

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2001

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HOUSE BILL 1472*
Committee Substitute Favorable 11/6/01

Short Title: Biological Agents Registry.

(Public)

Sponsors:

Referred to:

October 30, 2001

1 A BILL TO BE ENTITLED
2 AN ACT DIRECTING THE DEPARTMENT OF HEALTH AND HUMAN
3 SERVICES TO ESTABLISH A BIOLOGICAL AGENTS REGISTRY, AND
4 IMPOSING CIVIL PENALTIES FOR VIOLATION OF REGISTRY
5 REQUIREMENTS.

6 The General Assembly of North Carolina enacts:

7 **SECTION 1.** Part 1 of Article 6 of Chapter 130A of the General Statutes is
8 amended by adding the following new section to read:

9 **"§ 130A-149. Biological agents registry; rules; penalties.**

10 (a) The Department shall establish and administer a program for the registration
11 of biological agents. The biological agents registry shall identify the biological agents
12 possessed and maintained by any person in this State and shall contain other
13 information required under rules adopted by the Commission.

14 (b) The following definitions apply in this section:

15 (1) 'Biological agent' means:

16 a. Any select agent that is a microorganism, virus, bacterium,
17 fungus, rickettsia, or toxin listed in Appendix A of Part 72 of
18 Title 42 of the Code of Federal Regulations.

19 b. Any genetically modified microorganisms or genetic elements
20 from an organism on Appendix A of Part 72 of Title 42 of the
21 Code of Federal Regulations, shown to produce or encode for a
22 factor associated with a disease.

23 c. Any genetically modified microorganisms or genetic elements
24 that contain nucleic acid sequences coding for any of the toxins
25 listed on Appendix A of Part 72 of Title 42 of the Code of
26 Federal Regulations, or their toxic submits.

27 (2) 'Person' means any association, business, corporation, facility, firm,
28 individual, institution of higher education, organization, partnership,
29 society, State agency, or other legal entity.

1 (c) The Commission shall adopt rules for the implementation of the registry
2 program, as follows:

3 (1) Determining and listing the biological agents required to be reported
4 under this section.

5 (2) Designating persons required to make reports and specific information
6 required to be reported including time limits for reporting, form of
7 reports, and to whom reports shall be submitted.

8 (3) Providing for the release of information in the registry to State and
9 federal law enforcement agencies and the United States Centers for
10 Disease Control and Prevention pursuant to a communicable disease
11 investigation commenced or conducted by the Department, the
12 Commission, or other state or federal law enforcement agency having
13 investigatory authority, or in connection with any investigation
14 involving release, theft, or loss of biological agents.

15 (4) Establishing a system of safeguards that requires persons possessing
16 and maintaining biological agents subject to this section to comply
17 with the same federal standards that apply to persons registered to
18 possess the same agents under federal law.

19 (5) Establishing a process for persons that possess and maintain biological
20 agents to alert appropriate authorities of unauthorized possession or
21 attempted possession of biological agents. The rules shall designate
22 appropriate authorities for receipt of alerts from these persons.

23 (d) Any person that possesses and maintains any biological agent required to be
24 reported under this section shall report to the Department the information required by
25 the Commission for inclusion in the biological agent registry.

26 (e) Except as otherwise provided in this section, information prepared for or
27 maintained in the registry under this section shall be confidential and shall not be a
28 public record under G.S. 132-1. The Department may, in accordance with rules adopted
29 by the Commission, release information contained in the biological agent registry for
30 the purpose of conducting or aiding in a communicable disease investigation. The
31 Department shall cooperate with and may share information contained in the biological
32 agent registry with the United States Centers for Disease Control and Prevention, and
33 state and federal law enforcement agencies in any investigation involving the release,
34 theft, or loss of a biological agent required to be reported under this section. Release of
35 information from the registry as authorized under this subsection shall not render the
36 information released a public record under G.S. 132-1. Release of information from the
37 registry as authorized under this subsection also shall not render the information
38 prepared for or maintained in the registry a public record under G.S. 132-1.

39 (f) The Department shall impose a civil penalty for a willful or knowing
40 violation of this section in the amount of up to one thousand dollars (\$1,000). Each day
41 of a continuing violation shall be a separate offense. Any person wishing to contest a

1 penalty shall be entitled to an administrative hearing in accordance with Chapter 150B
2 of the General Statutes."

3 **SECTION 2.** G.S. 130A-29(c) is amended by adding the following
4 subdivision to read:

5 "(10) Pertaining to the biological agents registry in accordance with G.S.
6 130A-149."

7 **SECTION 3.** This act becomes effective January 1, 2002.