 2001. Thank you very much for your prompt and personal attention to this matter.

Sincerely,



Tom Harkin  
United States Senator



Orrin G. Hatch  
United States Senator

cc: Secretary Thompson  
Joe Leavitt

**THE ANABOLIC STEROID CONTROL ACT OF 2003 –**  
**SECTION-BY-SECTION ANALYSIS**

**Section 1 – Short Title**

Establishes the short title of the bill as the Anabolic Steroid Control Act of 2003.

**Section 2 – Amendments to the Controlled Substances Act**

Under current law, the term “anabolic steroid” is defined at 21 U.S.C. 802 as “any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that produces muscle growth.” This section amends that definition by removing the requirement that a substance be proven to promote muscle growth. This would make it easier to add steroid precursors such as androstenedione and other similar substances – many of which have been developed since the Steroid Control Act of 1990 passed in order to evade the law – to be added to the list of Schedule III anabolic steroids.

The provision also makes technical corrections to the current list of anabolic steroids, adds a number of known steroid precursors to the anabolic steroid list and exempts dehydroepiandrosterone (DHEA).

Finally, this section modifies the definition of “felony drug offense” in 21 U.S.C. 802 to apply to offenses involving anabolic steroids.

**Section 3 – Sentencing Commission Guidelines**

Directs the U.S. Sentencing Commission to review the Federal sentencing guidelines for crimes involving anabolic steroids and consider increasing them. Currently, the maximum sentence for offenses involving between 40,000 and 60,000 units of anabolic steroids (a unit is defined as a 10 cc vial or 50 tablets) is a level 20 (which translates to 33 - 41 months for first time offenders).

**Section 4 – Prevention and Education Programs**

Authorizes \$15 million for the Secretary of Health and Human Services to award grants to public and non-profit entities to carry out science-based education programs in elementary and secondary schools to highlight the harmful effects of steroids and steroid precursors. Preference will be given to programs based on the Athletes Training and Learning to Avoid Steroids program (ATLAS), the Athletes Targeting Healthy Exercise and Nutrition Alternatives (ATHENA) program, and other programs which the National Institute on Drug Abuse has determined to be effective. ATLAS, which is aimed at male

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student athletes, has been named as one of the Department of Education's Exemplary Programs and is one of the Substance Abuse and Mental Health Services Administration's Model Programs. ATHENA is ATLAS's companion program designed for female athletes.

### **Section 5 – National Survey on Drug Use and Health**

Directs the Secretary of Health and Human Services to include questions about the use of steroids and steroid precursors in the National Survey on Drug Use and Health, an annual survey to measure the extent of alcohol, drug and tobacco use in the United States. The bill authorizes \$1 million for this purpose.

Statement of  
Senator Orrin G. Hatch  
United States Senate  
before the  
Senate Committee on Commerce  
"Regulation of Dietary Supplements"

October 28, 2003

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to testify before you today and to discuss a topic very near and dear to my heart: the regulation of dietary supplements.

There is no question that tens of millions of Americans rely daily on safe dietary supplements to maintain and improve their healthy lifestyles. The popularity of these products and the concern over their regulation are what led to enactment of the Dietary Supplement Health and Education Act (DSHEA) in 1994, a bill that Senator Harkin and I were proud to author with now-Governor of New Mexico Bill Richardson.

The message I wish to leave with you is simple: DSHEA is a strong law that properly implemented will protect the interests of consumers. But, as with any law, it has to be implemented for it to work.

Enactment of DSHEA followed literally decades of Food and Drug Administration animosity toward dietary supplement products. This animosity and the lack of a clear regulatory structure for supplements were clearly demonstrated prior to passage of DSHEA.

That is why two-thirds of the Senate cosponsored our bill.

That is why a majority of the House cosponsored the bill.

And that is why it passed so overwhelmingly.

The basic structure of DSHEA allowed all products marketed as dietary supplements when the bill was enacted to stay on the market unless the FDA could show safety problems with a particular product or line of products – this is the so-called "grandfather" provision; manufacturers must notify the FDA before any new ingredients are marketed. At the same time, we provided the FDA with the full range of enforcement mechanisms to act against unsafe or misbranded supplements, including seizure, injunction, civil monetary penalties and even criminal penalties.

And, when Chairman Dingell and Chairman Waxman expressed lingering concerns that an unsafe product might be marketed and FDA would not have adequate authority to act against it, we

added a new tool – imminent hazard – so that the Secretary could take immediate action against a product that he believed poses an imminent hazard to public health. I might add, the definition as to what constitutes an “imminent hazard” is entirely up to the Department of Health and Human Services, so this is a very broad authority.

Even so, there are some who believe that dietary supplements should not be marketed in the United States without a preclearance similar to that for pharmaceuticals. We who drafted and passed DSHEA along with millions of Americans were persuaded that was not necessary.

First, most supplements cannot be patented, so there is little incentive for manufacturers to undergo the expensive and time-consuming FDA approval process.

Second, many, many supplements have been used safely for literally centuries, if not millennia, so it is not necessary to subject them to the approval process. That was why even the most liberal members felt comfortable with the grandfather structure.

Finally, we added a provision so that FDA would have the time to examine any ingredient not previously marketed and the evidence of its safety before that product actually reached the stores.

When we drafted DSHEA, ensuring the safety of products was at the forefront of our efforts. The law gives the FDA abundant tools to remove products that are unsafe from the market. It includes a safety standard that was carefully crafted with Senator Kennedy and Representatives Dingell and Waxman, the chairs of FDA-related panels in 1994.

There is no excuse for a supplement manufacturer to market products that are unsafe or inaccurately labeled or that make outlandish claims. Unfortunately, a small number of irresponsible supplement companies are taking advantage of consumers.

I contend that the law is adequate to deal with them if FDA implements and enforces it.

Yet, in the nine-plus years since DSHEA was enacted, there has been too much talk that the law handcuffs FDA and too little effort to apply the law.

It is impossible for this law to protect consumers if it is not enforced.

I have been pleased at the FTC’s actions to challenge companies with inaccurate or deceptive advertising.

The FDA’s record has not been as strong.

I am not here to criticize the FDA or throw barbs. Frankly, the FDA under Commissioner Mark McClellan has done more to enforce DSHEA than the previous administration had. I credit

Commissioner McClellan for his commitment to implement the law fully. I truly believe he wants to make this law work. Congress must support him.

That is why I have joined with Senator Harkin to introduce the DSHEA Full Implementation and Enforcement Act of 2003 (S. 1538).

Yes, there is a small number of products that do raise serious concerns.

Ephedra is one. As I have done for many years, I urge the FDA to act definitively on this issue based on the best available science, not politics. If the agency deems that ephedra poses a significant or unreasonable risk of illness or injury when used as labeled, than the agency can – and must – move to take the product off the market. This has gone on for too long.

Frankly, resources are a large issue here. The FDA simply does not have the staff or money it needs to do the job.

While FDA is constrained by the President's budget in not seeking new funding for DSHEA, I predict that members of the Committee who inquire of the FDA witness may receive support for my contention that the agency is woefully underfunded, especially in this area.

That is the only reason I can see that the safety standard we enacted has never been invoked.

That has to be the reason that it has taken almost a decade to promulgate the good manufacturing practice standards that can help guarantee the safety, the purity, and the accurate labeling of products.

And that must be the reason that a product like androstenedione, which I believe is not even a dietary supplement, continues to be marketed in this country.

I have been very concerned about the safety of steroid precursor products like andro -- and especially when they fall into the hands of our youth.

That is why I have joined with Senator Biden, Senator Harkin and Senator Grassley to cosponsor the Anabolic Steroid Control Act (S. 1780) that will add andro and other steroid precursors, as well as THG, to the list of controlled substances. I intend for the Judiciary Committee to make adoption of S. 1780 a priority and I hope my colleagues will join me in supporting both S. 1780 and S. 1538.

Mr. Chairman, you have been very generous with your time, so I will close here. The thought I wish to leave with my colleagues is that we have a solid law which can deal with the problems witnesses will discuss today. But the FDA must use that law for it to be effective, and Congress must support the agency in that effort.



**CO-SPONSORS: S 1780 (108)**

(W = Withdrawn)

**ORIGINAL COSPONSORS (by date)**

**Total = 3 ( Dem = 1 Rep = 2)**

10/23/2003

Sen. Chuck Grassley (R-IA)

Sen. Tom Harkin (D-IA)

Sen. Orrin G. Hatch (R-UT)

**ADDITIONAL COSPONSORS**

**Total = 3 ( Dem = 1 Rep = 2)**

10/30/2003

Sen. Ted Stevens (R-AK)

11/03/2003

Sen. John McCain (R-AZ)

02/26/2004

Sen. Bill Nelson (D-FL)

**TOTAL COSPONSORS**

**Total = 6 ( Dem = 2 Rep = 4)**

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## **Organizations Endorsing S. 1780, The Anabolic Steroid Control Act**

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Obstetricians and Gynecologists
- American College for Sports Medicine
- American Council on Exercise
- American Medical Association
- Association of Tennis Professionals
- Blue Cross Blue Shield Association
- Boys and Girls Clubs
- Community Anti-Drug Coalitions of America
- Consumer Healthcare Products Association
- Council for Responsible Nutrition
- The Endocrine Society
- The Hormone Foundation
- Little League
- Major League Baseball
- National Athletic Trainers Association
- National Basketball Association
- The National Center on Addiction and Substance Abuse at Columbia University
- National Collegiate Athletic Association
- National Federation of State High Schools Association
- National Football League
- National High School Athletic Coaches Association
- National Junior College Athletic Association
- National Nutritional Foods Association
- Pharmacists Planning Services, Inc.
- United States Anti-Doping Agency
- U.S. Olympic Committee
- U.S. Biathlon Association
- U.S. Soccer Federation
- USA Cycling
- USA Luge
- USA Swimming
- USA Track and Field
- Utah Natural Products Alliance
- Women's National Basketball Association

# Withdrawal Marker

## The George W. Bush Library

FORM	SUBJECT/TITLE	PAGES	DATE	RESTRICTION(S)
Memorandum	Proposed FDA and DEA Actions on Steroids - To: POTUS - From: Alan Gilbert	2	03/05/2004	P5;

**This marker identifies the original location of the withdrawn item listed above.  
For a complete list of items withdrawn from this folder, see the  
Withdrawal/Redaction Sheet at the front of the folder.**

**COLLECTION:**

Domestic Policy Council

**SERIES:**

Gilbert, Alan - Subject Files

**FOLDER TITLE:**

FDA 3: Steroids/Androstenedione [1]

**FRC ID:**

6635

**OA Num.:**

8813

**NARA Num.:**

8740

**FOIA IDs and Segments:**

2014-0126-F

**RESTRICTION CODES****Presidential Records Act - [44 U.S.C. 2204(a)]**

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

**Deed of Gift Restrictions**

- A. Closed by Executive Order 13526 governing access to national security information.
- B. Closed by statute or by the agency which originated the document.
- C. Closed in accordance with restrictions contained in donor's deed of gift.

**Freedom of Information Act - [5 U.S.C. 552(b)]**

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

**Records Not Subject to FOIA**

Court Sealed - The document is withheld under a court seal and is not subject to the Freedom of Information Act.

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DEA/DOJ Actions:

Baseball has come under intensifying scrutiny since a federal grand jury in San Francisco indicted four men -- including the personal weight trainer for San Francisco Giants left fielder Barry Bonds -- on Feb. 12 for allegedly distributing steroids to elite athletes. The indictments were announced in Washington by Attorney General John D. Ashcroft, a reflection of the administration's efforts to embrace the issue.

SS/ RM NO.

*NOON*

**WHITE HOUSE STAFFING MEMORANDUM**

Date: 03-05-04 8:20 PM ACTION / CONCURRENCE / COMMENT DUE BY: 03-06-04 NOON

**MEMORANDUM FOR THE PRESIDENT ON PROPOSED FDA AND DEA ACTIONS**

Subject: ON STEROIDS

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MANKIW	<input type="checkbox"/>	<input type="checkbox"/>
CARD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MARBURGER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BARTLETT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MCCLELLAN	<input type="checkbox"/>	<input type="checkbox"/>
BENNETT	<input type="checkbox"/>	<input type="checkbox"/>	MIERS <i>→</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MONTGOMERY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CONNAUGHTON	<input type="checkbox"/>	<input type="checkbox"/>	POWELL	<input type="checkbox"/>	<input type="checkbox"/>
FRIEDMAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input type="checkbox"/>	<input type="checkbox"/>
GAMBATESA	<input type="checkbox"/>	<input type="checkbox"/>	ROVE	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GERSON	<input type="checkbox"/>	<input type="checkbox"/>	SPELLINGS	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GONZALES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	CLERK	<input type="checkbox"/>	<input type="checkbox"/>
GORDON	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
HAGIN	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
HOBBS	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
KAVANAUGH	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

*called  
Doug*

*TEVP*

*G. ROSE  
ERIC  
called  
Doug*

REMARKS:

PLEASE FORWARD COMMENTS TO ALAN GILBERT, EXTENSION 67105/FAX 65557, BY NOON ON SATURDAY, MARCH 6, 2004 WITH A COPY TO THE STAFF SECRETARY. THANK YOU.

*OK*

RESPONSE:

*→*

Brett Kavanaugh  
Assistant to the President  
and Staff Secretary  
Ext. 62702  
FAX Ext. 62215

SS/ RM NO. \_\_\_\_\_

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BOLTEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	MONTGOMERY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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FRIEDMAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RICE	<input type="checkbox"/>	<input type="checkbox"/>
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HAGIN	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
HOBBS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
KAVANAUGH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

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*See Comments*

Brett Kavanaugh  
Assistant to the President  
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