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103D CONGRESS
1ST SESSION

H. R. 33

To amend the Public Health Service Act to establish standards for the certification of laboratories engaged in urine drug testing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 5, 1993

Mr. DINGELL (for himself and Mr. BLILEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to establish standards for the certification of laboratories engaged in urine drug testing, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug Testing Quality Act''.

SEC. 2. STANDARDS FOR CERTIFICATION OF LABORATORIES ENGAGED IN DRUG TESTING.

Title V of the Public Health Service Act is amended by adding at the end the following:

"PART F—DRUG TESTING

"SEC. 571. CERTIFICATION PROGRAM.

''(a) IN GENERAL.—Not later than one year after the date of enactment of this part, the Secretary shall, by regulation, establish a program (hereinafter referred to in this part as the 'certification program') for the certification of laboratories for the performance of toxicological urinalysis conducted for drug testing programs. The certification program shall, except as provided in subsection (b), conform, to the maximum extent practicable, to subpart C of the mandatory guidelines for Federal workplace drug testing programs published on April 11, 1988, by the Department of Health and Human Services at 53 Fed. Reg. 11979 and any amendments to such guidelines (hereinafter referred to in this part as the 'HHS guidelines').

''(b) SPECIFIC PROVISION.—The certification program established by the Secretary under subsection (a) shall, with respect to laboratory inspection, the monitoring of laboratory performance, and the conduct of quality control and performance testing programs, be consistent with the consensus of expert scientific and medical opinion on such matters as determined by the Secretary.

''(c) ADDITIONAL REGULATIONS.—

''(1) The certification program established by the Secretary under subsection (a) shall, in addition to the requirements of subsections (a) and (b)—

''(A) provide that the Secretary shall, in considering applications for certification under the certification program, consider whether the applicant has, directly or indirectly, owned or operated a laboratory which has had its certification suspended or revoked under the program, and

''(B)(i) include criteria for recognition by the Secretary of—

''(I) State agencies and private nonprofit accrediting bodies to certify laboratories in accordance with the requirements of this section if such agencies and bodies meet such criteria, and

''(II) State agencies and private nonprofit accrediting bodies to act on the Secretary's behalf in certifying laboratories in accordance with the requirements of this section if such agencies and bodies meet such criteria,

''(ii) provide that the Secretary shall oversee and review the performance of any agency or accrediting body recognized by the Secretary as meeting the criteria described in clause (i) to

ensure its compliance with the requirements of the certification program, and

''(iii) provide that the Secretary shall have the right to obtain from an agency or accrediting body described in clause (ii) and from any laboratory that may be certified by such an agency or accrediting body all records and materials that are necessary in the Secretary's judgment for the oversight and review required by clause (ii).

''(2) A laboratory may not be certified to perform drug testing under the certification program established under subsection (a) unless the laboratory is certified under section 353, except that a laboratory which only performs toxicological urinalyses is not required to be certified under section 353 to be certified under the certification program.

''(3)(A) A laboratory may not be certified to perform drug testing under the certification program established under subsection (a) unless it demonstrates to the Secretary its competence to perform toxicological urinalyses in accordance with the requirements of this section and section 572 for the following drugs and drug classes;

''(i) the drugs and drug classes for which test methods and cutoff levels are provided under subpart B of the HHS guidelines;

''(ii) barbiturates listed in schedules I and II under the Controlled Substances Act (21 U.S.C. 801 et seq.); and

''(iii) oxazepam and alprazolam.

''(B) Notwithstanding subparagraph (A), a laboratory certified under subpart C of the HHS guidelines prior to the date the Secretary establishes the certification program under subsection (a) shall be deemed by the Secretary to be competent to perform toxicological urinalyses for the drugs and drug classes described in subparagraph (A) and shall be certified by the Secretary to do so for drug testing programs as of such date.

''(4) A laboratory certified to perform drug testing under the certification program established under subsection (a), shall, in order to retain such certification, require its scientific, technical, and analytical personnel involved in such drug testing to participate in continuing education programs of a nature and at a frequency (not less than annually) specified by the Secretary in regulations.

''(d) REVISION.—The Secretary shall, in accordance with section 553 of title 5, United States Code, revise the requirements of the certification program as necessary to reflect improvements in drug testing methods for the purpose of ensuring the full reliability and accuracy of drug testing, the accurate reporting of full results, and the integrity and efficacy of drug testing programs.

"SEC. 572. PROVISIONS TO ENSURE INTEGRITY OF TOXICOLOGICAL URINALYSIS.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this part, the Secretary shall issue regulations to ensure the integrity of toxicological urinalysis which shall, except as provided in subsection (b), conform to the maximum extent practicable to subpart B of the HHS guidelines.

''(b) SPECIFIC PROVISIONS.—The regulations issued under subsection (a) shall—

''(1) except as otherwise provided in this subsection, treat any person conducting a drug testing program in the same manner as subpart B of the HHS guidelines treats the Federal agencies to which it is applicable,

''(2) expand the list of drugs and drug classes for which test methods and cutoff levels are provided under subpart B of the HHS guidelines to include

barbiturates listed in schedules I and II under the Controlled Substances Act, oxazepam and alprazolam, anabolic steroids, and such other drugs or drug classes as the Secretary determines under subsection (c) may be appropriate,

''(3)(A) neither require nor prohibit the establishment of a drug testing program by any person, and

''(B) neither require any person to test nor prohibit any person from testing for any particular drug or class of drugs described in paragraph (2) or subpart B of the HHS guidelines,

''(4) provide no specimen collection procedures other than those necessary to establish and maintain a proper chain of custody and to provide for transportation of specimens to the laboratory,

''(5) consistent with the consensus of expert medical and scientific opinion as determined by the Secretary, establish appropriate cutoff levels for each drug or class of drugs described in paragraph (2) or subpart B of the HHS guidelines for both initial and confirmatory tests,

''(6)(A) establish requirements to ensure the integrity and validity of blind performance testing of laboratories certified under the certification program

established under section 571, including a number or percentage of specimens (or both) to be submitted to a laboratory by a drug testing program for blind performance testing, set at the lowest level consistent with the consensus of expert medical and scientific opinion as determined by the Secretary and with the need to ensure accuracy, integrity, and protection of the interests of test subjects, and

''(B) establish procedures for drug testing programs to notify the Secretary of any false positive results discovered in blind performance testing or by a medical review officer and for the Secretary to take appropriate action on the basis of such notification,

''(7) provide no interim certification procedures, and

''(8) allow access by any test subject or any test subject's authorized representative, upon written request, to any record relevant to the results of such subject's drug test and to any record relating to the result of any relevant certification, review, suspension, or revocation of certification proceeding, and require a copy of such record to be provided to such test subject or representative upon written request.

Paragraphs (3) and (4) shall not be construed to affect the applicability of the requirements of subpart B of the HHS guidelines to drug testing programs conducted by Federal agencies under Executive Order 12564.

''(c) ADDITIONAL DRUGS.—

''(1)(A) Any person may file with the Secretary a petition proposing the issuance of a regulation under subsection (b)(2) prescribing test methods and cutoff levels for any drug or class of drugs for which such test methods and cutoff levels have not been previously prescribed. Notice of the regulation proposed by a petitioner shall be published in the Federal Register within 30 days after filing.

''(B) Twelve months following the issuance of regulations under subsection (a), and every 24 months thereafter, the Secretary shall publish in the Federal Register a request for public comment on the advisability of and need for including test methods and cutoff levels in such regulations for drugs or classes of drugs for which such test methods and cutoff levels have not been previously prescribed.

''(C) A petitioner or commenter under this paragraph shall be required to demonstrate in such person's petition or comment, as applicable, that—

''(i) widespread or otherwise significant abuse of such drug or class in the United States or any region of the United States poses a serious threat to public health or safety,

''(ii) there exists a well-documented and reliable method for toxicological urinalysis of such drug or class and for establishing cutoff levels applicable to such drug or class,

''(iii) such test methods and cutoff levels provide specificity and protection of the interests of test subjects equal to or greater than that provided with respect to the drugs or classes for which test methods and cutoff levels have been previously prescribed by the Secretary, and

''(iv) at least one laboratory certified under section 571 has an interest in providing toxicological urinalysis for the drug or class described in the petition or comment and is competent to do so.

A petitioner or commenter shall also furnish to the Secretary such additional explanatory and supporting data as the Secretary may require.

''(2)(A) Commencing 90 days following publication in the Federal Register of the request for public

comment described in paragraph (1)(B), and every 24 months thereafter, the Secretary shall review all petitions received and pending under paragraph (1)(A) and all comments received and pending under paragraph (1)(B), together with additional explanatory and supporting data submitted by petitioners and commenters and shall, with respect to each drug or class of drugs which is the subject of a petition or comment, determine whether the petitioner or commenter has made the demonstration required by paragraph (1)(C) and whether other facts, circumstances, or considerations outweigh the need to prescribe test methods and cutoff levels for such drug or class.

''(B)(i) If the Secretary determines under subparagraph (A) that a petitioner or commenter has made the demonstration required by paragraph (1)(C) and that no other facts, circumstances, or considerations outweigh the need to prescribe test methods and cutoff levels for such drug or class, the Secretary shall by order issue a regulation prescribing test methods and cutoff levels for such drug or class.

''(ii) If the Secretary determines that a petitioner has failed to make the demonstration required

by paragraph (1)(C) and that other facts, circumstances, or considerations outweigh the need to prescribe test methods and cutoff levels as requested in the petition, the Secretary shall by order deny the petition and within 30 days thereafter notify the petitioner of such order and of the reasons for such action.

''(C) The order required by subparagraph (B) shall be issued within 90 days after review by the Secretary commences under paragraph (2)(A), except that the Secretary may (prior to such 90th day), by written notice to a petitioner in the case of a petition or publication in the Federal Register in the case of a comment, extend such 90-day period to such time (not more than 180 days after commencement of such review) as the Secretary deems necessary to permit appropriate study and investigation.

''(d) AMATEUR ATHLETICS.—In issuing regulations under subsection (a), the Secretary shall take into consideration any special factors or circumstances applicable to the testing of participants in—

''(1) organized interscholastic or intercollegiate athletic competition, or

''(2) organized athletic competition conducted under the auspices of or sanctioned by the United States Olympic Committee or any member thereof, that warrant separate or different treatment of such testing under the regulations.

''(e) REVISION.—The Secretary shall, in accordance with section 553 of title 5, United States Code, revise the regulations issued under subsection (a) as necessary to reflect improvements in drug testing methods for the purpose of ensuring the full reliability and accuracy of drug testing, the accurate reporting of results, and the integrity and efficacy of drug testing programs.

"SEC. 573. SPECIMEN COLLECTION PROCEDURES.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this part, the Secretary shall issue model specimen collection procedures for the guidance of drug testing programs other than those conducted by Federal agencies under Executive Order 12564. Such model procedures shall include provisions for designation of a collection site, security, personnel access, and privacy in the collection process, and precautions to ensure the integrity and identity of specimens. In issuing such model procedures, the Secretary may recommend alternatives to address appropriate particularized needs or circumstances, including those applicable to athletic competition, and may

provide technical assistance to drug testing programs adopting or considering adoption of such model procedures.

''(b) SAVINGS PROVISION.—Subsection (a) shall not be construed to affect the applicability of the specimen collection procedures in subpart B of the HHS guidelines to drug testing programs conducted by Federal agencies under Executive Order 12564.

"**SEC. 574. PROHIBITIONS.**

''(a) CERTIFICATION REQUIREMENT.—(1) No person may perform any toxicological urinalysis in connection with any drug testing program unless that person is a laboratory which is certified under the certification program established under section 571.

''(2) It shall be unlawful for any laboratory certified to perform toxicological urinalysis under the certification program established under section 571 to perform toxicological urinalyses in connection with any drug testing program for any drug or drug class other than those listed in section 571(c)(3)(A) unless—

''(A) in a case where such other drug or drug class is one for which the Secretary has prescribed test methods and cutoff levels under section 572(b)(2) or 572(c), such laboratory is certified by

the Secretary to perform toxicological urinalyses for such other drug or drug class, or

''(B) in the case of any other drug or drug class, such drug testing program provides the laboratory with a statement signed by the test subject acknowledging that disclosure of a test for such other drug or drug class has been made and consenting to the performance of such test.

''(b) OTHER VIOLATIONS.—It shall be unlawful for any person—

''(1) who is a test subject to knowingly disclose the results of a toxicological urinalysis in connection with any drug testing program which was not performed on such person,

''(2) who is not a test subject and who has been directly or indirectly involved in a drug testing program or a toxicological urinalysis under such a program, to knowingly disclose the results of any toxicological urinalysis in connection with any drug testing program, except—

''(A) as provided in the regulations issued under section 572,

''(B) that if the person is authorized to represent—

''(i) an educational institution in which a participant described in section 572(d) is enrolled,

''(ii) an organized interscholastic or intercollegiate athletic team, league, or association, or

''(iii) an organization that conducts organized athletic competition under the auspices of or sanctioned by the United States Olympic Committee or any member thereof,

such person may disclose the results of a toxicological urinalysis performed on a participant described in section 572(d) in connection with a drug testing program, and

''(C) that if the person is authorized to represent a team, league, or association which conducts a drug testing program in which participants in athletic competitions who are paid for their performance are test subjects, such person may disclose the results of a toxicological urinalysis performed on such participant in connection with a drug testing program,

''(3) to knowingly—

''(A) alter or falsely report the results of a toxicological urinalysis, or

''(B) adulterate any urine specimen (other than a specimen spiked for use in performance testing),

in connection with any drug testing program or performance testing,

''(4) except in connection with epidemiological, biomedical, or other medical research in which the identity of the person providing the urine specimen is unknown, to knowingly perform or cause to be performed on a urine specimen a test for any medical condition or any substance, other than alcohol or a drug or drug class for which the Secretary has prescribed test methods and cutoff levels under section 572(a) or 562(b)(2), without the consent of the person providing the urine specimen following disclosure to such person of the medical condition or substance for which testing will be performed,

''(5) if the consent of a person providing a urine specimen is required under paragraph (4) before the specimen may be tested, to take any adverse action against such person for refusing to give such consent, unless such person is a participant described in section 572(d) or is a participant in ath-

letic competition who is paid for the participant's performance,

''(6) in the case of a toxicological urinalysis, to take any adverse action against any test subject based, in whole or in part, upon a positive result that has not been confirmed by a test—

''(A) which uses gas chromatography/mass spectrometry (or, in the case of alprazolam, which uses high-performance liquid chromatography), or

''(B) which, after the establishment of the certification program under section 571, is performed in accordance with the requirements of such program,

''(7) in the case of a toxicological urinalysis, where a confirmed positive result has not been verified by a medical review officer because there exists a legitimate medical explanation for the result consistent with legal drug use, including use of a drug pursuant to and in accordance with a valid prescription, or because the result is scientifically insufficient for further action, to take any adverse action against any test subject based in whole or in part upon such result, except that, in the case of a drug testing program conducted in connection with ath-

letic competition, a medical review officer may verify a confirmed positive result for any drug described in subsection (a)(2)(B) notwithstanding the existence of a legitimate medical explanation for the result, and adverse action may be taken against any participant in athletic competition based upon such result, or

''(8) to knowingly fail to administer or conduct any toxicological urinalysis or drug testing program in accordance with the requirements of the certification program established under section 571 or the regulations issued under section 572.

As used in paragraph (4), the term 'any medical condition or any substance' does not include creatinine, pH, or specific gravity.

"**SEC. 575. SANCTIONS AND REMEDIES.**

''(a) CRIMINAL PENALTY.—A person who violates section 574(a) shall be subject to imprisonment for not more than 3 years, or a fine under title 18, United States Code, or both.

''(b) ADMINISTRATIVE REMEDIES.—

''(1) A laboratory performing any toxicological urinalysis in connection with any drug testing program that violates any regulation issued under section 572 shall be subject to assessment by the Sec-

retary of a civil penalty of not less than $1,000 or more than $10,000, taking into account the previous record of the laboratory under sections 571 and 572 and the gravity of the violation.

''(2) If the Secretary discovers a violation of any regulation issued under section 572 by any person other than a laboratory, the Secretary shall refer the matter to the Attorney General for further investigation and appropriate action.

''(c) INJUNCTION.—The Secretary or the Attorney General, as appropriate, or any aggrieved person, may bring an action to restrain violations of section 574(a) or any regulation issued under section 572. In any action brought under this subsection, the district courts of the United States shall have jurisdiction for cause shown, to issue declaratory relief, temporary restraining orders, and preliminary and permanent injunctions to require compliance with such provisions.

''(d) CIVIL ACTION.—Any test subject who is tested, or whose test results are handled, in violation of, or is deprived of rights because of a violation under, subsection (a) or paragraphs (1) through (7) of subsection (b) of section 574, or who is adversely affected by a material breach in an applicable chain of custody under section 572, may institute a civil action in any district court of the United

States of competent jurisdiction for appropriate legal and equitable relief, including employment, reinstatement, promotion, the payment of lost wages and benefits, and damages. The costs of suit, including a reasonable attorney's fee, shall be allowed to a prevailing party. Such an attorney's fee shall be allowed in the manner in which attorney's fees are allowed under the last sentence of section 722 of the Revised Statutes (42 U.S.C. 1988). It shall not be a defense to such an action that the plaintiff has waived the rights or protections provided for in this section or has otherwise consented to a violation, deprivation, or breach. No action may be instituted under this subsection after the expiration of 2 years from the date the person discovers the violation, deprivation, or breach.

''(e) INDEMNIFICATION AND CONTRIBUTION.—Any person conducting a drug testing program who takes any adverse action against any test subject based, in whole or in part, upon a report by a laboratory of a positive test result which is thereafter found to have been a false positive result and who consequently is held liable under subsection (d) for damages or other sums may institute a civil action against such laboratory for indemnification or contribution, as appropriate, in any district court of the United States of competent jurisdiction. No action may be instituted under this subsection after the expiration of one

year from the date on which a judgment under subsection (d) becomes final.

"SEC. 576. CONSTRUCTIONS.

''(a) IN GENERAL.—Nothing in this part limits the authority—

''(1) of the Secretary under section 571(c)(1)(B)(i) to permit an agency or accrediting body described in section 571(c)(1)(B)(ii) to maintain, or

''(2) of any test subject or duly authorized representative of a test subject to contract for,

standards, procedures, or requirements more protective of test subjects than those provided by the certification program established under section 571 or the regulations issued under section 572.

''(b) LIMITATION.—Notwithstanding subsection (a)(1), the Secretary shall not permit an agency or accrediting body described in section 571(c)(1)(B)(ii) to deny certification under section 571 to any laboratory complying with the standards, procedures, and requirements established by the Secretary under section 571.

''(c) CERTIFICATION.—To the extent that this part imposes a more protective standard, procedure, or requirement on—

''(1) the Secretary,

''(2) laboratories performing toxicological urinalysis, or

''(3) a person conducting a drug testing program, such standard, procedure, or requirement shall supersede and replace that provided by the HHS guidelines and by any statute, rule, regulation, Executive order, or other law in effect on the date on which such standard, procedure, or requirement becomes effective.

''SEC. 577. PREEMPTION.

''(a) IN GENERAL.—No State or local government may adopt or enforce any law, rule, regulation, ordinance, standard, or order relating to—

''(1) the certification of laboratories which perform drug testing, or

''(2) requirements for the conduct of drug testing under the certification program established under this part,

which is different from such certification program.

''(b) PROHIBITION.—No State or local government may adopt or enforce any law, rule, regulation, ordinance, standard, or order that permits or requires any act prohibited by section 574.

"SEC. 578. FEES.

''The Secretary shall require the payment of fees by a laboratory for certification and recertification in such amounts as the Secretary may, from time to time, determine are necessary to recover the cost of granting or denying such certification or recertification under the certification program established under section 571. The Secretary shall also require the payment thereafter of annual fees by certified laboratories in such amounts as the Secretary may, from time to time, determine are necessary to recover the cost of ongoing testing, inspection, investigation, enforcement, and other supervisory activities with respect to certified laboratories under this part and such certification program. Subject to appropriation Acts, the Secretary may use fees collected under this section to administer the certification program under section 571 and to carry out the activities described in the preceding sentence.

"SEC. 579. DEFINITIONS.

''As used in this part—

''(1) the term 'blank specimen' means a urine specimen containing no drug,

''(2) the term 'controlled substance' has the meaning given to it in section 102(b) of the Controlled Substances Act (21 U.S.C. 802(6)),

''(3) the term 'drug' means any controlled substance and any metabolite of a controlled substance,

''(4) the term 'drug testing program' means any program or policy under which 2 or more individuals are, or can reasonably be expected to be, required or requested to submit urine specimens for toxicological urinalysis, but such term does not include—

''(A) any program for toxicological urinalysis—

''(i) administered by the armed forces (as defined in section 2101(2) of title 5, United States Code) or the intelligence community (as defined in Executive Order 12333 of December 4, 1981), or

''(ii) involving the testing of arrestees, detainees, probationers, incarcerated persons, or parolees in the criminal justice system, and

''(B) the submission to a laboratory of any urine specimen by an individual's physician if the testing by the laboratory of the specimen is to be conducted as part of the regular course of diagnosis or treatment prescribed by the physician,

''(5) the term 'false positive result' means a report in connection with any toxicological urinalysis of the presence of a drug in a urine specimen in which that drug is not in fact present at or above the cutoff level for that drug established by the Secretary,

''(6) the term 'medical review officer' has the meaning given such term in subpart A of the HHS guidelines,

''(7) the term 'person' includes the Federal Government, a State or local government, or any agency of such a government,

''(8) the term 'performance testing' means testing of a laboratory's ability—

''(A) to identify correctly whether a urine specimen contains a quantity of a drug, and

''(B) in the case of a spiked specimen, to identify correctly the amount of any drug in that specimen within qualitative threshold levels and quantitative ranges established by the regulations issued under section 572,

''(9) the term 'spiked specimen' means a urine specimen into which a quantity of a drug or drugs has intentionally been placed for use in performance testing,

''(10) the term 'test subject' means an individual who has been required or requested to submit a urine specimen for toxicological urinalysis in connection with a drug testing program, and

''(11) the term 'toxicological urinalysis' means the performance of any analytical procedure or set of procedures on a urine specimen to identify the presence in that specimen of any drug and the amount thereof.''.

SEC. 3. EFFECTIVE DATE.

Part F of title V of the Public Health Service Act, added by section 2, shall take effect on the date of the enactment of this Act, except that subsections (a), (b)(2), and (b)(8) of section 574 of such part shall take effect one year after the date the Secretary of Health and Human Services establishes the laboratory certification program under section 571 of such part.

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