

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 522
(A-22)

Introduced by: Medical Student Section

Subject: Encouraging Research of Testosterone and Pharmacological Therapies for Post-Menopausal Individuals with Decreased Libido

Referred to: Reference Committee E

1 Whereas, The most recent epidemiological research shows that approximately 40% of women
2 in the United States have sexual concerns, with 12% reporting distressing sexual problems¹;
3 and
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5 Whereas, It is estimated that 1.2 billion women worldwide will be menopausal or
6 postmenopausal by the year 2030²; and
7

8 Whereas, Sexual dysfunction in women can manifest in a number of ways, such as impaired
9 arousal, inability to achieve orgasm, pain with sexual activity, or Hypoactive Sexual Desire
10 Disorder (HSDD), which is defined as a deficiency or absence of sexual fantasies and desire for
11 sexual activity that may cause personal distress or interpersonal difficulty^{1,3}; and
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13 Whereas, Decreased libido in women is currently evaluated and treated using the
14 biopsychosocial model to account for biological, psychological, interpersonal, and sociocultural
15 factors, yet some women may have decreased libido that is refractory to standard treatments^{1,4};
16 and
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18 Whereas, Testosterone plays a key role in maintaining libido in women, as evidenced by
19 numerous studies that show testosterone significantly improves various aspects of libido in
20 androgen-deficient, premenopausal, naturally post-menopausal, and surgically post-
21 menopausal women, and testosterone levels in postmenopausal women are 50% lower
22 compared to premenopausal women⁵⁻¹⁰; and
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24 Whereas, A large meta-analysis, comprised of 43 articles, 36 randomized controlled trials, and
25 8,480 naturally or surgically post-menopausal women monitored for at least 12 weeks, indicated
26 that use of testosterone significantly increased various aspects of sexual function such as
27 sexual frequency, sexual desire, pleasure, and orgasms, irrespective of concurrent use
28 estrogens, with no statistically significant increase in adverse events¹¹⁻¹³; and
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30 Whereas, A double-blinded, placebo-controlled clinical trial with 53 postmenopausal women
31 with low libido who were given 10 milligrams of testosterone gel per day for three months, in
32 addition to their ongoing hormone replacement therapy, did not show any significant adverse
33 effects and showed a positive effect on psychological well-being⁶; and
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35 Whereas, Doses of testosterone therapy that approximate physiologically premenopausal
36 concentrations in postmenopausal women have been associated with mild increase in acne,
37 body and facial hair growth but not with hair loss, clitoromegaly or changes in voice, but safety
38 data is not available beyond 24 months and further studies are needed to evaluate potential
39 long-term adverse effects^{13,14}; and

1
2 Whereas, The effective dosage of testosterone for postmenopausal women has not been
3 elucidated, as a study of 71 surgically menopausal women suggested that positive change in
4 sexual function is achieved only with supraphysiologic dosing, while in 2019, a group of experts
5 from leading women's health societies worldwide published a consensus statement supporting
6 the benefit of testosterone therapy in doses that approximate physiologic concentrations in
7 premenopausal women^{14,15}; and

8
9 Whereas, Clinical practice guidelines published by the Endocrine Society and the American
10 College of Obstetricians and Gynecologists recommend a 3 to 6 month trial of testosterone
11 therapy for postmenopausal women with a diagnosis of HSDD, with close monitoring for
12 overuse and cessation of therapy if unresponsive after 6 months, but no current United States
13 Food & Drug Administration (FDA) approved testosterone treatments exist for women with
14 HSDD¹⁶; and

15
16 Whereas, Compounded and off-label medications such as flibanserin and bremelanotide have
17 been prescribed for many years for both men and women who want to boost levels of sexual
18 desire, arousal, and orgasm; however, these two medications received FDA approval for use in
19 pre-menopausal women only, in 2015 and 2019 respectively¹⁷; and

20
21 Whereas, Although there are many FDA-approved testosterone preparations for men, and
22 internationally accepted use of testosterone products in women, none are currently approved for
23 women in the United States, further highlighting gender biases in healthcare and medical
24 research that are evident from the incomplete understanding of pathophysiology of women's
25 sexual response and its treatment^{13,18}; and

26
27 Whereas, As evidenced by Code of Ethics 8.5 clause (i), the AMA supports "research that
28 examines health care disparities, including research on the unique health needs of all genders,
29 ethnic groups, and medically disadvantaged populations, and the development of quality
30 measures and resources to help reduce disparities;" and

31
32 Whereas, Due to the lack of FDA-approved medications for treating decreased libido in
33 postmenopausal women, physicians are often reluctant to prescribe medications unless
34 prompted by the patient and are forced to resort to modifying androgen formulations created for
35 men, which can make dosing difficult when using these preparations for postmenopausal
36 women^{17,18}; and

37
38 Whereas, Compounded or off-label medications like bremelanotide and flibanserin are
39 expensive for patients as they are not covered by insurance or available at discounted rates,
40 leaving many postmenopausal women to live with HSDD¹⁷; therefore be it

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42 RESOLVED, That our AMA encourage expansion of research on the use of testosterone
43 therapy and other pharmacological interventions in treatment of decreased libido in
44 postmenopausal individuals. (Directive to Take Action)

Fiscal Note: Not yet determined

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RELEVANT AMA POLICY

Code of Medical Ethics 8.5 Disparities in Health Care

Stereotypes, prejudice, or bias based on gender expectations and other arbitrary evaluations of any individual can manifest in a variety of subtle ways. Differences in treatment that are not directly related to differences in individual patients' clinical needs or preferences constitute inappropriate variations in health care. Such variations may contribute to health outcomes that are considerably worse in members of some populations than those of members of majority populations.

This represents a significant challenge for physicians, who ethically are called on to provide the same quality of care to all patients without regard to medically irrelevant personal characteristics.

To fulfill this professional obligation in their individual practices physicians should:

- (a) Provide care that meets patient needs and respects patient preferences.
- (b) Avoid stereotyping patients.
- (c) Examine their own practices to ensure that inappropriate considerations about race, gender identify, sexual orientation, sociodemographic factors, or other nonclinical factors, do not affect clinical judgment.
- (d) Work to eliminate biased behavior toward patients by other health care professionals and staff who come into contact with patients.
- (e) Encourage shared decision making.

(f) Cultivate effective communication and trust by seeking to better understand factors that can influence patients' health care decisions, such as cultural traditions, health beliefs and health literacy, language or other barriers to communication and fears or misperceptions about the health care system.

The medical profession has an ethical responsibility to:

(g) Help increase awareness of health care disparities.

(h) Strive to increase the diversity of the physician workforce as a step toward reducing health care disparities.

(i) Support research that examines health care disparities, including research on the unique health needs of all genders, ethnic groups, and medically disadvantaged populations, and the development of quality measures and resources to help reduce disparities.

AMA Principles of Medical Ethics: I,IV,VII,VIII,IX

Principles for the Implementation of clinical practice guidelines at the Local/State/Regional Level H-410.980

Our AMA has adopted the following principles regarding the implementation of clinical practice guidelines at the local/state/regional level: (1) Relevant physician organizations and interested physicians shall have an opportunity for input/comment on all issues related to the local/state/regional implementation of clinical practice guidelines, including: issue identification; issue refinement, identification of relevant clinical practice guidelines, evaluation of clinical practice guidelines, selection and modification of clinical practice guidelines, implementation of clinical practice guidelines, evaluation of impact of implementation of clinical practice guidelines, periodic review of clinical practice guideline recommendations, and justifications for departure from clinical practice guidelines..

(2) Effective mechanisms shall be established to ensure opportunity for appropriate input by relevant physician organizations and interested physicians on all issues related to the local/state/regional implementation of clinical practice guidelines, including: effective physician notice prior to implementation, with adequate opportunity for comment; and an adequate phase-in period prior to implementation for educational purposes.

(3) clinical practice guidelines that are selected for implementation at the local/state/regional level shall be limited to practice parameters that conform to established principles, including relevant AMA policy on practice parameters.

(4) Prioritization of issues for local/state/regional implementation of clinical practice guidelines shall be based on various factors, including: availability of relevant and high quality practice parameter(s), significant variation in practice and/or outcomes, prevalence of disease/illness, quality considerations, resource consumption/cost issues, and professional liability considerations.

(5) clinical practice guidelines shall be used in a manner that is consistent with AMA policy and with their sponsors' explanations of the appropriate uses of their clinical practice guidelines, including their disclaimers to prevent inappropriate use.

(6) clinical practice guidelines shall be adapted at the local/state/regional level, as appropriate, to account for local/state/regional factors, including demographic variations, patient case mix, availability of resources, and relevant scientific and clinical information.

(7) clinical practice guidelines implemented at the local/state/regional level shall acknowledge the ability of physicians to depart from the recommendations in clinical practice guidelines, when appropriate, in the care of individual patients.

(8) The AMA and other relevant physician organizations should develop principles to assist physicians in appropriate documentation of their adherence to, or appropriate departure from, clinical practice guidelines implemented at the local/state/regional level.

(9) clinical practice guidelines, with adequate explanation of their intended purpose(s) and uses other than patient care, shall be widely disseminated to physicians who will be impacted by the clinical practice guidelines.

(10) Information on the impact of clinical practice guidelines at the local/state/regional level shall be collected and reported by appropriate medical organizations.

CMS Rep. D, A-93; Reaffirmed: CMS Rep. 10, A-03; Reaffirmed: CMS Rep. 4, A-13