1999 SENATE HUMAN SERVICES

SB 2166

1999 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB2166

Senate Human Services Committee

❑ Conference Committee

Hearing Date JANUARY 18, 1999

Tape Number	Side A	Side B	Meter #
1	X		645 - 6211
		X	1 - 272
2/3/99 2		X	550
Committee Clerk Signature	Carol Kolodejchuk		

Minutes:

The Human Services Committee was called back to order by SENATOR THANE at 10:15 A.M. with all senators present except SENATOR FISCHER, who was absent. The hearing on SB 2166 was opened.

SENATOR DeMERS testified on behalf of SB2166 as the bill's prime sponsor. Testimony is attached.

SENATOR KILZER testified on behalf of SB2166 as one of the bill's co-sponsors. He stated that occasionally we run into the need for information that is not available under the current law, and that is the reason for the bill. There are some things that health providers simply need to know about and to have access to.

SENATOR LEE testified on behalf of SB2166 as one of the bill's co-sponsors. She stated that she is pleased that something is being done in this area of interest. Hope that something will be able to be worked out to everyone's protection.

MICHAEL J. MULLEN is the Senior Advisor for Health Care Policy , State Department of Health and he presented the Department's testimony in favor of SB2166. His testimony is attached.

SENATOR DeMERS asked if this would not apply to the registries also?

MIKE MULLEN answered yes, that we have a Cancer Registry, Trauma Registry. This protection would apply to any health care records that are submitted to the department under one of the registries maintained by the department.

SENATOR THANE asked if you believe circumstances are currently enough defined that law enforcement people would not be able to come up with something that is outside and be asking for information? Are there no gray areas where they might be asking for information that leaves a question in the minds of anybody? Do you think that is well taken care of?

MIKE MULLEN answered this section gives the public health authority the discretion to disclose the information. The law enforcement authorities can't really come in and say, Tell us everything about people with contagious diseases. This section has a number of procedural limitations on the use of this information after it is given to the law enforcement authorities. They can only use it to investigate the matter, or matters directly related to what it is used for and they have to keep it confidential, and only use it to the limit and the extent they need to pursue their investigation.

SENATOR DeMERS asked if on Page 2 of the bill, if the last part of line 12, line 13, line 14 and line 15 if they are a duplication that needs to be eliminated? It appears that it is saying the same thing twice, but maybe there was a reason for it.

MIKE MULLEN answered that it appears that it may be a duplication. Let us look at that again and we will correct the language. Maybe we made a mistake.

SENATOR DeMERS asked if on Page 2 where you are defining state as number 9, should we not include the 50 states in there too?

MIKE MULLEN answered that he will inquire of the legislative council on the proper style for that.

SENATOR DeMERS asked if on Page 5, line 27 of the bill, I don't understand the meaning of the word "redact"

MIKE MULLEN answered that redact is a legal term that is used in connection with litigation. Redact means that you take a document and you leave the page the way it looks. Redact means that you have removed certain names from a document.

CAL ROLFSON testified on behalf of The Pharmaceutical Research and Manufacturers of America (PHRMA) regarding SB2166. His testimony is attached.

CAL ROLFSON distributed a proposed amendment to SB2166 that identifies the changes that PHRMA suggests be made to SB2166. A copy of the proposed amendment is attached to MR. ROLFSON'S testimony.

BRUCE LEVI testified on behalf of the North Dakota Medical Association. The Medical Association has a minor concern with the bill and MR. LEVI is offering a proposed amendment to SB2166. A copy of the proposed amendment is attached.

SENATOR LEE asked if this means that if someone decided that they did not want to disclose that someone had a communicable disease, they would not have to and there would not be a penalty.

BRUCE LEVI answered that essentially it is a test regarding whether or not a disclosure will be made. There is a person, physician, or health care provider or other entity has to make a determination of whether there is a threat to the public health. Whether there would be a prevention or significant reduction in the possibility of the public being harmed. What we are looking for is just some protection that the decision has to be made and if the discretion in the eyes of the physician or other health care provider is that what we do not meet the standard and something happens where someone may come back and sue the health care provider for not disclosing when it was sort of a discretionary call at the time there is some protection for that.

SENATOR LEE said that it would strike her as being that we would want to err on the side of disclosing, so that the health department would be making the decision about whether or not it goes forward.

BRUCE LEVI answered I think it is just boils down to the comfort level of everybody involved providing the immunity regardless of the decision. There may be a difference of opinion as to whether or not it meets this particular standard. The health care provider may feel that it does not meet the standard and does not disclose, and someone later second guessing this decision.

SENATOR DeMERS asked some of the same questions only from a little different angle. There are several laws that require physicians to disclose and they must disclose a number of communicable diseases, they must disclose child diseases. By putting this in the law, are we not

telling them that they do not have to, that we are creating a conflict regarding those mandatory statutes elsewhere?

BRUCE LEVI answered that he understands that kind of concern. I think it is just in these kinds of statutes, where we do provide discretion for the health care provider that obviously we recognize that there are those differences of opinion. By providing the immunity both ways you provide the comfort for physicians or health care providers to make these decisions and knowing that they will not be second guessed one way or another.

SENATOR DeMERS asked are we not broadening the whole purpose of the bill fairly significantly for this one group?

BRUCE LEVI answered by making it a discretionary reporting requirement that it does raise issues with respect to liability. If a health care provider decides not to disclose based on its own good faith belief that a disclosure is not necessary, and in fact something bad happens and someone looks back at the statute and says that they had discretion, they could have disclosed, and decided not to. That was wrong and that person should be liable.

MIKE MULLEN commented with respect to the amendment of CAL ROLFSON and the NORTH DAKOTA MEDICAL ASSOCIATION. The state health department would be happy to look them over and consults with those people appearing as witnesses and see if we can come to some understanding and resolution with respect to them. With respect to the amendment MR. ROLFSON offered, I would like to point out that there is a section in existing law that uses language that is similar to what is contained in the bill. This relates to the confidentiality of medical records maintained by the health care data committee. Section 23-01.1-05 provides that the committee shall keep all records data and information that could be used to identify

individual patients confidential. MIKE MULLEN also requested that the committee delay action on this bill. A health department person will be going to Atlanta next week to a conference concerning health care data and a week from next Wednesday, January 27, to a special 1 day program on the confidentiality of medical records. The General Council of the Federal Medicare Agency is going to be there, and this conference is going to deal with the legal issues regarding the confidentiality information and also computer records, of the type MR. ROLFSON addressed. I would respectfully request that the committee might consider delaying action on this bill until we receive updated information from the national level on how to treat confidential data.

CAL ROLFSON indicated that they would be happy to work with the health department on this issue.

SENATOR THANE indicated that the committee should look at the proposed amendments. If they are to controversial, we have one committee member missing today, and it would not be fair to him or to us, to take action on this bill without him being here.

The hearing was closed on SB2166.

Discussion was resumed on 2/3/99. MIKE MULLEN explained new amendment. SENATOR DEMERS asked if all reported diseases were covered. Yes. SENATOR LEE moved amendment. SENATOR DEMERS seconded it. No more discussion. Roll call vote carried 5-0-1. Discussion of the amended bill was held. 23-02.1 - 28, subsection 3 allows the Health Department to provide data to organizations with confidentiality agreements. SENATOR LEE moved DO PASS AS AMENDED. SENATOR KILZER seconded. Roll call vote carried 5-0-1. SENATOR DEMERS will carry the bill.

Date: 2/3/99
Roll Call Vote #: 1

1999 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2166

Senate HUMAN SERVICES COMMITTEE Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken Amendment

Motion Made By Sen Lee Seconded By Sen DeMers

Senators	Yes	No	Senators	Yes	No
Senator Thane	✓				
Senator Kilzer	✓				
Senator Fischer					
Senator Lee	✓				
Senator DeMers	✓				
Senator Mutzenberger	✓				

Total 5 (yes) 0 (no)

Absent 1

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 2/3/99
Roll Call Vote #: 2

1999 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2166

Senate HUMAN SERVICES COMMITTEE Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass as amended

Motion Made By Sen Lee Seconded By Sen Kilzer

Senators	Yes	No	Senators	Yes	No
Senator Thane	✓				
Senator Kilzer	✓				
Senator Fischer					
Senator Lee	✓				
Senator DeMers	✓				
Senator Mutzenberger	✓				

Total 5 (yes) 0 (no)

Absent 1

Floor Assignment Sen DeMers

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2166: Human Services Committee (Sen. Thane, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (5 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). SB 2166 was placed on the Sixth order on the calendar.

Page 3, after line 31, insert:

"3. Except for the failure to report information required by chapters 23-07, 23-07.1, 23-07.3, or 23-07.4, or any other law requiring disclosure of information regarding a disease or condition, an entity described in subsection 1 is not liable for the failure to disclose protected health information to a public health authority."

Page 4, line 1, replace "3" with "4"

Page 4, line 4, replace "4" with "5"

Page 4, line 6, replace "5" with "6"

Page 4, line 9, replace "6" with "7"

Renumber accordingly

1999 HOUSE HUMAN SERVICES

SB 2166

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2166

House Human Services Committee

❑ Conference Committee

Hearing Date March 1, 1999

Tape Number	Side A	Side B	Meter #
1	x		13.1 - end
Committee Clerk Signature Wayne G. Hamilton			

Minutes:

Senator JUDY L. DEMERS, District 18 testified. (Testimony Attached)

MICHAEL J. MULLEN, Senior Advisor for Health Care Policy, State Department of Health testified. (Testimony Attached).

CALVIN ROLFSON, Attorney representing the Pharmaceutical Research and Manufacturers of American testified. (Testimony attached.)

Rep. CLARA SUE PRICE asked why the amendments had not been proposed in the senate.

CALVIN ROLFSON replied that the consortium making up the association didn't have time to complete their preparation at that time. Often federal law pre-empts each state. In this case it didn't so each state has to be looked at to insure there are no impediments to research being conducted.

Rep. ROBIN WEISZ asked if there are any problems under current laws. CALVIN ROLFSON replied there are current protections in other chapters that allows research access. The problem is without protections in this chapter a conflict could arise in the future.

Rep. CAROL NIEMEIER asked if there was currently an institutional review board that was referenced in the chapter. CALVIN ROLFSON replied that he was not aware of any in North Dakota although there are many around the United States.

OPPOSITION

Close hearing on SB 2166.

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB2166

House Human Services Committee

❑ Conference Committee

Hearing Date March 16, 1999

Tape Number	Side A	Side B	Meter #
1	x		0.0-6.8
Committee Clerk Signature			

Minutes:

COMMITTEE DISCUSSION

After reviewing amendments proposed by Cal Rolfson, Rep. TODD PORTER moved the amendments. Rep. RALPH METCALF seconded. Motion PASSED on voice vote: 14 YES, 0 NO, 1 ABSENT.

Rep. ROXANNE JENSEN move DO PASS AS AMENDED. Rep. WANDA ROSE seconded. Motion PASSED on roll call vote #1: 14 YES, 0 NO, 1 ABSENT.

CARRIER: Rep. WANDA ROSE.

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2166

Page 1, after line 14, insert:

"3. "Institutional review board" means any board, committee, or other group formally designated by an institution or public health authority or authorized under federal or state law to review, approve the initiation of, or conduct a periodic review of research programs to assure the protection of the rights and welfare of human research subjects."

Page 3, line 7, after the period insert:

"Nothing in this chapter shall prohibit a public health authority from disclosing information that has been anonymized to protect the identity of the patient through coding or encryption. Nothing in this chapter shall prohibit a public health authority from disclosing confidential information pursuant to guidelines approved by an institutional review board or to researchers operating pursuant to the federal common rule at 21 CFR 50 and 56 and 45 CFR 46."

↑ (CODE OF FED. REGULATIONS)

Renumber accordingly

Adopted by the Human Services Committee
March 16, 1999

VR 3/16/99

HOUSE AMENDMENTS TO ENGROSSED SENATE BILL NO. 2166 **HUMSER 3/16/99**

Page 1, after line 14, insert:

"3. "Institutional review board" means any board, committee, or other group formally designated by an institution or public health authority or authorized under federal or state law to review, approve the initiation of, or conduct a periodic review of research programs to assure the protection of the rights and welfare of human research subjects."

Page 1, line 15, replace "3" with "4"

Page 1, line 18, replace "4" with "5"

Page 1, line 23, replace "5" with "6"

HOUSE AMENDMENTS TO ENGROSSED SENATE BILL NO.2166 HUMSER 3/16/99

Page 2, line 3, replace "6" with "7"

Page 2, line 19, replace "7" with "8"

Page 2, line 26, replace "8" with "9"

Page 2, line 30, replace "9" with "10"

HOUSE AMENDMENTS TO ENGROSSED SENATE BILL NO.2166 HUMSER 3/16/99

Page 3, line 1, replace "10" with "11"

Page 3, line 7, after the period insert "Subject to section 23-01-15, subsection 1 of section 23-07-02.2, and any other requirements of this title, this chapter does not prohibit a public health authority from disclosing protected health information for use in a biomedical research project approved by an institutional review board or public health information that has been transformed to protect the identity of the patient through coding or encryption if the information is disclosed for use in an epidemiological or statistical study."

Renumber accordingly

Date: 3/16/99
Roll Call Vote #: 1

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB2166

House Human Services Committee

☐ Subcommittee on _____

or

☐ Conference Committee

Legislative Council Amendment Number #

Action Taken Do Pass As Amended

Motion Made By Rep Jensen Seconded By Rep Rose

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price - Chairwoman	✓		Bruce A. Eckre	✓	
Robin Weisz - Vice Chairman	✓		Ralph Metcalf	✓	
William R. Devlin	✓		Carol A. Niemeier	✓	
Pat Galvin	✓		Wanda Rose	✓	
Dale L. Henegar	✓		Sally M. Sandvig	✓	
Roxanne Jensen	✓				
Amy N. Kliniske					
Chet Pollert	✓				
Todd Porter	✓				
Blair Thoreson	✓				

Total **Yes** 14 No 0

Absent 1

Floor Assignment Rep Rose

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2166, as engrossed: Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (14 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). Engrossed SB 2166 was placed on the Sixth order on the calendar.

Page 1, after line 14, insert:

"3. "Institutional review board" means any board, committee, or other group formally designated by an institution or public health authority or authorized under federal or state law to review, approve the initiation of, or conduct a periodic review of research programs to assure the protection of the rights and welfare of human research subjects."

Page 1, line 15, replace "3" with "4"

Page 1, line 18, replace "4" with "5"

Page 1, line 23, replace "5" with "6"

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Page 2, line 26, replace "8" with "9"

Page 2, line 30, replace "9" with "10"

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Page 3, line 7, after the period insert "Subject to section 23-01-15, subsection 1 of section 23-07-02.2, and any other requirements of this title, this chapter does not prohibit a public health authority from disclosing protected health information for use in a biomedical research project approved by an institutional review board or public health information that has been transformed to protect the identity of the patient through coding or encryption if the information is disclosed for use in an epidemiological or statistical study."

Renumber accordingly

1999 TESTIMONY

SB 2166

TESTIMONY FOR SB 2166

Prepared by Senator Judy L. DeMers

Monday, January 18,1999

Mr. Chairman, members of the Senate Human Services Committee. For the record, my name is Judy L. DeMers. I am a State Senator, representing District 18 which consists of part of Grand Forks and part of Grand Forks Air Force Base. I appear this morning in support of SB 2166 and as the bill's prime sponsor.

SB 2166 was submitted at the request of the State Department of Health. It is an ambitious and important undertaking, dealing with confidential or protected health information in the possession of a public health authority. SB 2166 is an effort to codify the appropriate process for safeguarding the privacy of this information and defining, as specifically as possible, the conditions under which it can be disclosed.

I do not claim to be an expert in this area of the law, so I plan to defer the specific explanation to the State Department of Health. I know I had questions when I read through SB 2166 again in preparation for this hearing, and I assume you do too. I believe that by working together we can craft a piece of the legislation that appropriately balances the privacy rights of the individual, and the public health needs of our citizens.

Thank you.

Senator Judy L DeMers

TESTIMONY BY

CALVIN N. ROLFSON

ON BEHALF OF

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

REGARDING

SENATE BILL NO. 2166

MY NAME IS CAL ROLFSON. I AM AN ATTORNEY HERE IN BISMARCK AND I REPRESENT THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA. I APPEAR HERE IN SUPPORT OF SENATE BILL 2166, BUT I RECOMMEND AN AMENDMENT.

THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IS A CONSORTIUM OF ALL MAJOR PHARMACEUTICAL AND HEALTH RESEARCH COMPANIES IN THE UNITED STATES. PHRMA SUPPORTS CONFIDENTIALITY OF MEDICAL INFORMATION THAT IDENTIFIES PATIENTS, AS LONG AS THESE EFFORTS PRESERVE LEGITIMATE ACCESS TO AND USE OF SUCH DATA FOR RESEARCH IN THE CONTINUING DISCOVERY AND DEVELOPMENT OF MEDICINES.

INNOVATIONS IN MEDICINE AND BIOMEDICAL RESEARCH ARE REVOLUTIONIZING THE FUTURE OF HEALTH CARE. THIS RESEARCH REQUIRES INFORMATION FROM CLINICAL RESEARCH AND INFORMATION REGARDING THE SAFETY AND EFFICACY OF TREATMENTS IN THE REAL-LIFE CONDITIONS UNDER WHICH PEOPLE RECEIVE HEALTH CARE. ACCURATE AND COMPLETE RECORDS OF A PATIENT'S HEALTH AND HEATH CARE HISTORY ARE ALSO ESSENTIAL TO

ENSURE THE PROMPT AVAILABILITY AND OPTIMAL PROVISION OF HEALTH CARE FOR THE INDIVIDUAL PATIENT. OVERLY RESTRICTIVE LIMITATIONS ON ACCESS TO AND USE OF MEDICAL INFORMATION BY HEALTH CARE RESEARCHERS, PROVIDERS AND PAYERS COULD IMPEDE THE QUALITY OF HEALTH CARE AVAILABLE TO PATIENTS AND THE EFFECTIVENESS, INCLUDING COST EFFECTIVENESS, OF THE HEALTH CARE SYSTEM.

BIOMEDICAL RESEARCHERS SHOULD HAVE UNRESTRICTED ACCESS TO MEDICAL INFORMATION THAT DOES NOT IDENTIFY PATIENTS. RESEARCHERS SHOULD BE ALLOWED THE USE OF MEDICAL INFORMATION THAT HAS BEEN ANONYMIZED BY CODING OR ENCRYPTING SO THAT IT NO LONGER DIRECTLY IDENTIFIES THE PATIENT. ARCHIVES OF MEDICAL RECORDS AND BIOLOGICAL MATERIALS ARE AN INVALUABLE RESOURCE AND RESEARCHERS' ACCESS TO THIS DATA SHOULD NOT BE CONSTRAINED.

PHARMA FIRMLY BELIEVES THAT MEDICAL INFORMATION THAT IDENTIFIES PATIENTS SHOULD BE KEPT CONFIDENTIAL.

ATTACHED TO MY TESTIMONY ARE A SERIES OF ARTICLES YOU WILL FIND INTERESTING THAT IDENTIFY THE EXPONENTIAL GROWTH IN HEALTH ENHANCING AND LIFE-SAVING DRUGS THAT HAVE RECENTLY BEEN APPROVED OR ARE IN THE PROCESS OF RESEARCH AND DEVELOPMENT. FOR EXAMPLE, PHARMACEUTICAL COMPANIES REPORT A RECORD 187 DRUGS AND VACCINES IN DEVELOPMENT FOR CHILDREN, INCLUDING 44 FOR CANCER, THE LEADING DISEASE KILLER OF CHILDREN. THERE ARE CURRENTLY 350 BIO-TECHNOLOGY

PRODUCTS NOW IN DEVELOPMENT, UP SIGNIFICANTLY FROM 284 IN 1996. DRUG COMPANIES HAVE INVESTED ABOUT 20 BILLION DOLLARS ON RESEARCH AND DEVELOPMENT AS THEY CONTINUE TO WORK ON UP TO 1,000 NEW MEDICINES, INCLUDING 96 NEW DRUGS FOR HEART DISEASE AND STROKE, 316 ANTI-CANCER MEDICINES AND 146 DRUGS AND VACCINES FOR CHILDREN. DRUG RESEARCHERS ARE ALSO FOCUSING ON DISEASES OF WOMEN WITH MORE THAN 370 DRUGS CURRENTLY IN DEVELOPMENT, INCLUDING 27 NEW MEDICINES FOR OSTEOPOROSIS, 18 FOR DIABETES, 18 FOR ALZHEIMER'S DISEASE AND 55 FOR ALL TYPES OF ARTHRITIS. ALL OF THIS EXPONENTIAL GROWTH IN HEALTH-ENHANCING AND LIFE-SAVING DRUG DEVELOPMENT CAN ONLY OCCUR IF SCIENTISTS AND RESEARCHERS ARE ABLE TO ACCESS AND USE INDIVIDUALIZED HEALTH DATA FOR CONTINUING DISCOVERY AND DEVELOPMENT OF MEDICINES.

SENATE BILL 2166 APPEARS APPROPRIATE. HOWEVER, PHRMA HAS A CONCERN ABOUT THE DEFINITION OF "NON-IDENTIFIABLE HEALTH INFORMATION" FOUND ON PAGE 1 OF THE BILL.

THE FIRST PORTION OF THAT DEFINITION SEEMS FINE. HOWEVER, TO ADD THE SECOND PRONG OF THIS DEFINITION FOUND AT THE END OF LINE 20 ON PAGE 1 TO THE END OF THAT DEFINITION APPEARS TO BE UNNECESSARILY RESTRICTIVE AND MAY IMPEDE THE ABILITY OF THOSE WHO MANAGE AND CONTROL PROTECTED HEALTH INFORMATION FROM FURNISHING NON-IDENTIFIABLE HEALTH INFORMATION TO PHARMACEUTICAL SCIENTISTS AND RESEARCHERS.

IF THIS COMMITTEE WOULD CONSIDER DELETING THAT PORTION FROM THE DEFINITION, I BELIEVE THE DEFINITION OF "NON-IDENTIFIABLE HEALTH INFORMATION" WOULD BE ACCEPTABLE.

IN MY READING OF SENATE BILL 2166, I ONLY SEE ONE LOCATION WHERE "NON-IDENTIFIABLE HEALTH INFORMATION" IS FOUND, AND THAT IS ON PAGE 5 AT LINE 11. WHILE THE LOCATION OF NON-IDENTIFIABLE HEALTH INFORMATION" AT THAT LOCATION DOES NOT GENERALLY POSE A PROBLEM FOR DRUG RESEARCHERS AND SCIENTISTS, SINCE THAT SECTION WHERE IT IS FOUND ONLY DEALS WITH ACCESS OF PROTECTED HEALTH INFORMATION TO LAW ENFORCEMENT, NEVERTHELESS, THE DEFINITION IS STILL UNNECESSARILY BROAD AND IF USED ELSEWHERE, MAY TEND TO RESTRICT DRUG RESEARCHERS AND SCIENTISTS IN THEIR WORK.

THE DEFINITION OF "NON-IDENTIFIABLE HEALTH INFORMATION" SPECIFICALLY INCLUDES THE PROTECTION OF CONFIDENTIALITY OF THE INDIVIDUAL HEALTH INFORMATION. TO ALSO ADD THE REQUIREMENT THAT THERE BE "NO REASONABLE BASIS TO BELIEVE THAT THE INFORMATION COULD BE USED" TO IDENTIFY THAT INDIVIDUAL, I BELIEVE WILL UNNECESSARILY CREATE SUCH CONCERN BY THOSE HOLDING THE INFORMATION THAT NO ONE WILL DARE RISK PROVIDING "NON-IDENTIFIABLE HEALTH INFORMATION" TO RESEARCHERS.

BY THE USE OF THE WORDS "COULD BE" YOU ARE ASKING THE HOLDERS OF THAT INFORMATION TO SPECULATE ABOUT THE FUTURE TO SUCH AN

UNREASONABLE DEGREE THAT NO HOLDER OF THAT INFORMATION WOULD LIKELY DARE TO DIVULGE IT EVEN IF ALL POSSIBLE PERSONAL IDENTITIES ARE CONFIDENTIAL. IF THE MEDICAL RECORD DOES NOT REVEAL THE IDENTITY OF THE INDIVIDUAL, THAT SHOULD BE SUFFICIENT AND THERE SHOULD BE NO REASON TO ADD THE REQUIREMENT THAT THE RECORD-HOLDER MUST SPECULATE WHETHER SUCH INFORMATION COULD, IN THE FUTURE, BE USED TO IDENTIFY THE INDIVIDUAL.

I URGE THE AMENDMENT TO SENATE BILL 2166 THAT IS ATTACHED TO MY TESTIMONY AND THAT REMOVES THE SECOND PORTION OF THE DEFINITION OF "NON-IDENTIFIABLE HEALTH INFORMATION." THANK YOU FOR THE OPPORTUNITY TO APPEAR BEFORE YOU.

PROPOSED AMENDMENTS TO SENATE BILL NO. 2166

Cal Rolfson

Page 1, line 20, remove "and there is"

Page 1, remove line 21

Page 1, line 22, remove "individual"

RENUMBER ACCORDINGLY

Statement

PhRMA

September 17, 1998

PRINCIPLES FOR MAINTAINING CONFIDENTIALITY OF MEDICAL INFORMATION THAT IDENTIFIES PATIENTS

Recent developments in science and technology have given rise to public concern over the confidentiality of medical information that identifies patients. PhRMA shares this concern and supports efforts to ensure the confidentiality of such medical information as long as these efforts preserve legitimate access to and uses of such data for research in the continuing discovery and development of medicines.

Innovations in medicine and biomedical research, including genomic technology, are revolutionizing the future of health care as they begin to reveal the molecular basis of human illnesses and individuals' different responses to medicines. Biomedical research requires information from clinical research and information regarding the safety and efficacy of treatments in the real-life conditions under which people receive health care. Accurate and complete records of a patient's health and health care history also are essential to ensure the prompt availability and optimal provision of health care for the individual patient. Moreover, information from disease management programs and outcomes research is increasingly important to assure high quality, cost-effective health care. Overly restrictive limitations on access to and use of medical information by health care researchers, providers and payers could impede the quality of health care available to patients and the effectiveness (including cost effectiveness) of the health care system.

Accordingly, PhRMA proposes the principles below to safeguard medical information that identifies patients, while preserving access to information critical to the discovery, development and improvement of medicines and the delivery of health care.

1. **Protect and Promote Research and Development.** Confidentiality laws must not hinder research that improves the public health. Any new laws applicable to the confidentiality of medical information that identifies patients should acknowledge both the importance of research and development and the extent of existing laws and regulations that govern clinical and other biomedical research, including safety and efficacy surveillance and reporting. New laws should not impose additional requirements on such research, surveillance, or reporting. Both voluntary and mandatory safety and efficacy surveillance and reporting contribute to continued safe and effective use of medicines and must be preserved without additional burdensome restrictions.

Existing federal laws and regulations already provide assurance that the confidentiality interests of patients participating in biomedical research are well-served through oversight by the U.S. Food and Drug Administration and independent Institutional Review Boards (IRBs).

2. **Permit Biomedical Researchers' Unrestricted Access to Medical Information That Does Not Identify Patients.** Researchers should be allowed to use medical information that has been anonymized by coding or encrypting so that it no longer directly identifies the patient. Epidemiological and outcomes research that helps us to better understand the incidence and progress of disease, and the quality and cost-effectiveness of various health care interventions, depends on researchers' access to medical information generated in ordinary health care interactions (rather than prospective clinical research data). Archives of medical records and biological materials are an invaluable resource, and researchers' access to these data and samples should not be constrained. With respect to these data and archives, patients' confidentiality can be maintained by using coding and encryption techniques that prevent disclosure of any patient's identity. To provide accurate and complete data useful for longer-term research, the information must include some mechanism for tracking each patient over time and in various health care settings – but the mechanism need not reveal the identity of any patient to the individual researcher. Any keys that unlock encryption systems and codes used to protect patients' identities should be securely maintained to prevent their use by an unauthorized individual.

3. **Protect Medical Information That Identifies Patients.** Medical information that identifies patients should be kept confidential. Medical information includes information that describes a patient's medical conditions, treatments, family medical histories, and any results of genetic or other laboratory tests. Medical information disclosed by the patient to a health care professional, hospital, or health plan is part of an interaction in which there is a strong expectation of confidentiality; accordingly, it should be considered sensitive and held in confidence.

4. **Ensure Reasonable Informed Consent Requirements.** Informed consent requirements for access to and use of medical information that identifies patients should be reasonable, and recognize the value of, and ensure opportunities for, epidemiological, medical outcomes, and pharmacoeconomic research that rely on historical, patient-level databases, as well as recognize the importance of breakthrough research that uses collections of biological materials. Reasonable exceptions or alternatives to the typical informed consent process should be permitted in certain circumstances, for example, where there is a question of public health or safety, where such information is used for safety surveillance and reporting, where the patient is incompetent or incapacitated, where the patient's life is at imminent risk, or to comply with existing laws and regulations.

5. **Protect and Promote Health Care Quality**. Any new legislation or regulation must protect the availability of information needed to ensure the delivery of high-quality, cost-effective health care without imposing undue administrative burdens. Health plans, integrated delivery systems, health care professionals and providers depend on accurate data to ensure that appropriate and effective treatment is rendered to patients. To appropriately manage the complex array of sophisticated treatments and diagnostics, health care professionals increasingly rely on disease management and outcomes research to support development of patient-care pathways and treatment protocols.

6. **Treat Information Disclosed by Consumers Outside of a Patient-Provider Relationship as Consumer Information**. Consumer-provided health-related information, including consumers' requests for information about health issues or health care products outside of the patient-provider relationship, should be treated the same as other voluntarily provided personal information, such as financial information. Consumers voluntarily provide information about themselves in a variety of settings other than settings in which they seek or receive health care. Health information voluntarily disclosed outside of a protected patient-provider relationship should be considered consumer information, not medical information.

7. **Provide Uniform, National Protection for All Medical Information.** The same confidentiality standards for all types of medical information should apply nationwide. Legislative distinctions among types of medical information – genetic, psychological, or physical – would conflict with the patient's expectation that all health care information shared with a provider to obtain appropriate treatment should be maintained in confidence. Further, to ensure that individuals' expectations of confidentiality of medical information are valid in every jurisdiction, Federal law should provide a uniform set of national requirements that would preempt state laws. Otherwise, the patchwork of inconsistent and potentially conflicting requirements would create ambiguity about patients' rights and impede biomedical research conducted in multiple states. Uniformity would also facilitate compliance with confidentiality safeguards.

8. **Support the Enactment of Strong Penalties**. When medical information has been coded or encrypted to prevent disclosure of the identities of patients, anyone who, by unauthorized manipulation of the data or by unauthorized use of a key or encryption device, uses the coded or encrypted data to identify individuals, should be subject to strong penalties. Comparable penalties should apply to anyone who gains unauthorized access to medical information that directly identifies patients or who permits unauthorized disclosure of such information.

PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES
MARCH 1998

CONTACT: JEFF TREWHITT
202/835-3464

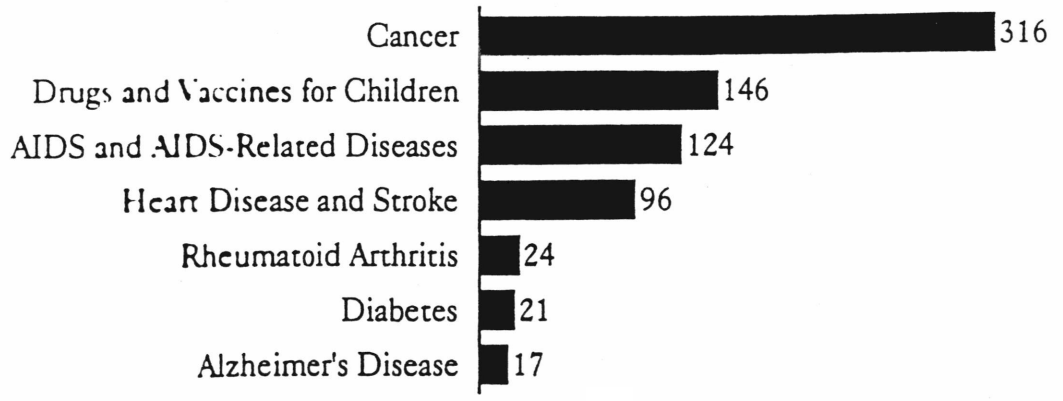
DRUG COMPANIES TO INVEST $20 BILLION ON R&D AS THEY CONTINUE WORK ON 1,000 NEW MEDICINES

Right now, U.S. pharmaceutical research companies have more than 1,000 new medicines in development, including:

- 96 new drugs for heart disease and stroke
- 316 anti-cancer medicines
- 124 drugs to treat AIDS
- 146 drugs and vaccines for children
- 17 new treatments for Alzheimer's disease
- 24 drugs for rheumatoid arthritis, and
- 21 new medicines for diabetes.

PhRMA member companies anticipate investing more than $20 billion on research and development in 1998.

NEW MEDICINES IN DEVELOPMENT FOR SELECTED DISEASES



Source: PhRMA Annual Surveys, 1997–1998

PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES
JANUARY 1998

CONTACT: JEFF TREWHITT
202/835-3464

PHARMACEUTICAL COMPANIES UP RESEARCH SPENDING TO $20.6 BILLION

R&D investment by research-based pharmaceutical firms continues to break records. In 1998, pharmaceutical companies expect to invest $20.6 billion to discover and develop new medicines. That figure represents a 10.7 percent increase over last year's record-setting R&D spending of $18.6 billion.

R&D spending by research-based pharmaceutical companies has more than five-fold since 1985, when it was $4.1 billion.

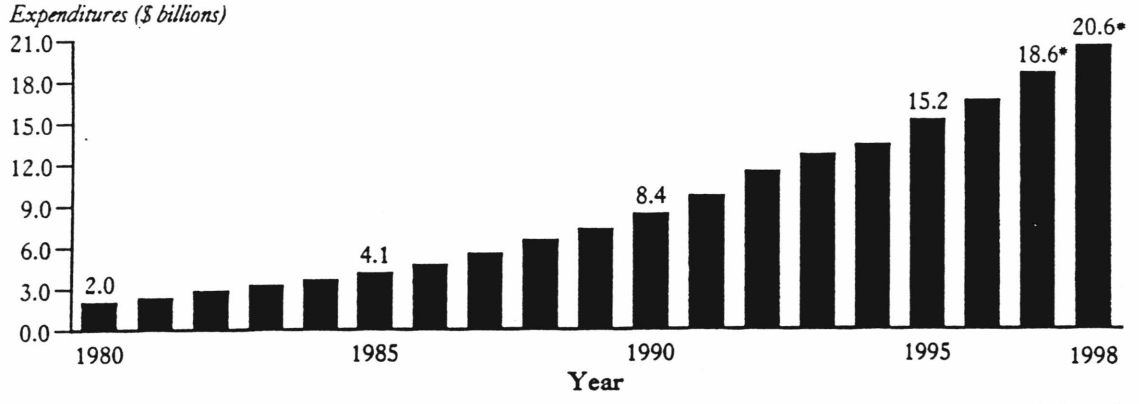
Industry sales have more than quadrupled since 1985, when they were $31.6 billion. Projected sales for 1998 are $124.6 billion.

Pharmaceutical research companies pour back about one dollar in every five dollars of domestic sales into R&D. In 1998, companies will spend 19.6 percent of domestic revenues to discover and develop new medicines.

Over the past twenty-one years, the share of pharmaceutical company revenues devoted to R&D has increased from 10.9 percent in 1978 to an estimated 19.6 percent in 1998.

The pharmaceutical industry's ratio of R&D to sales dwarfs that of other major industry sectors. The electronics industry, for example, invests only 6.4 percent of sales revenues in R&D, while the aerospace and defense industry invests 3.9 percent.

R&D INVESTMENTS BY RESEARCH-BASED PHARMACEUTICAL COMPANIES



Source: PhRMA Annual Survey, 1998

**Estimated*

PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL COMPANIES April 1998

Biotechnology: The Map of our Future

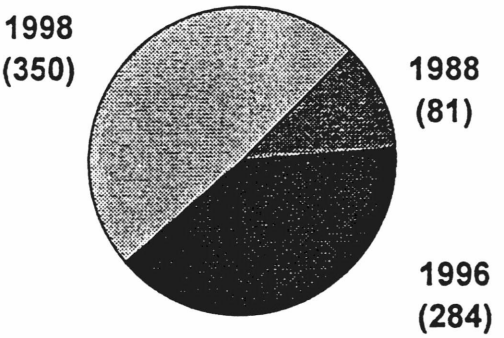
Now more than ever, society is reaping the benefits of biotechnology. The "biotechnology revolution" has allowed scientists to discover more targeted and more effective medicines which may eventually lead to potential cures for such debilitating diseases as AIDS, cancer, sickle cell disease, rheumatoid arthritis and many others. 350 biotechnology products now in development – up from 284 in 1996 – brings hope for potential cures one step closer.

What are the benefits of biotechnology? Ask the 60 million patients who have benefited from such advances as:

- **A medicine that breaks up the blood clots that cause heart attacks and strokes.**
- **A medicine that replaces the growth hormone in children who lack a sufficient supply.**
- **A medicine that breaks up the mucus in the lungs of cystic fibrosis patients.**
- **A medicine that interferes with the ability of certain cancer cells to overgrow and intrude on normal tissues.**

Such rapidly-expanding advances spurred by biomedical research and computer science are shaping our future to better health through better medicines.

A Decade of Progress



PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES
MAY 1998

CONTACT: JEFF TREWHITT
202/835-3464

A RECORD NUMBER OF DRUGS IN DEVELOPMENT FOR CHILDREN

Pharmaceutical companies report a record 187 drugs and vaccines in development for the nation's youngest patients.

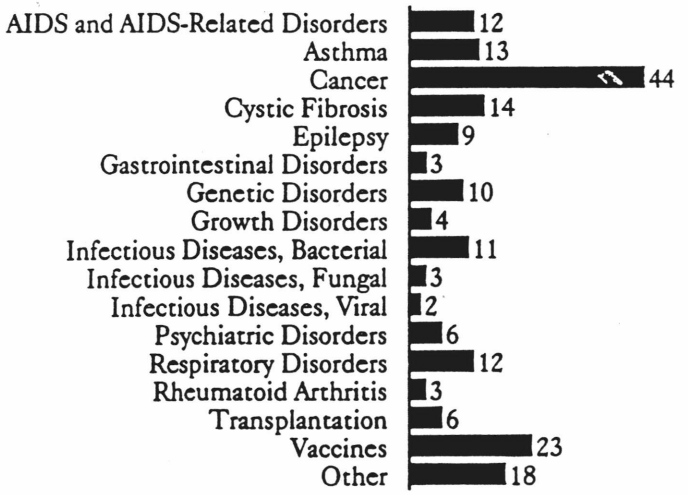
Medicines being clinically tested in children have increased 28 percent in just a year, and 20 new drugs have been approved and brought to the market in the last 12 months.

The medicines in development include:

- 44 for cancer, the leading disease killer of children;
- 14 for cystic fibrosis, the most common fatal genetic disease in the United States;
- 13 for asthma, including one to treat children as young as six months;
- 12 for AIDS, the leading cause of death among young children in some urban areas;
- 9 for epilepsy, which affects 600,000 children in the United States;
- 3 for juvenile rheumatoid arthritis, which afflicts about 50,000 children and can lead to blindness;
- a gene therapy for brain tumors, the second-leading cancer killer of children who are 15 and younger; and
- a vaccine to prevent ear infections, which cause 35 million visits to the doctor each year at a cost of about $3.5 billion.

The growing number of drugs in development shows that despite the practical, legal and ethical difficulties of testing medicines in children, pharmaceutical companies are rising to the challenge to meet the special needs of the youngest patients.

MEDICINES IN DEVELOPMENT FOR CHILDREN—BY THERAPEUTIC CATEGORY



Source: New Medicines in Development for Children, PhRMA Annual Surveys, 1998

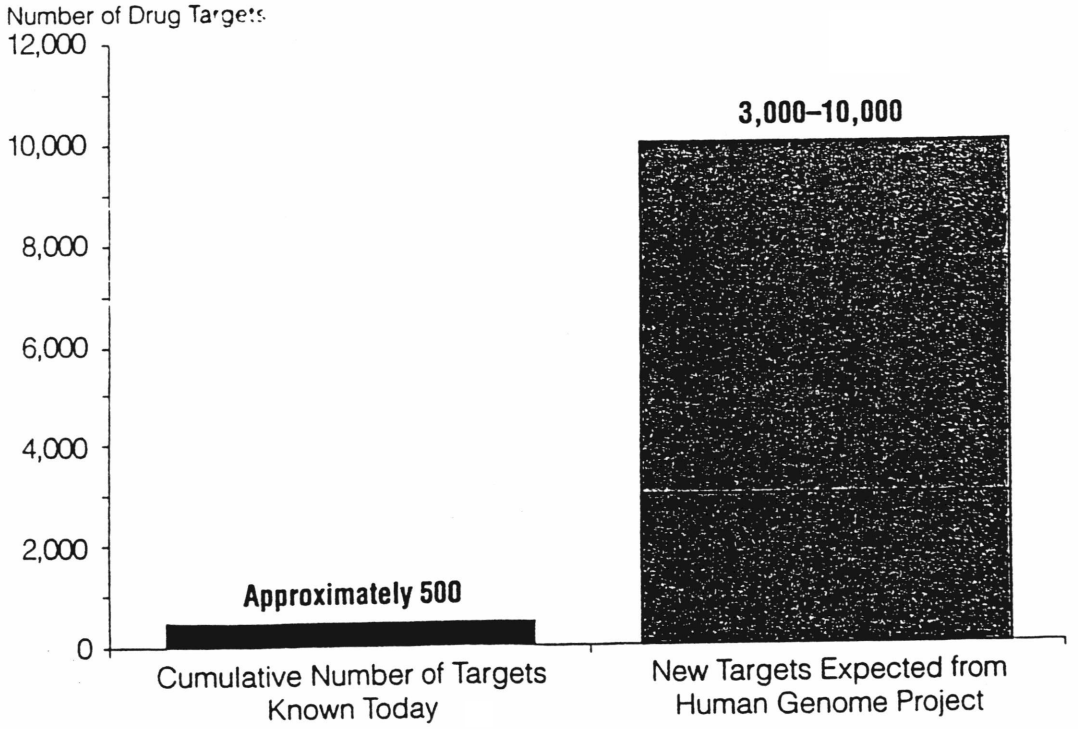
PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL COMPANIES
JULY 1998

Biomedical Research: More Targets, More Medicines

Scientific advances in biochemistry, molecular biology, cell biology, genetics and information technology are transforming the drug discovery and development process. This explosion of advances has helped pharmaceutical company researchers to target the underlying cause of disease and use this knowledge to discover new medicines. Genetic research allow researchers to make biological discoveries in days that previously would have taken years. The more genes discovered the more targets there are for developing new medicines.

HUMAN GENOME PROJECT TO SPARK EXPONENTIAL GROWTH IN NUMBER OF TARGETS FOR DRUG INNOVATION



Source: Drews, Jurgen, M.D., "Genomic Sciences and the Medicine of Tomorrow: Commentary on Drug Development," Nature Biotechnology, *Vol. 14, November 1996.*

PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL COMPANIES
JULY 1998

Pharmaceutical Companies Are Developing 85 New Medicines For Mental Disorders That Affect 51 Million Americans

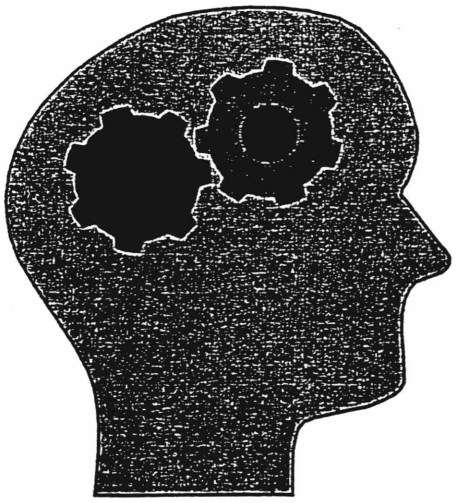
Mental health disorders cost Americans nearly $150 billion a year for treatments including, hospitalization, physician and other services. For patients and their families, the toll -- both physically and emotionally -- is even greater. But pharmaceutical advances are making a huge difference in restoring health and quality of life for patients and their caregivers. In fact, the innovations of America's pharmaceutical companies have transformed mental illness from a disease of shame and fear into a highly treatable condition. Medicines have helped boost the success rates for treatments of mental illnesses to between 60 to 80 percent.

Here's a look at new medicines in development:

16 for Anxiety Disorders

4 for Attention-Deficit Hyperactivity Disorder

23 for Dementias



2 for Post Traumatic Stress Disorder

19 for Substance Use Disorders

5 for Eating Disorders

18 for Depression

15 for Schizophrenia

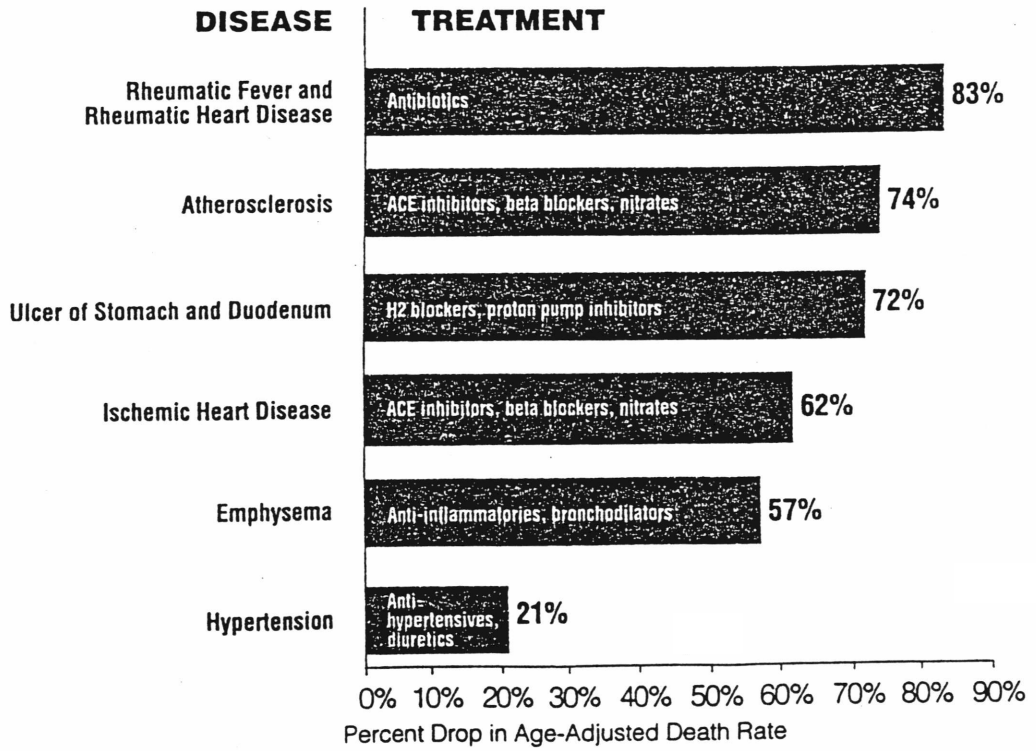
PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL COMPANIES
JULY 1998

Pharmaceutical Innovation: Leads the Way in Progress Against Disease

Breakthrough medicines and vaccines have played a central role in this century's unprecedented progress in the treatment of certain diseases. Pharmaceutical discoveries since the 1950s have helped cut death rates for chronic and acute conditions allowing patients to lead longer, healthier lives.

DROP IN DEATH RATES FOR DISEASES TREATED WITH PHARMACEUTICALS, 1965–1996

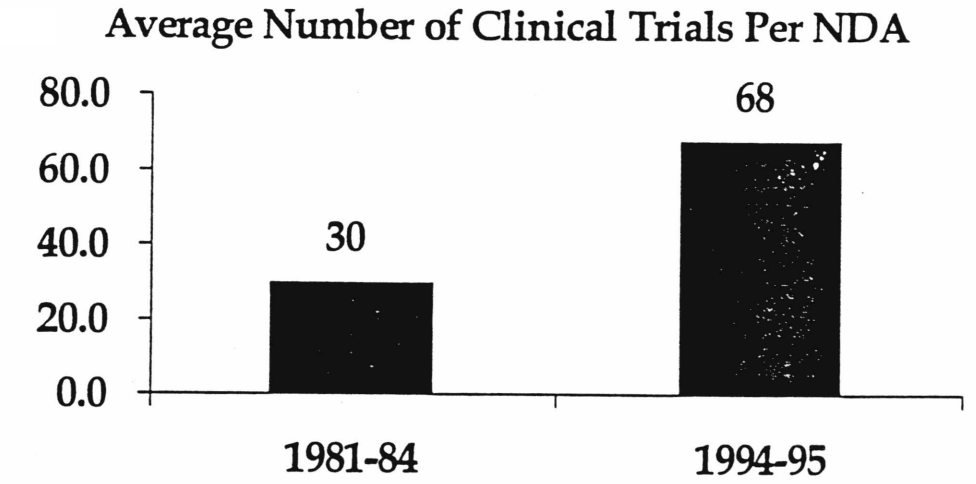


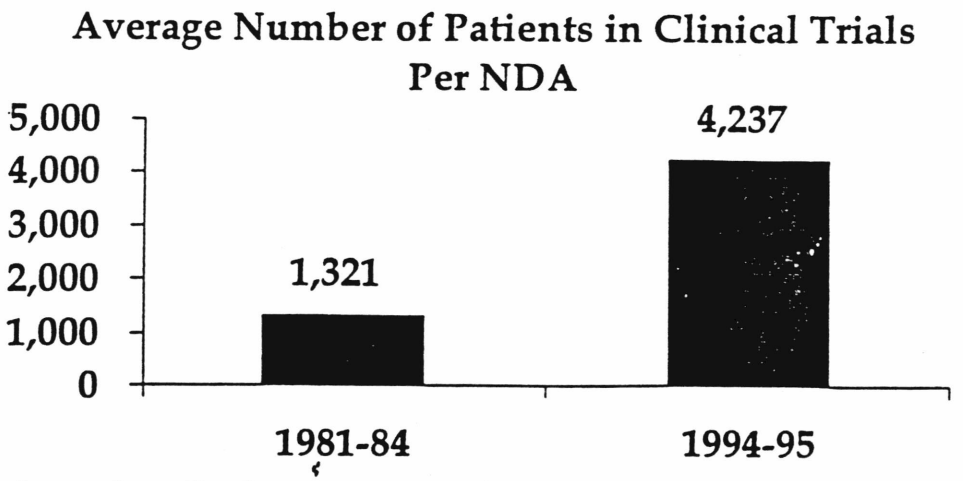
Source: PhRMA, 1998, based on Boston Consulting Group, 1993, and U.S. National Center for Health Statistics, 1998.

PhRMA FACTS
A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL COMPANIES
JULY 1998

New Medicines Undergo Extensive Safety Testing

Medicines go through one of the most rigorous testing procedures in the world. It takes 12 to 15 years to discover and develop a new medicine, during which time all medicines are tested for safety and efficacy. Safety standards have never been sacrificed. In fact, in the last decade the average number of clinical trials per new drug application has more than doubled and the number of patients participating in clinical trials per NDA has increased threefold.





Source: Boston Consulting Group, 1993; Peck, C., "Drug Development: Improving the Process," Food Drug Law Journal, Vol.52,1997
Pharmaceutical Research and Manufacturers of America

PhRMA FACTS

A MONTHLY REPORT FROM AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES
JANUARY 1998

CONTACT: HEATHER KOLASCH
202/835-3466

DRUG RESEARCHERS FOCUSING ON DISEASES OF WOMEN WITH MORE THAN 370 DRUGS IN DEVELOPMENT

Not too many years ago, women had no effective treatments for osteoporosis and little relief for many other debilitating diseases that primarily afflict women.

In an effort to give women of all ages more options and better medicines, pharmaceutical companies today are developing:

- 27 new medicines for osteoporosis,
- 18 for diabetes,
- 18 for Alzheimer's disease and
- 55 for all types of arthritis, which afflicts more than 23 million American women, including half of all those 65 and older.

Overall, 144 U.S. pharmaceutical and biotechnology companies are working on more than 370 new medicines that target diseases that affect only women, affect them disproportionately or are among the top 10 killers of women.

The new drugs in development are an addition to medicines already approved for these diseases. For osteoporosis—which affects one out of four women and is four times more common in women—patients have had, since 1996, a medicine that builds bone mass by up to 10 percent. Estrogen replacement treatment, which costs $3,000 over 15 years, can now prevent hip fractures caused by osteoporosis, which cost about $41,000 per fracture.

PhRMA

THE VALUE OF PHARMACEUTICALS

Innovative pharmaceuticals have value not only for individuals and their families but also for society and for the health care system. In some cases, modern medicines can save health care dollars, by reducing the need for more expensive treatments. Here are some examples of different ways in which pharmaceuticals give value.

- **Medical value: Drugs save lives, relieve pain, cure and prevent disease.**
  - Antibiotics and vaccines have virtually wiped out diphtheria, syphilis, whooping cough, measles, and polio in the US.
  - Thanks in large part to innovative medicines, 8 out of 10 children survive leukemia.
  - Over the last 30 years, medicines have helped reduce deaths from heart disease and stroke by half.

- **Social value: Medicines help keep families together longer and improve the quality of life for patients.**
  - Medicines allow many mentally ill people to be treated in the community, enabling them to stay with their families.
  - Anti-nausea medicines have improved the quality of life for cancer patients undergoing chemotherapy.
  - A biotechnology medicine replaces a hormone kidney dialysis patients lack, giving them renewed energy.

- **Economic value: Medicines keep employees on the job and help to avoid disability, surgery, hospitalization, and nursing home care.**
  - A new medicine for stroke saves an estimated $4 million for every 1,000 patients treated by reducing the need for rehabilitation and nursing home care.
  - A study showed that a new drug for migraine headaches saved employers $435 per employee per month – ten times the cost of the drug – by reducing lost productivity costs.
  - Osteoporosis causes more than a million hip fractures a year. A drug that can prevent osteoporosis costs about $3,000 for 15 years of treatment, while a hip fracture costs an estimated $41,000.

- **Increased drug utilization is good for patients and for the health care system.**
  Outpatient prescription drugs account for only six cents out of every health care dollar. As more and better medicines are developed – and as their effectiveness and cost-effectiveness becomes apparent – the drug component of health care will grow. This is good news because:
  - Drug treatment is the least invasive form of health care, allowing patients to stay with their families and on the job.
  - In many cases, drug treatment lowers the overall cost of treating a disease or condition.
  - Pharmaceuticals add value to health care, helping patients at every stage of life.

- **Policies that restrict the use of pharmaceuticals and discourage innovation hurt patients and the health care system.**
  Legislation and other initiatives that attempt to cut the sue of innovative medicines may save money today but will kill the promise of tomorrow's cures. Such threats include:
  - Restrictive formularies, prior authorization systems and other limitations on patient access to innovative pharmaceuticals.
  - Initiatives that would curtail the free market for pharmaceuticals.
  - Proposals that would weaken protection of intellectual property.

Pharmaceutical Research and Manufacturers of America

325 Cedar Street • Suite 321 • St. Paul, MN 55101 • Tel: 612-221-4047 • FAX: 612-221-4048

North Dakota Medical Association
January 18, 1999

PROPOSED AMENDMENTS TO SENATE BILL NO. 2166

Page 3, line 24, after "liable" insert "for the failure to disclose protected information, or"

Renumber accordingly

PROPOSED AMENDMENT TO SB 2166

On page 3, after line 31, insert:

"3. Except for the failure to report information required by chapters 23-07, 23-07.1, 23-07.3, 23-07.4, or any other law explicitly requiring disclosure of information about a disease or condition, an entity described in subsection 1 is not liable for the failure to disclose protected health information to a public health authority."

Renumber accordingly

TESTIMONY: SB 2166

March 1, 1999

Presented by: Senator Judy L. DeMers

Presented to: House Human Services Committee

Representative Clara Sue Price, Chairman

Chairman Price and Members of the House Human Services Committee. For the record, I am Senator Judy L. DeMers. I represent District 18, consisting of part of Grand Forks and part of the Grand Forks Air Force Base. I am appearing this morning as the prime sponsor of SB 2166.

I introduced SB 2166 at the request of the State Department of Health. It defines certain narrow circumstances in which the Department is authorized to disclose confidential or protected health information. Protected health information is defined on page 2, lines 3-18, of SB 2166. Although technically complex, the bill is quite narrow in scope and really just provides a clarification of current policy and practice.

Mike Mullens of the State Department of Health will review SB 2166, section by section, for you. Before he begins, however, I want to stress that SB 2166 only relates to protected health information which is maintained by the State Department of Health. It does not apply to information maintained by others (such as physicians, hospitals, or insurance companies).

The only amendment made by the Senate is an addition found at the top of page 4 (lines 1-4). It responded to a concern expressed by the North Dakota Medical Association in relation to needed protection for health

care providers and other entities from failure to disclose protected health information unless required to make the disclosure by North Dakota law.

Madam Chairman and Committee Members, I ask you favorable consideration of SB 2166.

Thank you.

Testimony
on
SB 2166, regarding Confidential Medical Records

before the
House Human Services Committee

by
Michael J. Mullen, State Department of Health

March 1, 1999

Good morning Madame Chair and members of the Committee. I am Michael J. Mullen, Senior Advisor for Health Care Policy, State Department of Health. I am pleased to present the Department's testimony in support of Senate Bill 2166, which is a bill regarding the treatment of confidential medical records that are received or maintained by the Department of Health.

Madame Chair, let me emphasize at the outset that although this is a technically complex bill, it is rather narrow in scope and is, in many respects, simply a clarification of the confidential status of certain protected -- personal -- health information. The Department has narrowly circumscribed authority to disclose that information to another public health authority as part of the Department's ongoing responsibility to prevent the spread of contagious and infectious diseases. This bill is not applicable to protected health information maintained by hospitals, physicians, and insurance companies.

The bill would establish a new chapter in title 23 (The Health and Safety Code) that specifies certain narrow circumstances in which the Department of Health is authorized to disclose confidential or "protected health information" (which is information about a person's health status or health care that identifies that individual).

The new chapter [which is **SECTION 1** of the bill] consists of nine sections: (1) definitions; (2) general limitations regarding disclosure; (3) patients' rights to their own records; (4) disclosure and sharing of information with a public health authority; (5) disclosure in an emergency; (6) disclosure in a law-enforcement inquiry; (7) disclosure of a "public health incident"; (8) the confidential status of protected health information held by a local public health unit; and, (9) a penalty for knowing disclosure of protected health information in violation of this chapter.

I will explain only one of the bill's definitions at this time, the others will be discussed in connection with the operative provisions in which they appear. ***Section 23-01.3-01(6)*** defines "protected health information" – which is a basic concept in this bill -- as information, including genetic information, demographic information, and fluid or tissue samples collected from an individual, diagnostic and test results, whether oral or recorded, that is created or received by a health care provider, health researcher, health plan, health oversight authority, public health authority, employer, health or life insurer, school or university; and that relates to past, present, or future physical or mental health or condition of an individual (including individual cells and their components), the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and that either identifies an individual or establishes a reasonable basis to believe that the information can be used to identify an individual. This definition is intentionally broad so that all kinds of personal health care information from whatever source are within its scope. As explained in more detail in the discussion of the operative sections of the bill, this definition will apply to "protected health information" *only when* it is received or maintained by a **public** health authority.

Section 23-01.3-02 sets forth the general limitation on the disclosure of protected health information. Protected health information in possession of a public health authority may be disclosed *only* as authorized by this chapter, or another North Dakota law explicitly authorizing the disclosure of that information; except that protected health information received or maintained under chapter 23-01.1 (defining the duties of the health care data committee) may be disclosed only as authorized by that chapter.

Section 23-01.3-03 permits a person to obtain from a public health authority confidential or protected health care information about themselves, *if* no other person is identified in the requested record. A person may be required to sign a written consent prior to the disclosure of any information, and the information may not be disclosed to the agent or guardian of a person, if disclosure to them is prohibited by law (e.g., conflict of interest).

Section 23-01.3-04(1) authorizes a health care provider, public health authority, law-enforcement official, school or university, or the agent of such an individual or entity to disclose protected health information concerning an individual *if* there is a "specific *nexus* between the individual's identity and the threat of a specific disease, death, or injury" to any individual or to the public health, and the individual's identity would allow the public health authority to prevent or significantly reduce the possibility of disease, injury, or death to any individual or the public at-large through the creation and use of a disease registry established under federal or state law. The other subsections of this section place limits on the use of any information disclosed under this section.

Section 23-01.3-05 authorizes the *non-public disclosure* of protected health information in emergency circumstances. *Subsection 1* provides that if there is an imminent threat of physical or mental harm to the subject of protected health information, a public health authority may, in order to allay or remedy that threat, disclose protected health information about that subject to a health care practitioner, health care facility, law-enforcement authority, or emergency medical personnel to protect the health or safety of that subject.

Subsection 2 provides that in the event of a threat of harm to any individual *other than* the subject of protected health information, a public health authority *may disclose* protected health information about that subject, if: [1] there is an identifiable threat of serious disease, injury, or death to an identifiable individual or group of individuals; [2] the subject of the protected health information has the ability to carry out that threat; and, [3] the disclosure of that information is necessary to prevent or significantly reduce the possibility of the threat.

This section would cover situations, for example, when a person has tuberculosis, AIDS, or some other infectious disease, and it is important to make emergency medical personnel or law-enforcement officers aware of this fact so they can take measures to protect themselves against the risk posed by that person's condition.

Section 23-01.3-06 allows disclosure for a law-enforcement inquiry in certain limited situations. *Subsection 1* provides that notwithstanding any other law, a public health authority may disclose protected health information to a law-enforcement authority, *if the state health officer determines* that the protected health information is necessary to a legitimate law-enforcement inquiry that has begun or may be initiated into a particular violation of criminal or civil law being conducted by that authority; and the investigative or evidentiary needs of a law-enforcement authority cannot be satisfied by non-identifiable health information, or by any other information.

This section would cover certain fairly narrow circumstances in which the Department is aware that a person is violating a criminal or civil law and this information is needed to initiate an inquiry, or supply otherwise unobtainable information to law-enforcement officers.

Section 23-01.3-07 allows the health officer, in certain limited situations, to disclose confidential or protected health information to a health care provider, or to the public, if the health officer determines that disclosure of the information is required to prevent the spread of disease, to identify the cause or source of disease, or that disclosure of information is required to allay fear and aid the public in understanding the risk of its exposure to disease.

Subsection 2 provides that the health officer may disclose protected health information under this section *only to the extent necessary* to accomplish the purposes of the section, and may require any health care provider receiving confidential or protected health information to keep that information confidential under written terms.

The purpose of this section is to give the Health Officer the discretionary authority to make a public statement about a significant public health risk if the Health Officer determines that it is reasonable and necessary to do so. Examples of such a situation would be when there has been a serious outbreak of food-borne illness, contamination of a water supply, or some other major or environmental incident or epidemic of contagious disease. It is important to note that information may be disclosed under this section *only to the extent necessary* to accomplish the purposes of the section. Therefore, in most cases the "protected health information" will be used as the basis for a public statement, but will not itself be disclosed to the public.

Section 23-01.3-08 clarifies the *confidential status* of protected health information that is created or received by a local public health authority if that information is submitted, or is required to be submitted, to the State Department of Health. Under this section, if a local public health unit receives protected health information that the unit is *required* to submit to the state Department of Health, or that is, *in fact, submitted to the Department*, the information is confidential and may be disclosed only as authorized by this chapter.

SECTION 2 of the bill is a new section of chapter 32-17. 3, relating to home health agencies. The section provides that information received by the Department of Health about a home health agency or its services under chapter 23-17.3, through inspections or otherwise, is confidential and may not be disclosed except in a proceeding involving the question of license, in a judicial proceeding (upon a court order), or to a health or social agency specifically interested in a patient's care. The circumstances authorizing disclosure of information about a home agency, or home its services are based on, are those set forth in chapter 23-16, regarding the licensing of a hospital.

In closing, let me briefly mention two additional items. First, the Senate adopted an amendment to clarify that: except for the failure to report information required to be reported by chapters 23-07, 23-07.1, 23-07.3, or 23-07.4, or any other law requiring disclosure of information regarding a disease or condition, an entity [such as a hospital, physician, or nurse] is not liable for the failure to disclose protected health information to

a public health authority. [See proposed section 23-01.3-04(3), page 4, lines 1 - 4.] This simply provides appropriate symmetry in the immunity from liability for reporting information to a public health authority.

Second, concern was expressed about whether the definition of "protected health information" – which is intentionally quite broad – would limit the ability of researchers to gain access to health care data for legitimate research projects. In our view, it will not. The particular section of the bill in which the term appears relates to sharing certain limited information with a law enforcement agency when no other source of information is available. [See proposed section 23-01.3-06, page 5, lines 8 - 17.] But, nothing in that section or the bill as a whole applies to the use of information for research, which is controlled by other provisions of the law. See, e.g. sections 23-01-15 and 23-07-02.2(1).

* * *

Madame Chair, this completes my prepared testimony. I have with me Pam Vukelic, Director of the Division of Disease Control, who overseas most of the Department's work related to contagious and infectious diseases. We would be pleased to answer any questions you or other members may have about this legislation.

Rev. 2/27/99 2:27 PM

SB 2166, a bill regarding --
Treatment of Confidential Medical Records

This bill would establish a new chapter in the title 23 (The Health and Safety Code) that would define certain narrow circumstances in which the Department of Health is authorized to disclose confidential or "protected health information" (which is information about a person's health status or health care that identifies an individual, or that includes enough other information to establish a reasonable basis to believe the information can be used to identify an individual).

The new chapter [which is **SECTION 1** of the bill] consists of nine sections: (1) definitions; (2) general limitations regarding disclosure; (3) a patient's right to their own records; (4) disclosure and sharing of information with a public health authority; (5) disclosure in an emergency; (6) disclosure in a law-enforcement inquiry; (7) disclosure of a "public health incident"; (8) the confidential status of protected health information held by a local public health unit; and, (9) a new section establishing the confidentiality of records relating to home health services.

Section 23-01.3-01 contains the definitions applicable to confidential and protected health records. [*It may be efficient to skim through the definitions, and come back to them as they are used in the operative sections of the bill. The key term is "protected health information", which is defined in subsection (6).*]

Subsection 1 defines "confidential information" as including any confidential record as defined in the open records law, section 44-04-17.1(3), any protected health information (which is defined in subsection (6) of this section), and any other information declared confidential by law.

Subsection 2 defines "disclose" broadly to include a transfer, or permission for access to, or otherwise divulging protected health information to any person, other than the person who is the subject of that information, including any subsequent redisclosure of individually identifiable health care information.

Subsection 3 defines "law-enforcement inquiry" as any executive branch investigation or official proceeding inquiring into any violation of, or failure to comply with any criminal or civil statute or any regulation, rule, or order issued pursuant to such a statute. This is intended to include an action to commit or quarantine a person to protect the public health.

Subsection 4 defines "non-identifiable health information" as any information that would otherwise be protected health information, except that it does not reveal the identity of the individual whose health or health care is the subject of the information, and for which there is no reasonable basis to believe that the information could be used to identify that individual.

Subsection 5 defines "person" broadly to include a government, governmental subdivision of an executive branch agency or authority; corporation; company; association; firm; partnership; society; estate; trust; joint venture; individual; individual representative; tribal government; and any other legal entity.

Subsection 6 defines "protected health information" – which is a basic concept in this bill -- as information, including genetic information, demographic information, and fluid or tissue samples collected from an individual, diagnostic and test results, whether oral or recorded, that is created or received by health care provider, health researcher, health plan, health oversight authority, public health authority, employer, health or life insurer, school or university; and that relates to past, present, or future physical or metal health or condition of an individual (including individual cells and their components), the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and that either identifies an individual or establishes a reasonable basis to believe that the information can be used to identify an individual.

Subsection 7 defines "public health authority" as the state Department of Health, a local public health unit, and any authority or instrumentality of the United States, a tribal government, a state, or a political subdivision of a state , a foreign nation, or a political subdivision of a foreign nation, that is primarily responsible for public health matters; and primarily engaged in activities such as injury reporting, public health surveillance, and public health investigation or intervention.

Subsection 8 defines "school or university" as an institution or place for instruction or education, including an elementary school, secondary school, or institution of higher learning, a college, or an assemblage of colleges united under one corporate organization or government.

Subsection (9) defines "state" to include the District of Columbia, or Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Subsection (10) defines "writing" or "written" as writing in either a paper-based or computer-based form, including electronic signatures.

Section 23-01.3-02 sets forth the general limitation on the disclosure of protected health information. Protected health information in possession of a public health authority may be disclosed *only* as authorized by this chapter, or another North Dakota law explicitly authorizing the disclosure of that information; except that protected health information received or maintained under chapter 23-01.1 (defining the duties of the health care data committee) may be disclosed only as authorized by that chapter.

Section 23-01.3-03 permits a person to obtain from a public health authority confidential or protected health care information, *if* no other person is identified in the requested record. A person maybe required to sign a written consent prior to the disclosure of any information, and the information may not be disclosed to the agent or guardian of a person, if disclosure to them is prohibited by law (e.g., conflict of interest).

Section 23-01.3-04(1) authorizes a health care provider, public health authority, law-enforcement official, school or university, or the agent of such an individual or entity to disclose protected health information concerning an individual *if* there is a "specific *nexus* between the individual's identity and the threat of a specific disease, death, or injury" to any individual or to the public health, and the individual's identity would allow the public health authority to prevent or significantly reduce the possibility of disease, injury, or death to any individual or the public at-large through the creation and use of a disease registry established under federal or state law.

Subsection 2 provides that a person is not liable for the disclosure of protected health information to a public health authority based on a good faith belief and credible representation made by the authority that this information is required to protect an individual or the public health from the threat of a specific disease, injury, or death, or if that disclosure is made pursuant to a federal or state law that is designed to protect public health or safety.

Subsection 3 provides that any disclosure of protected health information under this section must be limited to the minimum amount of information necessary to achieve the purposes of the section; and *Subsection 4* provides that a person who receives information under this section may use our disclose that information *solely* to achieve the purposes of the section.

Subsection 5 provides that nothing in the section permitting the disclosure of protected health information may be construed to require that disclosure, unless the disclosure is otherwise required by law.

Subsection 6 provides that protected health information disclosed under this section must be clearly identified as *confidential* protected health information subject to this chapter.

Section 23-01.3-05 authorizes the *non-public disclosure* of protected health information in emergency circumstances.

Subsection 1 provides that if there is an imminent threat of physical or mental harm to the subject of protected health information, a public health authority may, in order to allay or remedy that threat, disclose protected health information about that subject to a health care practitioner, health care facility, law-enforcement authority, or emergency medical personnel to protect the health or safety of that subject.

Subsection 2 provides that in the event of a threat of harm to any individual *other than* the subject of protected health information, a public health authority *may disclose* protected health information about that subject, if: [1] there is an identifiable threat of serious disease, injury, or death to an identifiable individual or group of individuals; [2] the subject of the protected health information has the ability to carry out that threat; and, [3] the disclosure of that information is necessary to prevent or significantly reduce the possibility of the threat.

This section would cover situations, for example, when a person with a serious mental illness has failed to take their medication, has become psychotic, and is threatening to kill a particular individual, blow up a building, or attack an employer or a law-enforcement officer. It might also cover a situation when a person has tuberculosis, AIDS, or some other infectious disease, and it is important to make emergency medical personnel or law-enforcement officers aware of this fact so they can take measures to protect themselves against the risk posed by that person's condition.

Subsection 3 provides that any disclosure of protected information under this section *must be limited* to the minimum amount of information necessary to achieve the purposes of the section; and *Subsection 4* requires that any recipient of information under the section may use or disclose that information *solely* to carry out the purposes of the section.

Subsection 5 provides that information disclosed under this section must be clearly identified as protected health information subject to the confidential treatment required under this chapter.

Section 23-01.3-06 allows disclosure for a law-enforcement inquiry in certain limited situations

Subsection 1 provides that notwithstanding any other law, a public health authority may disclose protected health information to a law-enforcement authority, *if the state health officer determines* that the protected health information is necessary to a legitimate law-enforcement inquiry that has begun or may be initiated into a particular violation of criminal or civil law being conducted by that authority; and the investigative or evidentiary needs of a law-enforcement authority cannot be satisfied by non-identifiable health information, or by any other information. *Subsection 2* provides that if a public health authority discloses protected health information under this section, that authority must impose appropriate written safeguards to ensure the confidentiality of the information and to protect against unauthorized or improper use or disclosure.

Subsection 3 provides that protected health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in any administrative, civil, or criminal action or investigation directed against the individual, unless the action or investigation arises out of, or is directly related to, the law enforcement inquiry for which the information was obtained.

Subsection 4 provides that when the matter or need for which protected health information was disclosed to a law-enforcement authority or grand jury has concluded, including any derivative matters arising from the matter or need, the law-enforcement authority or grand jury must either destroy the protected health information, or return it to the person from whom it was obtained.

Subsection 5 provides that to the extent practicable, and consistent with the requirements of due process, a law-enforcement authority must redact "personally identifying information" from protected health information prior to the *public disclosure* of that protected health information in a judicial or administrative proceeding.

Subsection 6 provides that any disclosure of protected health information under this section shall be limited to the minimum amount of information necessary to fulfill purposes of the section.

Subsection 7 provides a recipient of information under the section may use or disclose that information *solely* to fulfill purposes of the section.; and *subsection 8* provides that information disclosed under the section must be clearly identified as protected health information that is subject to this chapter.

Subsection 9 provides that this section may not be construed to limit or restrict the ability law-enforcement authority to gain information while in hot pursuit of a suspect or if other exigent circumstances exist.

This section would cover certain fairly narrow circumstances in which the Department is aware that a person is violating a criminal or civil law and this information is needed to initiate an inquiry, or supply otherwise unobtainable information to law-enforcement officers.

Section 23-01.3-07 allows the health officer, in certain limited situations, to disclose confidential or protected health information to a health care provider, or to the public, if the health officer determines that disclosure of the information is required to prevent the spread of disease, to identify the cause or source of disease, or that disclosure of information is required to allay fear and aid the public in understanding the risk of its exposure to disease. (This is the so-called "Wood House" section.)

Subsection 2 provides that the health officer may disclose protected health information under this section *only to the extent necessary* to accomplish the purposes of the section, and may require any health care provider receiving confidential or protected health information to keep that information confidential under written terms.

Subsection 3 provides that any person receiving information under this section who discloses any protected health information contrary to those written terms is guilty of a class A misdemeanor. The purpose of this section is to give the Health Officer the discretionary authority to make a public statement about a significant public health risk if the Health Officer determines that it is reasonable and necessary to do so.

Examples of such a situation would be when there has been a serious outbreak of food-born illness, contamination of a water supply, or some other major or environmental incident or epidemic of contagious disease. It is important to note that information may be disclosed under this section *only to the extent necessary* to accomplish the purposes of the section. Therefore, in most cases the "protected health information" will be used as the basis for a public statement, but will not itself be disclosed to the public.

Section 23-01.3-08 clarifies the *confidential status* of protected health information that is created or received by a local public health authority if that information is submitted, or is required to be submitted, to the State Department of Health. Under this section, if a local public health unit receives protected health information that the unit is *required* to submit to the state Department of Health, or that is, *in fact, submitted to the Department*, the information is confidential and may be disclosed only as authorized by this chapter.

SECTION 2 of the bill is a new section of chapter 32-17. 3, relating to home health agencies. The section provides that information received by the Department of Health about a home health agency or its services under chapter 23-17.3, through inspections or otherwise, is confidential and may not be disclosed except in a proceeding involving the question of license, in a judicial proceeding (upon a court order), or to a health or social agency specifically interested in a patient's care. The circumstances authorizing disclosure of information about a home agency or home its services are based on those set forth in chapter 23-16, regarding the licensing of a hospital.

# # #

11/24/98 12:19 PM

TESTIMONY BY

CALVIN N. ROLFSON

ON BEHALF OF

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

REGARDING

SENATE BILL NO. 2166

MY NAME IS CAL ROLFSON. I AM AN ATTORNEY HERE IN BISMARCK AND I REPRESENT THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA. I APPEAR HERE IN GENERAL SUPPORT OF THE CONCEPT OF SENATE BILL 2166, BUT I URGE AN AMENDMENT, WITHOUT WHICH WE OPPOSE THE BILL AS DRAFTED.

THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) REPRESENTS THE COUNTRY'S LEADING RESEARCH-BASED PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES, WHICH ARE DEVOTED TO INVENTING MEDICINES THAT ALLOW PATIENTS TO LEAD LONGER, HAPPIER, HEALTHIER AND MORE PRODUCTIVE LIVES. INVESTING $24 BILLION ANNUALLY IN DISCOVERING AND DEVELOPING NEW MEDICINES, PhRMA COMPANIES ARE LEADING THE WAY IN THE SEARCH FOR CURES. PhRMA INTERNET ADDRESS: http://www.phrma.org

PhRMA STRONGLY SUPPORTS CONFIDENTIALITY OF MEDICAL INFORMATION THAT IDENTIFIES PATIENTS, BUT SUCH LEGISLATION MUST PRESERVE AND PROTECT LEGITIMATE ACCESS TO AND USE OF SUCH DATA FOR

BIOMEDICAL AND EPIDEMIOLOGICAL SCIENCE RESEARCH IN THE CONTINUING DISCOVERY AND DEVELOPMENT OF MEDICINES.

TO FOSTER CONTINUED IMPROVEMENTS IN HEALTH CARE FOR FUTURE PATIENTS, LEGISLATION MUST ASSURE RESEARCHERS' UNFETTERED ACCESS TO MEDICAL INFORMATION THAT DOES NOT IDENTIFY PATIENTS, AND SHOULD PERMIT MEDICAL INFORMATION THAT DOES IDENTIFY PATIENTS TO BE ACCESSIBLE THROUGH PATIENT CONSENT OR AS AUTHORIZED BY APPROPRIATE REVIEW BOARDS AND EXISTING FEDERAL LAW.

★ **RESEARCHERS SHOULD BE ALLOWED TO USE MEDICAL INFORMATION THAT HAS BEEN ANONYMIZED BY CODING OR ENCRYPTION SO THAT IT NO LONGER IDENTIFIES THE PATIENT.** EPIDEMIOLOGICAL AND OUTCOMES RESEARCH THAT HELPS US TO BETTER UNDERSTAND THE INCIDENCE AND PROGRESS OF DISEASE, AND THE QUALITY AND COST-EFFECTIVENESS OF VARIOUS HEALTH CARE INTERVENTIONS, DEPENDS ON RESEARCHERS' ACCESS TO MEDICAL INFORMATION GENERATED IN ORDINARY HEALTH CARE SITUATIONS. SUCH RESEARCH COMMONLY USES MEDICAL INFORMATION THAT HAS BEEN ANONYMIZED BY CODING OR ENCRYPTION OF PERSONAL IDENTIFIERS TO PROTECT PATIENT CONFIDENTIALITY. AS WRITTEN, SENATE BILL 2166 DOES NOT RECOGNIZE ANONYMIZED INFORMATION AS AN EXEMPTION TO THE DISCLOSURE PROHIBITIONS. PhRMA RECOMMENDS THAT THE BILL BE AMENDED TO PERMIT THE

DISCLOSURE OF ANONYMIZED DATA TO RESEARCHERS CONDUCTING EPIDEMIOLOGICAL AND OUTCOMES RESEARCH.

★ **REQUIREMENTS FOR IDENTIFIABLE INFORMATION SHOULD ACKNOWLEDGE THE EXTENT OF EXISTING FEDERAL LAWS AND REGULATIONS THAT GOVERN CLINICAL AND OTHER MEDICAL RESEARCH - INCLUDING SAFETY AND EFFICACY SURVEILLANCE AND REPORTING AND EPIDEMIOLOGICAL STUDIES - AND SHOULD NOT IMPOSE ADDITIONAL REQUIREMENTS ON SUCH RESEARCH ACTIVITIES.** THE CONFIDENTIALITY INTERESTS OF PATIENTS PARTICIPATING IN SUCH RESEARCH ARE WELL-SERVED THROUGH OVERSIGHT BY THE U.S. FOOD AND DRUG ADMINISTRATION AND INDEPENDENT INSTITUTIONAL REVIEW BOARDS (IRBs). SENATE BILL 2166 NEITHER RECOGNIZES THE PROTECTIONS THAT EXIST UNDER CURRENT FEDERAL LAWS AND GUIDELINES NOR THE NEED FOR RESEARCHERS TO ACCESS INFORMATION. THE EXISTING FEDERAL REQUIREMENTS SHOULD BE RECOGNIZED AS ADEQUATE TO PROTECT THE CONFIDENTIALITY INTERESTS OF INDIVIDUALS WHOSE IDENTIFIABLE INFORMATION IS ACCESSED BY RESEARCHERS.

★ **PhRMA SUPPORTS A NATIONALLY UNIFORM SET OF RULES THAT CAN BE APPLIED CONSISTENTLY FROM STATE-TO-STATE.** UNIFORM RULES ALLOW CLINICAL AND EPIDEMIOLOGICAL RESEARCH TO BE CONDUCTED USING DATA FROM ANYWHERE IN THE COUNTRY, SO THAT NO REGION OR LOCALITY IS LEFT OUT OF THE SCIENTIFIC PICTURE THAT EMERGES. IF

RESEARCHERS ARE NOT GRANTED ACCESS TO INFORMATION FROM CERTAIN PATIENT POPULATIONS OR RESEARCH CANNOT BE CONDUCTED ACROSS STATE LINES BECAUSE OF DIFFERING STATE REQUIREMENTS, MUCH VALUABLE INFORMATION MAY NOT BE GATHERED. TO FOSTER NATIONWIDE RESEARCH, WE RECOMMEND THAT STATES WORK WITH THE U.S. CONGRESS TO DEVELOP CONSISTENT POLICIES RATHER THAN ENACT SEPARATE STATE CONFIDENTIALITY MEASURES.

★ **IN SUMMARY, THE RESEARCH-BASED PHARMACEUTICAL INDUSTRY RESPECTS THE PRIVACY OF PATIENTS AND THE CONFIDENTIALITY OF IDENTIFIABLE IINFORMATION. PhRMA MEMBER COMPANIES COULD NOT CONDUCT THEIR RESEARCH IF THEY DID NOT. WE URGE THE NORTH DAKOTA LEGISLATURE TO ASSURE ADEQUATE ACCESS TO RESEARCHERS OPERATING PURSUANT TO FEDERAL LAW AND REGULATIONS IN ORDER TO PROMOTE LIFE-SAVING BIOMEDICAL RESEARCH.**

ATTACHED TO MY TESTIMONY ARE A SERIES OF ARTICLES YOU WILL FIND INTERESTING THAT IDENTIFY THE EXPONENTIAL GROWTH IN HEALTH-ENHANCING AND LIFE-SAVING DRUGS THAT HAVE RECENTLY BEEN APPROVED OR ARE IN THE PROCESS OF RESEARCH AND DEVELOPMENT. FOR EXAMPLE, PHARMACEUTICAL COMPANIES REPORT A RECORD 187 DRUGS AND VACCINES IN DEVELOPMENT FOR CHILDREN, INCLUDING 44 FOR CANCER, THE LEADING DISEASE KILLER OF CHILDREN. THERE ARE CURRENTLY 350 BIO-TECHNOLOGY

PRODUCTS NOW IN DEVELOPMENT, UP SIGNIFICANTLY FROM 284 IN 1996. DRUG COMPANIES HAVE INVESTED ABOUT ~~20~~ 24 BILLION DOLLARS ON RESEARCH AND DEVELOPMENT AS THEY CONTINUE TO WORK ON UP TO 1,000 NEW MEDICINES, INCLUDING 96 NEW DRUGS FOR HEART DISEASE AND STROKE, 316 ANTI-CANCER MEDICINES AND 146 DRUGS AND VACCINES FOR CHILDREN. DRUG RESEARCHERS ARE ALSO FOCUSING ON DISEASES OF WOMEN WITH MORE THAN 370 DRUGS CURRENTLY IN DEVELOPMENT, INCLUDING 27 NEW MEDICINES FOR OSTEOPOROSIS, 18 FOR DIABETES, 18 FOR ALZHEIMER'S DISEASE AND 55 FOR ALL TYPES OF ARTHRITIS. ALL OF THIS EXPONENTIAL GROWTH IN HEALTH-ENHANCING AND LIFE-SAVING DRUG DEVELOPMENT CAN ONLY OCCUR IF SCIENTISTS AND RESEARCHERS ARE ABLE TO ACCESS AND USE INDIVIDUALIZED HEALTH DATA FOR CONTINUING DISCOVERY AND DEVELOPMENT OF MEDICINES.

ALSO ATTACHED TO MY TESTIMONY IS A PROPOSED AMENDMENT TO SENATE BILL 2166 THAT WILL RESPOND TO THESE VITAL CONCERNS I HAVE RAISED. I URGE THE COMMITTEE'S ADOPTION OF THESE AMENDMENTS, WHICH, IF ADOPTED, WILL MAKE THE BILL VERY ACCEPTABLE TO PhRMA.

THANK YOU.