

113TH CONGRESS
1ST SESSION

S. 348

To provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 14, 2013

Mr. ROCKEFELLER (for himself, Mr. MANCHIN, and Mrs. GILLIBRAND) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

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 “Prescription Drug
5 Abuse Prevention and Treatment Act of 2013”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) Nonmedical use of prescription pain reliev-
9 ers is a matter of increasing public health concern.

1 According to the Substance Abuse and Mental
2 Health Services Administration, the proportion of all
3 substance abuse treatment admissions aged 12 or
4 older that reported any pain reliever abuse increased
5 more than 400 percent between 1998 and 2008,
6 from 2.2 to 9.8 percent.

7 (2) In 2008, among the population of the
8 United States aged 12 or older, nonmedical use of
9 prescription pain relievers was the second most prev-
10 alent type of illicit drug use, after marijuana use.

11 (3) When used properly under medical super-
12 vision, prescription opiates enable individuals with
13 chronic pain to lead productive lives. However, when
14 taken without a physician's oversight and direction,
15 opiates can cause serious adverse health effects, re-
16 sulting in dependence, abuse, and death.

17 (4) As with any controlled substance, there is a
18 risk of abuse of methadone and other opiates.

19 (5) Methadone is an extensively tested, federally
20 approved, and widely accepted method of treating
21 addiction to prescription pain relievers or opiates.

22 (6) For more than 30 years, this synthetic pre-
23 scription drug has been used for pain management
24 and treatment for addiction to heroin, morphine,
25 and other opioid drugs.

1 (7) The efficacy and lower cost of methadone
2 has resulted in its being prescribed for pain manage-
3 ment.

4 (8) Prescriptions for methadone have increased
5 by nearly 700 percent from 1998 through 2006.

6 (9) According to the Centers for Disease Con-
7 trol and Prevention, the number of poisoning deaths
8 involving methadone increased nearly 7-fold from al-
9 most 790 in 1999 to almost 5,420 in 2006, which
10 is the most rapid increase among opioid analgesics
11 and other narcotics involved in poisoning deaths.

12 (10) The age-specific rates of methadone death
13 are higher for persons age 35 to 44 and 45 to 54
14 than for other age groups. However, the rate of
15 methadone deaths in younger individuals (age 15 to
16 24) increased 11-fold from 1999 through 2005.

17 (11) Deaths from methadone and other opiates
18 may actually be underreported. There is no com-
19 prehensive database of drug-related deaths in the
20 United States.

21 (12) The lack of standardized reporting by
22 Medical Examiners precludes a uniform definition of
23 “cause of death” on death certificates.

24 (13) The Controlled Substances Act (21 U.S.C.
25 801 et seq.) requires that every person who dis-

1 penses or who proposes to dispense controlled nar-
 2 cotics, including methadone, whether for pain man-
 3 agement or opioid treatment obtain a registration
 4 from Drug Enforcement Administration. Unfortu-
 5 nately there is no requirement as a condition of re-
 6 ceiving the registration that these practitioners re-
 7 ceive any education on the use of these controlled
 8 narcotics, including methadone.

9 (14) Current Federal oversight of methadone
 10 and other opioids is inadequate to address the grow-
 11 ing number of opioid-related overdoses and deaths.

12 (15) Federal legislation is needed to avert
 13 opioid abuse, misuse, and death, without reducing
 14 patient access to needed care.

15 **SEC. 3. CONSUMER EDUCATION CAMPAIGN.**

16 Part A of title V of the Public Health Service Act
 17 (42 U.S.C. 290aa et seq.) is amended by adding at the
 18 end the following:

19 **“SEC. 506C. CONSUMER EDUCATION CAMPAIGN.**

20 “(a) IN GENERAL.—The Administrator shall award
 21 grants to States and nonprofit entities for the purpose of
 22 conducting culturally sensitive consumer education about
 23 opioid abuse, including methadone abuse. Such education
 24 shall include information on the dangers of opioid abuse,
 25 how to prevent opioid abuse including through safe dis-

posals of prescription medications and other safety precautions, and detection of early warning signs of addiction.

“(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

“(1) be a State or nonprofit entity; and

“(2) submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

“(c) PRIORITY.—In awarding grants under this section, the Administrator shall give priority to applicants that are States or communities with a high incidence of abuse of methadone and other opioids, and opioid-related deaths.

“(d) EVALUATIONS.—The Administrator shall develop a process to evaluate the effectiveness of activities carried out by grantees under this section at reducing abuse of methadone and other opioids.

“(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section \$15,000,000 for each of fiscal years 2014 through 2018.”.

SEC. 4. PRACTITIONER EDUCATION.

(a) EDUCATION REQUIREMENTS.—

(1) REGISTRATION CONSIDERATION.—Section 303(f) of the Controlled Substances Act (21 U.S.C.

1 823(f)) is amended by inserting after paragraph (5)
2 the following:

3 “(6) The applicant’s compliance with the train-
4 ing requirements described in subsection (g)(3) dur-
5 ing any previous period in which the applicant has
6 been subject to such training requirements.”.

7 (2) TRAINING REQUIREMENTS.—Section 303(g)
8 of the Controlled Substances Act (21 U.S.C. 823(g))
9 is amended by adding at the end the following:

10 “(3)(A) To be registered to prescribe or otherwise
11 dispense methadone or other opioids, a practitioner de-
12 scribed in paragraph (1) shall comply with the 16-hour
13 training requirement of subparagraph (B) at least once
14 during each 3-year period.

15 “(B) The training requirement of this subparagraph
16 is that the practitioner has completed not less than 16
17 hours of training (through classroom situations, seminars
18 at professional society meetings, electronic communica-
19 tions, or otherwise) with respect to—

20 “(i) the treatment and management of opioid-
21 dependent patients;

22 “(ii) pain management treatment guidelines;
23 and

1 “(iii) early detection of opioid addiction, includ-
 2 ing through such methods as Screening, Brief Inter-
 3 vention, and Referral to Treatment (SBIRT),
 4 that is provided by the American Society of Addiction
 5 Medicine, the American Academy of Addiction Psychiatry,
 6 the American Medical Association, the American Osteo-
 7 pathic Association, the American Psychiatric Association,
 8 the American Academy of Pain Management, the Amer-
 9 ican Pain Society, the American Academy of Pain Medi-
 10 cine, the American Board of Pain Medicine, the American
 11 Society of Interventional Pain Physicians, or any other or-
 12 ganization that the Secretary determines is appropriate
 13 for purposes of this subparagraph.”.

14 (b) REQUIREMENTS FOR PARTICIPATION IN OPIOID
 15 TREATMENT PROGRAMS.—Effective July 1, 2014, a phy-
 16 sician practicing in an opioid treatment program shall
 17 comply with the requirements of section 303(g)(3) of the
 18 Controlled Substances Act (as added by subsection (a))
 19 with respect to required minimum training at least once
 20 during each 3-year period.

21 (c) DEFINITION.—In this section, the term “opioid
 22 treatment program” has the meaning given such term in
 23 section 8.2 of title 42, Code of Federal Regulations (or
 24 any successor regulation).

1 (d) FUNDING.—The Drug Enforcement Administra-
 2 tion shall fund the enforcement of the requirements speci-
 3 fied in section 303(g)(3) of the Controlled Substances Act
 4 (as added by subsection (a)) through the use of a portion
 5 of the licensing fees paid by controlled substance pre-
 6 scribers under the Controlled Substances Act (21 U.S.C.
 7 801 et seq.).

8 **SEC. 5. MORATORIUM ON METHADONE HYDROCHLORIDE**
 9 **TABLETS.**

10 (a) IN GENERAL.—Notwithstanding any other provi-
 11 sion of law, during the period beginning on the date of
 12 enactment of this Act and ending on the date described
 13 in subsection (b), no individual or entity may prescribe
 14 or otherwise dispense a 40-mg diskette of methadone un-
 15 less such prescription or dispensation is consistent with
 16 the methadone 40-mg diskette policy of the Drug Enforce-
 17 ment Administration as in effect on the date of enactment
 18 of this Act, except that such prohibition shall extend to
 19 hospitals unless such hospitals provide for direct patient
 20 supervision with respect to such methadone.

21 (b) ENDING DATE OF MORATORIUM.—The morato-
 22 rium under subsection (a) shall cease to have force and
 23 effect—

24 (1) on the date that the Controlled Substances
 25 Clinical Standards Commission publishes in the Fed-

1 eral Register dosing guidelines for all forms of meth-
2 adone, in accordance with section 506D(b)(1)(A) of
3 the Public Health Service Act (as added by section
4 7); and

5 (2) if, as part of such dosing guidelines, such
6 Commission finds that 40-mg diskettes of metha-
7 done are safe and clinically appropriate.

8 **SEC. 6. OPERATION OF OPIOID TREATMENT PROGRAMS.**

9 Section 303 of the Controlled Substances Act (21
10 U.S.C. 823) is amended by adding at the end the fol-
11 lowing:

12 “(i)(1) An opioid treatment program that is reg-
13 istered under this section, and that closes for business on
14 any weekday or weekend day, including a Federal or State
15 holiday, shall comply with the requirements of this sub-
16 section.

17 “(2) The program shall make acceptable arrange-
18 ments for each patient who is restricted, by Federal regu-
19 lation or guideline or by the determination of the program
20 medical director, from having a take home dose of a con-
21 trolled substance related to the treatment involved, to re-
22 ceive a dose of that substance under appropriate super-
23 vision during the closure.

24 “(3) The Administrator of the Substance Abuse and
25 Mental Health Services Administration shall issue a notice

1 that references regulations on acceptable arrangements
 2 under this subsection, or shall promulgate regulations on
 3 such acceptable arrangements.”.

4 **SEC. 7. ESTABLISHMENT OF THE CONTROLLED SUB-**
 5 **STANCES CLINICAL STANDARDS COMMIS-**
 6 **SION.**

7 Part A of title V of the Public Health Service Act
 8 (42 U.S.C. 290aa et seq.), as amended by section 3, is
 9 further amended by adding at the end the following:

10 **“SEC. 506D. ESTABLISHMENT OF THE CONTROLLED SUB-**
 11 **STANCES CLINICAL STANDARDS COMMIS-**
 12 **SION.**

13 “(a) IN GENERAL.—The Secretary shall establish a
 14 Controlled Substances Clinical Standards Commission (re-
 15 ferred to in this section as the ‘Commission’), to be com-
 16 posed of representatives from the Administration, the Cen-
 17 ters for Disease Control and Prevention, the Food and
 18 Drug Administration, the Pain Management Consortia of
 19 the National Institutes of Health, and other agencies that
 20 the Secretary may deem necessary, to develop—

21 “(1) appropriate and safe dosing guidelines for
 22 all forms of methadone, including recommendations
 23 for maximum daily doses of all forms as provided for
 24 in subsection (b)(1);

1 “(2) benchmark guidelines for the reduction of
2 methadone abuse, as provided for in subsection
3 (b)(2);

4 “(3) appropriate conversion factors for use by
5 health care providers in transitioning patients from
6 one opioid to another;

7 “(4) specific guidelines for initiating pain man-
8 agement with methadone that prescribing practi-
9 tioners shall comply with in order to meet certifi-
10 cation requirements set forth in part C of the Con-
11 trolled Substances Act (21 U.S.C. 821 et seq.); and

12 “(5) patient and practitioner education guide-
13 lines for both methadone maintenance therapy and
14 pain management that apply to safe and effective
15 use and include detoxification.

16 “(b) GUIDELINES.—

17 “(1) PUBLICATION OF DOSING GUIDELINES.—

18 “(A) IN GENERAL.—Not later than 2 years
19 after the date of enactment of this section, the
20 Commission established under subsection (a)
21 shall publish in the Federal Register—

22 “(i) safe and clinically appropriate
23 dosing guidelines for all forms of metha-
24 done used for both pain management and
25 opioid treatment programs, including rec-

ommendations for maximum daily doses of all forms, including recommendations for the induction process for patients who are newly prescribed methadone;

“(ii) requirements for individual patient care plans, including initial and follow-up patient physical examination guidelines, and recommendations for screening patients for chronic or acute medical conditions that may cause an immediate and adverse reaction to methadone;

“(iii) appropriate conversion factors for use by health care providers in transitioning patients from one opioid to another;

“(iv) specific guidelines for initiating pain management with methadone, that prescribing physicians or other clinicians shall comply with in order to meet Drug Enforcement Administration certification and re-certification requirements; and

“(v) consensus guidelines for pain management with prescription opioid drugs.

1 “(B) UPDATING OF GUIDELINES.—Not
 2 later than 3 years after the publication of
 3 guidelines under subparagraph (A), and at least
 4 every 3 years thereafter, the Commission shall
 5 update such guidelines.

6 “(2) PUBLICATION OF BENCHMARK GUIDE-
 7 LINES.—

8 “(A) IN GENERAL.—Not later than 3 years
 9 after the date of enactment of this section, the
 10 Commission established under subsection (a)
 11 shall publish in the Federal Register—

12 “(i) the initial benchmark guidelines
 13 for the reduction of methadone abuse to be
 14 used—

15 “(I) by opioid treatment pro-
 16 grams in providing methadone ther-
 17 apy; and

18 “(II) by entities in the initial ac-
 19 creditation or certification, and the re-
 20 accreditation and re-certification, of
 21 such opioid treatment programs;

22 “(ii) a model policy for dispensing
 23 methadone to be used by pharmacists that
 24 dispense methadone, which should include

1 education and training guidelines for such
2 pharmacists;

3 “(iii) the continuing education guide-
4 lines that all prescribers shall comply with
5 in order to meet Drug Enforcement Ad-
6 ministration certification and re-certifi-
7 cation requirements, as set forth in section
8 303(g)(3) of the Controlled Substances Act
9 (21 U.S.C. 823(g)(3)), which should in-
10 clude a minimum of 16 training hours at
11 least every 3 years that include the inte-
12 gration of both addiction and pain man-
13 agement curricula; and

14 “(iv) patient education guidelines for
15 both opioid treatment programs and pain
16 management, including recommendations
17 for patient counseling prior to and during
18 opioid addiction treatment or treatment for
19 pain.

20 “(B) UPDATING OF GUIDELINES.—Not
21 later than 1 year after the publication of guide-
22 lines under subparagraph (A), and at least an-
23 nually thereafter, the Commission shall update
24 the guidelines published under clauses (iii) and
25 (iv) of such subparagraph.

1 “(3) CONSULTATION.—In developing and pub-
2 lishing the guidelines under this section, the Com-
3 mission shall consult with relevant professional orga-
4 nizations with expertise in the area of addiction, rel-
5 evant professional organizations with expertise in the
6 area of pain management, physician groups, phar-
7 macy groups (including the National Association of
8 Boards of Pharmacy), patient representatives, and
9 any other organization that the Secretary determines
10 is appropriate for purposes of this section.

11 “(c) WEBSITE.—Not later than 180 days after the
12 date of enactment of this section, the Commission shall
13 establish and operate a Commission website.

14 “(d) METHADONE TOOLKIT.—Not later than 1 year
15 after the date of enactment of this section, the Commis-
16 sion shall establish, and distribute to practitioners that are
17 registered to prescribe or otherwise dispense methadone,
18 a methadone toolkit. The Commission shall make the com-
19 ponents of the toolkit that are available in electronic form
20 available on the Commission website.

21 “(e) PRACTITIONER EDUCATION PROGRAM.—The
22 Commission shall develop a practitioner education pro-
23 gram that shall be used for the practitioner education de-
24 scribed in section 303(g)(3) of the Controlled Substances

1 Act, and shall make such program available to providers
 2 of such practitioner education.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
 4 is authorized to be appropriated to carry out this section
 5 such sums as may be necessary for each of fiscal years
 6 2014 through 2018.”.

7 **SEC. 8. PRESCRIPTION MONITORING PROGRAM.**

8 Section 399O of the Public Health Service Act (42
 9 U.S.C. 280g–3) is amended—

10 (1) in subsection (d)(1), by inserting “(includ-
 11 ing prescribers of methadone)” after “dispensers”;

12 (2) in subsection (e), by adding at the end the
 13 following:

14 “(5) Subject to the requirements of section 543,
 15 the State shall, at the request of a Federal, State,
 16 or local officer whose duties include enforcing laws
 17 relating to drugs, provide to such officer information
 18 from the database relating to an individual who is
 19 the subject of an active drug-related investigation
 20 conducted by the officer’s employing government en-
 21 tity.”; and

22 (3) by striking subsection (n) and inserting the
 23 following:

1 “(n) APPROPRIATIONS.—There is authorized to be
 2 appropriated to carry out this section \$25,000,000 for
 3 each of fiscal years 2014 through 2018.”.

4 **SEC. 9. MORTALITY REPORTING.**

5 Part A of title V of the Public Health Service Act
 6 (42 U.S.C. 290aa et seq.), as amended by section 7, is
 7 further amended by adding at the end the following:

8 **“SEC. 506E. MORTALITY REPORTING.**

9 “(a) MODEL OPIOID TREATMENT PROGRAM MOR-
 10 TALITY REPORT.—

11 “(1) IN GENERAL.—Not later than July 1,
 12 2014, the Secretary, acting through the Adminis-
 13 trator, shall require that a Model Opioid Treatment
 14 Program Mortality Report be completed and sub-
 15 mitted to the Administrator for each individual who
 16 dies while receiving treatment in an opioid treatment
 17 program.

18 “(2) REQUIREMENT OF STATES THAT RECEIVE
 19 FUNDING FOR THE CONTROLLED SUBSTANCE MONI-
 20 TORING PROGRAM.—As a condition for receiving
 21 funds under section 399O, each State shall require
 22 that any individual who signs a death certificate
 23 where an opioid drug is detected in the body of the
 24 deceased, or where such drug is otherwise associated
 25 with the death, report such death to the Adminis-

trator by submitting a Model Opioid Treatment Program Mortality Report described in paragraph (3). Such report shall be submitted to the Administrator on or before the later of—

“(A) 90 days after the date of signing the death certificate; or

“(B) as soon as practicable after the date on which the necessary postmortem and toxicology reports become available to such individual, as required by the Secretary.

“(3) DEVELOPMENT.—The Administrator, in consultation with State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Administrator determines appropriate, shall develop a Model Opioid Treatment Program Mortality Report to be used under paragraphs (1) and (2).

“(b) NATIONAL OPIOID DEATH REGISTRY.—

“(1) IN GENERAL.—Not later than July 1, 2014, the Administrator shall establish and implement, through the National Center for Health Statistics, a National Opioid Death Registry (referred to in this subsection as the ‘Registry’) to track opioid-related deaths and information related to such deaths.

1 “(2) CONSULTATION.—In establishing the uni-
 2 form reporting criteria for the Registry, the Director
 3 of the Centers for Disease Control and Prevention
 4 shall consult with the Administrator, State and local
 5 medical examiners, prescribing physicians, hospitals,
 6 and any other organization that the Director deter-
 7 mines is appropriate for purposes of this subsection.

8 “(3) REQUIREMENTS.—The registry shall be
 9 designed as a uniform reporting system for opioid-
 10 related deaths and shall require the reporting of in-
 11 formation with respect to such deaths, including—

12 “(A) the particular drug formulation used
 13 at the time of death;

14 “(B) the dosage level;

15 “(C) a description of the circumstances
 16 surrounding the death in relation to the rec-
 17 ommended dosage involved;

18 “(D) a disclosure of whether the medica-
 19 tion involved can be traced back to a physi-
 20 cian’s prescription;

21 “(E) a disclosure of whether the individual
 22 was in an opioid treatment program at the time
 23 of death;

24 “(F) the age and sex of the individual; and

1 “(G) other non-personal information such
2 as that included in filed National Association of
3 Medical Examiners Pediatric Toxicology Reg-
4 istry case reports as required under the privacy
5 standard for the de-identification of health in-
6 formation pursuant to the regulations contained
7 in part 164 of title 45, Code of Federal Regula-
8 tions.

9 “(4) AUTHORIZATION.—There is authorized to
10 be appropriated \$5,000,000 for each of fiscal years
11 2014 through 2018 to carry out this subsection.

12 “(c) REPORT ON REGISTRY INFORMATION.—Not
13 later than the January 1 of the first fiscal year beginning
14 2 years after the date of enactment of this section, and
15 each January 1 thereafter, the Director of the Centers for
16 Disease Control and Prevention shall submit to the Sec-
17 retary a report, based on information contained in the
18 Registry described in subsection (b), concerning the num-
19 ber of methadone-related deaths in the United States for
20 the year for which the report is submitted.”.

21 **SEC. 10. ADDITIONAL REPORTING.**

22 Part A of title V of the Public Health Service Act
23 (42 U.S.C. 290aa et seq.), as amended by section 9, is
24 further amended by adding at the end the following:

1 **“SEC. 506F. ADDITIONAL REPORTING.**

2 “(a) REPORT ON METHADONE USAGE.—

3 “(1) IN GENERAL.—Not later than January 1
4 of the first fiscal year beginning 2 years after the
5 date of enactment of this section, and each January
6 1 thereafter, the Administrator and the Commis-
7 sioner of Food and Drugs shall submit to the Sec-
8 retary a report containing detailed statistics on
9 methadone usage for opioid treatment and pain
10 management. Such statistics shall include—

11 “(A) information on the distribution of
12 prescribed doses of methadone at federally
13 qualified health centers, opioid treatment clin-
14 ics, other health-related clinics, physician of-
15 fices, pharmacies, and hospitals; and

16 “(B) information relating to adverse health
17 events resulting from such methadone usage.

18 “(2) AVAILABILITY OF INFORMATION.—The
19 Secretary shall make the reports submitted under
20 paragraph (1) available to the general public, includ-
21 ing through the use of the Internet website of the
22 Department of Health and Human Services.

23 “(b) ANNUAL REPORT ON EFFECTIVENESS.—Not
24 later than September 30, 2014, and annually thereafter
25 until September 30, 2016, the Secretary shall submit to
26 the appropriate committees of Congress, a report con-

cerning the effectiveness of the methadone maintenance
therapy program. Such report shall evaluate the success
of efforts to reduce opioid addiction and methadone-re-
lated deaths, including the impact of health care provider
and patient education.

“(c) AUTHORIZATION OF APPROPRIATIONS.—There
is authorized to be appropriated to carry out this section
such sums as may be necessary for each of fiscal years
2014 through 2018.”.

**SEC. 11. DEVELOPMENT OF PRESCRIPTION DRUG ABUSE
PREVENTION AND TREATMENT QUALITY
MEASURES ACROSS EACH RELEVANT PRO-
VIDER SETTING.**

Subpart I of part D of title IX of the Public Health
Service Act (42 U.S.C. 299b–31 et seq.) is amended by
adding at the end the following:

**“SEC. 932. DEVELOPMENT OF PRESCRIPTION DRUG ABUSE
PREVENTION AND TREATMENT QUALITY
MEASURES ACROSS EACH RELEVANT PRO-
VIDER SETTING.**

“(a) IN GENERAL.—The Secretary, acting through
the Director of the Agency for Healthcare Research and
Quality and in consultation with the Director of the Cen-
ters for Disease Control and Prevention, the Adminis-
trator of the Substance Abuse and Mental Health Services

1 Administration, and the Director of the Centers for Medi-
2 care & Medicaid Services, shall require the development
3 and application of specific prescription drug abuse preven-
4 tion and treatment quality measures for each relevant
5 health care provider setting, as identified by the Director.

6 “(b) DISSEMINATION.—Not later than April 1, 2016,
7 the Secretary shall disseminate the quality measure re-
8 quirements developed under subsection (a) to all affected
9 providers.

10 “(c) TYPES OF MEASURES.—Quality measures devel-
11 oped under this section may be structure-oriented (such
12 as the required presence of a hospital-based treatment
13 program), process-oriented (such as requiring patients to
14 be informed of the addictive qualities of the medication
15 being prescribed), or outcome-oriented (such as assessing
16 family satisfaction with care).”.

○