1999 SENATE JUDICIARY

SB 2349

1999 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB2349

Senate Judiciary Committee

❑ Conference Committee

Hearing Date February 3, 1999

Tape Number	Side A	Side B	Meter #
1	X		0 - 3420
2-15-99 2	x		2880 - 3210
Committee Clerk Signature	Jackie Follman		

Minutes:

SB2349 relates to limitations on punitive damages.

SENATOR STENEHJEM opened the hearing on SB2349 at 9:00 a.m.

All were present.

SENATOR GRINDBERG, District 41, testified in support of SB2349. Testimony attached.

This bill is an economic development bill. This bill sends a message to the medical industry that North Dakota is serious about their possible expansions. Testimony attached.

SENATOR STENEHJEM asked if he had someone on the hook to come into the state.

SENATOR GRINDBERG stated that no, not yet.

JOY JOHNSTON, GNDA, testified in support of SB2349. Testimony attached.

JACK KAVANEY, NFIB, testified in support of SB2349. Testimony attached.

DAVE PESKE, North Dakota Medical Association, testified in support of SB2349. We think this is forward step in the medical profession.

JACK MCDONALD, North Dakota Trial Lawyers Association, testified in opposition of SB2349. What is progressive about this bill? This bill will protect the people who do egregious activity. This bill covers medical devices and also drugs. Under this bill, people can only get economic damages.

SENATOR STENEHJEM asked if someone came into North Dakota and manufactured a defective product and sold in Iowa, that aren't going to be suing under this law. They will sue under the law in their state.

JACK MCDONALD stated that he was not so sure.

SENATOR STENEHJEM asked what the company of FenFen do that would warrant punitive damages under current law that wouldn't be covered under this bill.

JACK MCDONALD stated that he is not that familiar with the cases of FenFen, but I would imagine what it would be is the rush the product in without successful research and marketing provisions.

SENATOR STENEHJEM asked what a company could do that is terrible that is not covered in this bill.

JACK MCDONALD stated that the bill sets up an automatic device to exempt them.

SENATOR STENEHJEM asked what else should be an exception that is not listed in this bill.

JACK MCDONALD stated that he will submit some testimony to provide for this.

JOHN RISCH, United Transportation Union, testified in opposition to SB2349. Testimony attached.

SENATOR STENEHJEM asked Senator Grindberg, if we included a provision about failure to warn of well-known dangers, if this would be in agreement with him.

SENATOR GRINDBERG stated that he didn't believe it will hurt the bill.

SENATOR STENEHJEM CLOSED the hearing on SB2349.

February 15, 1999 Tape 2, Side A

JOY JOHNSTON proposed and explained some amendments.

Discussion.

SENATOR WATNE made a motion on Amendments, SENATOR TRAYNOR seconded.

Motion carried. 6 - 0 - 0

SENATOR WATNE made a motion for DO PASS AS AMENDED, SENATOR TRAYNOR seconded. Motion carried. 6 - 0 - 0

SENATOR BERCIER will carry the bill.

Date: 2-15-99
Roll Call Vote #: 1

1999 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB2349

Senate Judiciary Committee

☐ Subcommittee on

or

☐ Conference Committee

Legislative Council Amendment Number

Action Taken motion on Amendments

Motion Made By Watne Seconded By Traynor

Senators	Yes	No	Senators	Yes	No
Senator Wayne Stenehjem	X				
Senator Darlene Watne	X				
Senator Stanley Lyson	X				
Senator John Traynor	X				
Senator Dennis Bercier	X				
Senator Caroloyn Nelson	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment

Date: 2-15-99
Roll Call Vote #: 2

1999 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2349

Senate Judiciary Committee

☐ Subcommittee on

or

☐ Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass As Amended.

Motion Made By Watne Seconded By Traynor

Senators	Yes	No	Senators	Yes	No
Senator Wayne Stenehjem	X				
Senator Darlene Watne	X				
Senator Stanley Lyson	X				
Senator John Traynor	X				
Senator Dennis Bercier	X				
Senator Caroloyn Nelson	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment Senator Bercier

REPORT OF STANDING COMMITTEE

SB 2349: Judiciary Committee (Sen. W. Stenehjem, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2349 was placed on the Sixth order on the calendar.

Page 1, line 22, remove the second "or"

Page 2, line 2, after "plaintiff" insert ";

d. Made a significant or knowing departure from official food and drug administration requirements; or

e. Acted with conscious disregard for human safety"

Renumber accordingly

1999 HOUSE JUDICIARY

SB 2349

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. 2349

House Judiciary Committee

❑ Conference Committee

Hearing Date 3/15/99

Tape Number	Side A	Side B	Meter #
1	x		21.1-36.4
Committee Clerk Signature			

Minutes: DISCUSSION

REP. GORDER is talking about the attractiveness to do business around here. REP. CLEARY is talking about buying the products that are not from around here. REP. KLEMIN states that other states laws apply. REP. DISRUD comments that an amendment by AL WOLF is coming still. REP. KOPPELMAN and REP. KLEMIN are talking about the amendments. REP. DISRUD asks about an additional tool. REP. KLEMIN comments to the committee about the terminology. REP. KLEMIN then gives a handout to the committee.

REP. KLEMIN moves to accept the amendment, seconded by REP. GORDER. The voice vote passes. REP. KOPPELMAN moves for a DO PASS AS AMENDED, seconded by REP. HAWKEN. The roll call vote was taken with 12 YES, 0 NO, 3 ABSENT. The motion carries. The CARRIER of the bill is REP. KLEMIN.

VR
3/15/99

90017.0301
Title.0400

Adopted by the Judiciary Committee
March 15, 1999

HOUSE AMENDMENTS TO ENGROSSED SENATE BILL NO. 2349 **3/15/99 JUD.**

Page 1, line 2, replace "punitive" with "exemplary"

Page 1, line 6, replace "**punitive**" with "**exemplary**"

Page 1, line 7, replace "Punitive" with "Exemplary"

Renumber accordingly

Date: 3.15.99
Roll Call Vote #: 1

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 3349

House JUDICIARY Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken accept the amendment

Motion Made By Klemin Seconded By seconded by

Representatives	Yes	No	Representatives	Yes	No
REP. DEKREY			REP. KELSH		
REP. CLEARY			REP. KLEMIN		
REP. DELMORE			REP. KOPPELMAN		
REP. DISRUD			REP. MAHONEY		
REP. FAIRFIELD	voice carried		REP. MARAGOS		
REP. GORDER			REP. MEYER		
REP. GUNTER			REP. SVEEN		
REP. HAWKEN					

Total Yes _____ No _____

Absent _____

Floor Assignment _____

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

Date: 3.15.99
Roll Call Vote #: 2

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2349

House JUDICIARY Committee

☐ Subcommittee on

or

☐ Conference Committee

Legislative Council Amendment Number

Action Taken 2349 Do Pass as Amended

Motion Made By Koppelman Seconded By Hawken

Representatives	Yes	No	Representatives	Yes	No
REP. DEKREY	✓		REP. KELSH		
REP. CLEARY	✓		REP. KLEMIN	✓	
REP. DELMORE	✓		REP. KOPPELMAN	✓	
REP. DISRUD	✓		REP. MAHONEY		
REP. FAIRFIELD			REP. MARAGOS	✓	
REP. GORDER	✓		REP. MEYER	✓	
REP. GUNTER	✓		REP. SVEEN	✓	
REP. HAWKEN	✓				

Total Yes 12 No 0

Absent 3

Floor Assignment Klemin

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

REPORT OF STANDING COMMITTEE

SB 2349, as engrossed: Judiciary Committee (Rep. DeKrey, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (12 YEAS, 0 NAYS, 3 ABSENT AND NOT VOTING). Engrossed SB 2349 was placed on the Sixth order on the calendar.

Page 1, line 2, replace "punitive" with "exemplary"

Page 1, line 6, replace "**punitive**" with "**exemplary**"

Page 1, line 7, replace "Punitive" with "Exemplary"

Renumber accordingly

1999 TESTIMONY

SB 2349

North Dakota Legislative Assembly

North Dakota Legislative
Assembly
2832 39 1/2 Ave
argo, ND 58104

Phone: 701-232-4691
FAX: 701-293-7819
email: TGrindbe@state.nd.us

Wednesday, February 3, 1999

Senator Wayne Stenehjem, Chairman Senate Judiciary & Members of Judiciary Committee

56th Legislaive Assembly

RE: S.B. 2349

Chairman Stenehjem, members of the committee, I am Tony Grindberg, State Senator, District #41, Fargo. I appear before you today in support of S.B. 2349.

Enclosed with my testimony is a copy of the letter, dated May 1, 1998 from the ND Legislative Council. I would like to review that with you to give you a better understanding of the bill's intent.

(Review of Legislative Council letter)

Mr. Chairman, S.B. 2349 is an economic development bill. Passage of this legislation would allow our state and local economic development organizations an additional tool to market the state's business climate to medical manufacturing companies.

The Department of Economic Development and Finance two years ago initiated a target industry study that identified the Medical Products Industry as a state-wide target. The Department is implementing strategies to assist local Economic Development Corporations and to provide them the technical assistance they need to garner the attention of the Medical Products Industry. This legislation is very similar to the aircraft "tort" reform efforts passed during the 1993 legislative session.

Mr. Chairman, members of the committee, thanks for your kind attention and I would be happy to answer any questions.

Tony Grindberg
State Senator
District #41

North Dakota Legislative Council

STATE CAPITOL, 600 EAST BOULEVARD, BISMARCK, ND 58505-0360 (701) 328-2916 TTY: 1-800-366-6888

May 1, 1998

Honorable Tony Grindberg
State Senator
2832 39 ½ Avenue SW
Fargo, ND 58104-7014

Dear Senator Grindberg:

This letter is in response to our recent conversation during which we discussed the similarities and differences between your bill draft regarding a prohibition on punitive damages for certain medical devices and several sections of the North Dakota Century Code. For your ease of comparing the two documents discussed in this letter, enclosed are copies of your bill draft and the sections of the North Dakota Century Code to which references are made.

As we discussed, North Dakota Century Code (NDCC) Section 32-03.2-11(6) provides that:

> Exemplary damages may not be awarded against a manufacturer or seller if the product's manufacture, design, formulation, inspection, testing, packaging, labeling, and warning complied with:
>
> a. Federal statutes existing at the time the product was produced;
>
> b. Administrative regulations existing at the time the product was produced that were adopted by an agency of the federal government which had responsibility to regulate the safety of the product or to establish safety standards for the product pursuant to a federal statute; **or**
>
> c. Premarket approval or certification by an agency of the federal government. (emphasis added)

Section 1 of the bill draft provides that punitive damages may not be awarded against a manufacturer or seller of a product or device that caused the harm if the product or device was subject to approval under 21 U.S.C. § 355 or premarket approval under 21 U.S.C. § 360e by the Food and Drug Administration **and** the product or device was approved by the Food and Drug Administration.

E-mail: notes.lcouncil@ranch.state.nd.us Fax: 701-328-3615 Web site: http://www.state.nd.us/lr

While NDCC Section 32-03.2-11(6) and Section 1 of the bill draft are similar in that both provide prohibitions on exemplary or punitive damages against the manufacturer or seller of a product, there are differences. First, subsection 6 does not apply to a specific product or type of product but rather applies generally to any product. The prohibition on punitive damages in the bill draft applies only to those medical devices subject to approval or premarket approval by the Food and Drug Administration. Second, subsection 6 only requires one of the criteria (a, b, **or** c) be met for the prohibition on damages to apply. Section 1 of the bill draft requires that the product or device be subject to approval or premarket approval **and** that the product or device was approved by the Food and Drug Administration. Thus, the bill draft is more specific as to the product or type of product to which it applies and the bill draft requires more criteria be met for the provision to apply.

Section 32-03.2-11(7) can also be compared to subsection 2 of Section 1 of the bill draft. Subsection 7 provides that subsection 6 does not apply if there is clear and convincing evidence that the manufacturer or seller knowingly withheld or misrepresented information or made an illegal payment to an official of the federal agency for the purpose of securing approval of the product. Subsection 2 of Section 1 of the bill draft also contains these provisions; however, the bill draft version includes a third alternative that the manufacturer or seller failed to use reasonable care to comply with the federal agency requirements and that the failure to comply caused the harm.

Finally, we discussed the similarities and differences between NDCC Section 28-01.3-05 and the bill draft. Section 28-01.3-05 provides that when a product liability action is brought against a seller for a defectively manufactured product, the manufacturer must assume cost of defense of the action and must assume any liability that may be imposed on the seller. This section provides indemnity for the seller for a defectively manufactured product and does not conflict with the subject of the bill draft which is to limit or prohibit punitive damages against a seller or manufacturer.

We hope this information will be helpful. Please contact this office if we can be of further assistance.

Sincerely,

Vonette J. Richter
Counsel

VJR/LMM
Enc.

GNDA
Greater North Dakota Association

Testimony in Support of SB 2349
Senate Judiciary Committee
February 3, 1999

My name is Joy Johnston. I am the Executive Director of the Manufacturers and Processors Division of the Greater North Dakota Association. This morning I am testifying in favor of SB 2349 on behalf of GNDA, its divisions and the Economic Development Association of North Dakota.

The Greater North Dakota Association is the North Dakota Chamber of Commerce. GNDA is the voice of business and principal advocate for positive change for North Dakota.

The Economic Development Association of North Dakota, formerly known as the Industrial Development Association, has a membership of professional developers, banks, utility companies and other entities committed to enhancing the standard of living of North Dakotans by encouraging economic development opportunities. GNDA is a member of the Economic Development Association of North Dakota.

The manufacture of medical devices is an industry that North Dakota is attempting to attract to the state. Medical device manufacture is a target industry for North Dakota according to experts from the Enhancing Growing North Dakota Study commissioned by the North Dakota Department of Economic Development and Finance.

The study was conducted by Flour-Daniel and Arthur Anderson. The consultants held meetings throughout the state using the Vision 2000 model. They conducted interviews with North Dakota business owners, entrepreneurs who decided to start businesses in North Dakota, entrepreneurs who decided not to come to North Dakota after studying the business climate of the state and businesses who decided to leave North Dakota. The consultants analyzed the resources and barriers of North Dakota's economy. Using information that illustrates the economic trends of the globe and filtered to North Dakota, the study pinpointed some target industries that North Dakota was in the right position to take on as potentially successful ventures. Medical device manufacture is one.

North Dakotans in the Enhancing Growing North Dakota Progress Report were very honest about identifying what we want and what may be stopping us from achieving those goals. We know we need to diversify the economy in North Dakota. But diversification has to come by increasing the standard of living in North Dakota. More succinctly we don't just want jobs; we want good paying jobs. We also know we don't have a large labor pool to draw from for those jobs. We acknowledge our education system is excellent, but we need to concentrate more in the high skilled technical areas.

How does SB 2349 factor into this?

Box 2639 • 2000 Schafer St. • Bismarck, ND 58502 • (701) 222-0929 • Fax: (701) 222-1611 • 1-800-382-1405 • gnda@btigate.com • web site: www.gnda.com

SB 2349 extends the progressive pro-manufacturing business climate to the medical device manufacture industry. Medical devices are small companies in size of number of employees. North Dakota isn't looking for large factories. However, medical device manufacture companies use a high skilled, highly compensated workforce. North Dakota urban or rural could attract the medical device manufacture industry.

The North Dakota legislature has enacted some of the most progressive tort reform in the US. SB 2349 extends the same progressive reform to the medical device industry.

Section 2 of SB 2349 provides an extra consumer protection standard that is not listed in NDCC 32-03.2-11. The defense against exemplary damages does not under SB 2349 if the manufacturer failed to comply with the FDA's investigation and correction of defects in design or manufacture of a medical device if the failure to comply has caused the plaintiff harm.

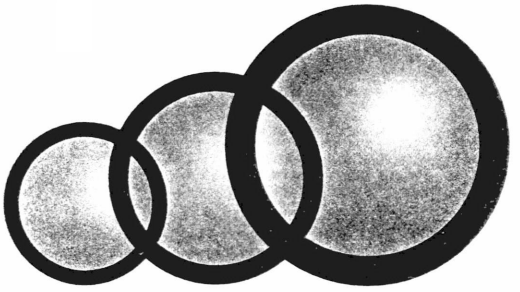
The legislature provided the aircraft manufacture industry progressive product liability law in 1995. It provided aviation manufacturer products liability law under NDCC 28-01.1. It enabled the insurance industry to provide aftermarket coverage of tort exposure under North Dakota law in NDCC 23.1-48. North Dakota can point to new companies in North Dakota because of the work by the legislature. Cirrus Industries in Grand Forks and Dakota Aero in Devils Lake are new ventures with high wage jobs.

SB 2349 can do the same for medical device manufacture. It provides limited punitive damage protection for a product manufacturer but does not eliminate the ability for a claim due to negligence by a company. Punitive damages are the damages awarded above and beyond actual damages and pain and suffering. These are the "punishment" damages for companies who do egregious acts or refuse rectify something they know will injure people. SB 2349 disallows punitive damages for a company that complies with FDA regulations.

GNDA, its divisions and EDND urge the Senate Judiciary Committee to recommend a "do pass" to SB 2439.

Enhancing Growing North Dakota

A Progress Report



It's time for us to forge a link between government, education and the private sector. . . to create an economic destiny of our own choosing.

Printed by: Economic Development & Finance
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Kevin Cramer, Director • September, 1997
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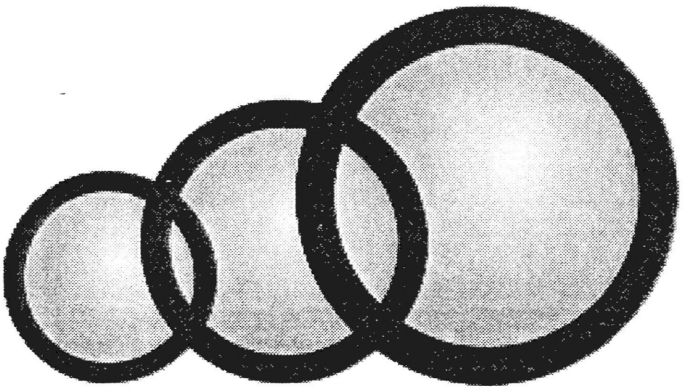
SB 2349

North Dakota Target Industry Study

Medical Device
Tort Reform
Sec 3, p. 53



FORGING A LINK TO THE FUTURE

ENHANCEMENT TO GROWING NORTH DAKOTA

Prepared by
Fluor Daniel Consulting
with a state tax comparison
prepared by
Arthur Andersen LLP

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Kevin Cramer, Director • November, 1997 (Revised)
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SIC 3841 - SURGICAL AND MEDICAL INSTRUMENTS AND APPARATUS

SIC 3841 - SURGICAL AND MEDICAL INSTRUMENTS AND APPARATUS

Surgical and Medical Instruments and Apparatus—Industry Overview

The current cost cutting climate in the managed care industry is expected to abate in the near future. According to Standard & Poor's (S&P), surgical and medical instrument manufacturers that produce "high-tech, lifesaving equipment or cost-effective products" replacing expensive, invasive surgical procedures will "enjoy high double-digit sales and earnings over the next few years." As a mature industry whose products are mostly commodities supplied by a small number of large manufacturers, the industry, according to S&P, is not subject to the same "economic cycles that affect most other industries.... However, with disproportionately large amounts of its products used by elderly persons, the upcoming rapid expansion in these demographic sectors bodes well for device sales growth in the years ahead."

As managed care replaces traditional healthcare delivery systems, medical and surgical instrument purchases in the U.S. by managed care providers are expected to expand from their current level of 50 percent of the market to nearly 75 percent within the next five years. However, managed care providers prefer purchasing from fewer, large medical supply firms that can offer greater benefits, including quantity discounts, reduced administrative costs from contracting with fewer vendors, and after-market product support. For commodity-type medical instruments and products, e.g., scalpels, stethoscopes, etc., the result will be increased pressures on small medical supply firms either to merge or establish joint-venture agreements with larger, established medical supply firms.

"Although," according to S&P, "the United States remains the single most important medical technology products market, accounting for about 42 percent of the $120 billion global business," there has been significant hesitance to committing major research and development funds to new products in the U.S. This is caused by U.S. Food and Drug Administration (FDA) guidelines for product review and subsequent regulatory delays, as well as the resulting higher development and marketing costs incurred by device manufacturers. As a result of this trend and the expansion of the foreign market, which is forecast by S&P "to double within the next seven years," more medical device production will be shifted to overseas factories in Asia and Eastern Europe, where countries have fewer regulatory hurdles in the production, marketing, and distribution of medical products. According to a recently completed Gallup survey of 58 U.S.-based medical electronics manufacturing companies, "40 percent had reduced the number of employees in the U.S. because of FDA regulatory delays, and 22 percent noted that they had already moved U.S. jobs overseas."

Strong growth is predicted in the orthopedics and cardiology markets. As baby boomers pass through middle age into their later years, they will become a significant customer base for healthcare services and products. Specifically, research will focus on enhancing the quality of materials—plastics, ceramics, metals, and composites—used in the manufacture of medical instruments. Estimated by S&P to "expand by about 15 percent annually over the next four of five years, compared with annual growth of only 7 percent to 8 percent for the overall medical device market," cardiovascular devices will see extraordinary growth in the near future. Although dietary, lifestyle, and pharmaceutical therapies are often first employed to treat cardiovascular problems, surgical techniques are often necessary for more advanced or difficult-to-treat situations.

The surgical and medical instruments industry is poised for substantial projected growth; however, the majority of the greatest growth will be in foreign markets. Nonetheless, significant growth will occur in the U.S. market based on the demographic profile of the U.S. population, the longer average life span of the U.S. population, and scientific and medical advances in the treatment of disease.

The surgical and medical instruments industry continues to become less labor intensive and more capital intensive. Typical of many manufacturing industries, there continues to be a reduction in the number of laborers and assemblers and movement toward more semi-skilled and skilled workers operating increasingly more sophisticated machines. Newer machinery and robotics require operators to possess stronger reading and math skills, as well as a comfort level with industrial computer controls and related programming activities.

Increased automation is creating more mechanical and technical jobs, primarily electricians and maintenance workers. To reduce the downtime caused by lost time waiting for maintenance workers to assess and repair machine malfunctions, manufacturers are training line operators to diagnose and perform routine maintenance and repair activities, resulting in a greater need for factory workers with mechanical and technical aptitudes.

Surgical and medical instruments manufacturers are also moving toward more people-based manufacturing processes, such as plants within plants, employee teams, and cell configurations. This divergence from traditional manufacturing models requires a new worker. Today, manufacturers are looking for locations that supply workers who are team-oriented and cross-trainable. Workers are needed who can take responsibility for a cell, team, or plant within a plant. Finally, all workers must be trained to ensure and be responsible for quality. Quality is no longer the sole responsibility of one department or individual.

General Description and Products

SIC 3841 comprises establishments primarily engaged in manufacturing medical, surgical, ophthalmic, and veterinary instruments and apparatus. [1] Examples of products include the following:

- Ophthalmic instruments and apparatus
  - Ophthalmic lasers
  - Slit lamps
- Medical diagnostic apparatus
  - Biopsy instruments
  - Blood pressure apparatus
  - Bronchoscopes, cystoscopes, gastroscopes, otoscopes
  - Eye examination instruments and apparatus
  - Pelvimeters
- Veterinarian instruments and apparatus
- Surgical instruments and apparatus
  - Anesthesia apparatus
  - Catheters
  - Clamps, surgical
  - Forceps
  - Hypodermic needles and syringes
  - Knives and scalpels, surgical
  - Probes, retractors, speculums
  - Surgical lasers
  - Surgical stapling devices
- Medical instruments and equipment for blood and bone work
  - Blood transfusion equipment
  - Bone drills, plates, and screws
  - Hemodialysis and IV transfusion apparatus
- Surgical and medical instruments, not elsewhere classified
  - Inhalation therapy equipment
  - Operating tables
  - Oxygen tents
  - Physiotherapy equipment, electrical
  - Skin grafting equipment
  - Stethoscopes
  - Ultrasonic medical cleaning equipment

SIC 3841 - Product Segment Shares

Product	Market Share (%)
Surgical and medical instruments and apparatus, including suture needles; eye, ear, nose, and throat instruments; orthopedic instruments; diagnostic apparatus; anesthesia equipment; blood transfusion and IV equipment; catheters	88.33
Surgical and medical instruments, not specified in kind	8.53
Hospital furniture	3.13

Source: *Manufacturing USA.* [2]

Location Requirements

General

Jim Bruce, of Fluor Daniel Consulting, states that the site selection process involving SIC 3841 firms is strongly influenced by a clustering effect. Medical supply companies have tended to cluster around major R&D centers such as universities. Bruce mentions Research Triangle Park, North Carolina; Austin, Texas; Minneapolis; and California as cluster locations. Countering this tendency is the very strong influence of cost pressure. For many producers in this industry, production costs are under pressure from both competitors (Asian suppliers) and customers (large healthcare organizations).

MD&DI Site Selection Survey

A 1995 study by *Medical Device and Diagnostic Industry* magazine was based on a survey of executives of medical device companies. Of the factors cited by the corporate leaders as influencing site selection, the one most often mentioned (by 40 percent of respondents) was the availability of skilled labor. Cost and regulatory environment were tied for second place with 32 percent, followed by the economic environment (31 percent), location (29 percent), taxes (23 percent), and distribution and transportation (14 percent). Surprisingly, labor costs were not ranked high in the survey; only 9 percent of the respondents included labor cost among their top three concerns.[3]

Sites, Buildings, and Utilities

The wide variety of products produced by firms in this industry means there can be a wide variety of facility requirements. SIC 3841 companies typically have a need for modest facility investment, although there may be a specialty sanitation or sterilization component. Investment in personal property (machinery and equipment) will generally

be more critical. Greenfield sites are not usually attractive to prospects in this industry; high-end industrial park sites will generally be preferred.

Water and wastewater demand will be a moderately important issue for the company. However, energy availability and costs will be important to the 3841 firm. Electric and gas will likely both be required, although generally electric will be more important.

Firms in SIC 3841 require reliable, low-cost energy. Precision turning and drilling, lathes, and other precision metalworking equipment characterize facilities in the instrument classifications. In addition, there can be all types of extrusion processes involved. These operations will be characterized by integration of computer-aided manufacturing, including programmable logic controls. Such operations are very sensitive to electric interruption. Even minor electric problems can result in costly and time-consuming restarts and reprogramming. As a result, electric reliability is as critical as electric cost to firms in this SIC code.

Access and Transportation

Proximity to Suppliers and Customers

Since the size and weight-to-value ratio of raw materials for SIC 3841 products is small, proximity to suppliers is not critical. However, location and access to national and regional markets is very important, particularly for the less specialized products. Customers are putting tremendous pressure on their own costs, and so seek to manage with less inventory. As a result, they are looking to suppliers to manage a more contemporary retail supply process.

Transportation

Easy access to interstate highways is the most important transportation issue. For some product manufacturers, excellent access to overnight air freight services will also be a location consideration.

Labor and Work Force Issues

Production in this industry is highly technical and requires skilled workers who are productive and trainable. Previous experience in this or similar industries would be preferable to employers in this industry. Some firms, which produce more commodity products, will seek locations with available pools of trainable low-skill labor.

In an interview by Fluor Daniel Consulting, Peter Garra, head of real estate for Ohmeda Inc., Liberty Corners, New Jersey, reiterated the importance of the availability of skilled labor. Ohmeda manufactures anesthesia apparatus and inhalators and disposable medical instruments, and Mr. Garra stated that availability and skills were the foremost qualities that Ohmeda seeks in a local work force. The kind of

skills sought depend on the activity: for assembly jobs, availability is paramount; for precision work, a trained work force is sought.

Garra says that local training programs are very important, and he looks for incentives in this area.

The main types of workers employed by the three-digit 384 group include the following:

- Assemblers, hand workers, and fabricators, nec;
- Sales and related workers;
- Precision inspectors, tester, and graders;
- Blue collar worker supervisors;
- Precision assemblers; and
- Secretaries. [3]

Sixty percent of employees in SIC 3841 in 1995 were production workers, [4] and the average hourly wage for these workers in 1996 was $11.57. [5]

Quality of Life

Identifying the locations that can provide the necessary skilled labor force is a driving issue; in some cases, the location itself attracts top people. Cordis Corporation, a division of Johnson & Johnson headquartered in Miami Lakes, Florida, placed an R&D facility for its neuroscience products on the French Riviera; this location made it "very easy to attract people to live there. We get good job candidates very easily," says Ron Sierra of Cordis. [6]

As seen above, attracting a quality, skilled work force consistently ranks as the greatest locational concern of companies in the surgical and medical instruments industry. An article in *Plants Sites & Parks* states that "brain power is the raw material that drives the nation's pharmaceutical and medical device industries. So it shouldn't be any wonder that lifestyle considerations loom large in site selection plans..."[7]

Other Issues -- Financial Considerations

State and local taxes have a big impact on operations. Spokesman Garra of Ohmeda Inc. says that incentives, especially in the areas of taxes and training, are very important, as is the local attitude toward the business community. For Ohmeda, the most important location requirements for a profitable and satisfactory operation are quality of labor force, cost of doing business, and accessibility of transportation.

Trade Organizations, Publications, and Shows/Conferences

Trade Organizations

Health Industry Manufacturers Association
1200 G Street NW, Suite 400
Washington, DC 20005
202-783-8700

Medical Device Manufacturers Association
1900 K Street NW, Suite 300
Washington, DC 20006
202-496-7150

Trade Publications

Medical Device and Diagnostic Industry
Canon Publications Inc.
3340 Ocean Park Boulevard, Suite 1000
Santa Monica, CA 90405
310-392-5509

Trade Shows/Conferences

Annual Conference, Association of Medical Diagnostics Manufacturers
Rockville, Maryland
October 20-21, 1997

Annual Conference, Medical Device Manufacturers Association
Washington, DC
May 14-16, 1998

Medical Design & Manufacturing West
Sponsored by Canon Communications Inc.
Anaheim, California
January 19-22, 1998

Medical Design & Manufacturing Minneapolis
Sponsored by Canon Communications Inc.
Minneapolis, Minnesota
November 4-6, 1997

References

[1] *Standard Industrial Classification Manual*, Executive Office of the President, 1987.

[2] *Manufacturing USA*, Gale Research Inc., 1996.

[3] *Industry-Occupation Matrix*, Bureau of Labor Statistics, 1995.

[4] *Annual Survey of Manufactures: Statistics for Industry Groups and Industries*, Bureau of the Census, 1995.

[5] *Employment* and *Earnings*, Bureau of Labor Statistics, March 1997.

[6] *Medical Device and Diagnostic Industry, "Site Selection: Device Firms Seek Growth Through Location," March 1995.*

[7] *Plants Sites and Parks*, "Quality of Life Key to Attracting Talent," March-April 1993.

SIC 3841 - SURGICAL AND MEDICAL INSTRUMENTS AND APPARATUS

ANNUAL AVERAGES PER ESTABLISHMENT
(1994 Data)

Category	All Manufacturing	SIC 3841
Number of establishments	386,868	1,366
Production workers per establishment	31.00	43.00
Production wages per establishment	$787,511	$996,632
Per production worker	$25,403	$23,177
Cost of materials per establishment	$4,530,576	$3,249,414
Per production worker	$146,147	$75,567
New capital expenditures per establishment	$291,529	$452,928
Per production worker	$9,404	$10,533
Cost of electricity per establishment	$97,559	$77,672
Per production worker	$3,147	$1,806
Value of shipments per establishment	$8,654,166	$10,841,288
Per production worker	$279,166	$252,122
Value added by manufacture per establishment	$4,151,235	$7,549,121
Per production worker	$133,910	$175,560

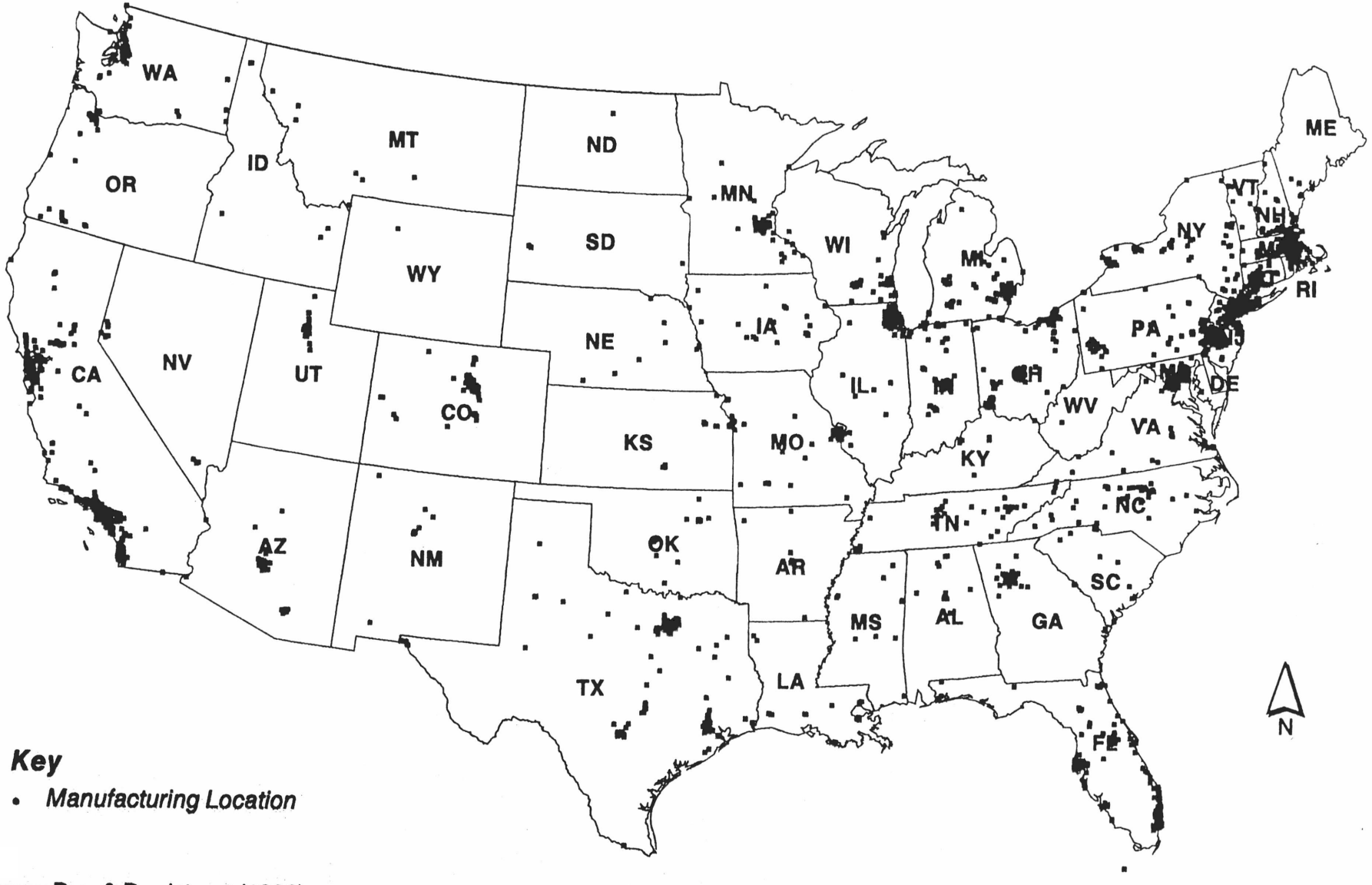
Sources of data:
Number of establishments: *County Business Patterns*, 1995 (1994 data), Table 1b.
All other: *Annual Survey of Manufactures, Statistics for Industry Groups and Industries*, 1995 (1994 data), Tables 2 and 4.

New Employment
Firms Opened Within the Past 3 Years
SIC 3841: Surgical and Medical Instruments and Apparatus

Rank	State	Total New Employment	Number of New Firms	% of Total New Employment
1	California	4,121	88	23.61%
2	Florida	2,568	29	14.71%
3	Massachusetts	2,246	30	12.87%
4	Minnesota	1,510	12	8.65%
5	Pennsylvania	1,091	18	6.25%
6	Missouri	762	9	4.37%
7	Ohio	714	9	4.09%
8	Georgia	659	13	3.78%
9	Connecticut	589	12	3.37%
10	Washington	414	5	2.37%
11	New York	319	25	1.83%
12	Michigan	265	12	1.52%
13	Mississippi	250	2	1.43%
14	Texas	237	17	1.36%
15	Virginia	231	3	1.32%
16	New Jersey	225	21	1.29%
17	Utah	192	8	1.10%
18	Rhode Island	163	4	0.93%
19	Wisconsin	152	8	0.87%
20	Illinois	129	12	0.74%
21	Indiana	109	11	0.62%
22	Oregon	106	4	0.61%
23	Alabama	67	4	0.38%
24	Tennessee	57	11	0.33%
25	Colorado	49	13	0.28%
26	Maryland	48	4	0.28%
27	North Carolina	30	5	0.17%
28	Maine	30	1	0.17%
29	South Carolina	27	1	0.15%
30	Nevada	21	5	0.12%
31	Kentucky	20	2	0.11%
32	Arizona	15	6	0.09%
33	Kansas	9	2	0.05%
34	South Dakota	8	1	0.05%
35	New Hampshire	8	3	0.05%
36	Vermont	5	1	0.03%
37	Louisiana	3	1	0.02%
38	Oklahoma	3	2	0.02%
39	Nebraska	2	1	0.01%
40	Iowa	N/A	1	N/A
	Total	17,454	416	100.00%

Source: Dun and Bradstreet; calculations by Lockwood Greene, 1997

Surgical and Medical Instruments and Apparatus
SIC 3841



Source: Dun & Bradstreet (1996)

July 29, 1997

NORTH DAKOTA

NFIB

National Federation of
Independent Business

Testimony of Jack Kavaney, Leadership Council Chairman for the National Federation of Independent Business/ North Dakota.

IN SUPPORT OF SB 2349--February 3, 1999-Senate Judiciary Committee.

NFIB/North Dakota represents about 3000± small business owners throughout North Dakota. Our positions on issues before the legislature is determined entirely by member ballots.

SB 2349 relates to limitations on punitive damages for manufacturers and sellers. Even though this bill refers to the medical industry, we are concerned because it is part of our continuing effort to reform product liability issues.

Small-business owners' cry for meaningful legal reform has been loud and clear for a long time. In 1995 and again in 1998, the attendees at the White House Conference on Small Business identified the need to "Reform Product Liability Laws, Cap Punitive Damages, and Abolish Joint and Several Liability".

Damages awards in civil lawsuits often resemble a lottery jackpot rather than just compensation. Any movement to limit the amount of punitive damages or control the punitive damages is movement in the right direction--for small business and the consumer.

Without reform, small-business owners will continue to live in fear of and be crippled by litigation. Entrepreneurs today often settle out of court, even when innocent, because they simply cannot afford the legal fees involved in fighting a suit.

ON BEHALF OF SMALL BUSINESS OWNERS I URGE YOUR SUPPORT OF SB2349

1910 N. 11th Street, #13 · Bismarck, North Dakota 58501 · 701-224-8333 · Fax 701-222-3699

The Guardian of Small Business for Fifty Years

[redacted] RISCH
Legislative Director
DAKOTA LEGISLATIVE BOARD

united transportation union

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Testimony of John Risch
Before the Senate Judiciary Committee
In Opposition to
Senate Bill 2349
February 3, 1999

Mr. Chairman and members of the committee, my name is John Risch. I am the North Dakota Legislative Director of the United Transportation Union. The UTU is the largest rail labor union in North America. Our membership includes conductors, engineers, switchmen, trainmen and yardmasters.

We oppose SB 2349 because we believe in the basic principle of "equal justice under law." Passing a special law to protect one industry erodes our standard of equal justice.

Neither drug manufacturer's or any other company should receive special legal treatment, which is precisely what this bill would do. Beyond that, this special law would provide no benefit to North Dakota consumers if it passes.

At the outset we need to understand that FDA approval does not guarantee that a product is safe.

The same industries that have argued for a bans on punitive damages in cases involving FDA-approved devices have been lobbying Congress to weaken FDA pre-market approval standards. And in 1997 they were successful.

That year Congress passed the FDA Modernization Act. That Act lowered the standards for FDA approval in a way that will make it even more likely that dangerous drugs and devices will be sold in the future.

The act allows drug and medical device companies to promote their products for unapproved purposes without having to first prove the product is safe and effective for those uses.

The new federal law also permits medical device manufacturers to hire private, for-profit firms to review their products instead of the FDA's professional staff. In addition, the law lowers the minimum number of clinical investigations required to establish a drug or medical device's safety and effectiveness from two to one. It also it makes tracking and post-market monitoring of high-risk medical devices such as heart valves optional.

All of which means the FDA's weakened approval and oversight authority will make injuries from drugs and medical devices even more common in the future.

Now more than ever consumers need our courts to hold drug manufacturers accountable for their actions. This judicial accountability is a powerful tool in preventing the sale of dangerous products.

While no corporate interest should be granted special legal protection, there certainly is no need for this law since North Dakota already has a cap on punitive damage awards against manufacturers.

Passage of SB 2349 will take away the power of North Dakota judges and juries to decide when a company's behavior should be punished. In the end corporations will be held less accountable and will be less careful in how they manufacture and monitor their products.

Corporations that manufacturer drugs and medical devices do not need a special law to protect them from North Dakota consumers.

That is why we urge a "DO NOT PASS" on SB 2349.

Examples of Dangerous Drugs and Medical Devices Approved by the FDA That Have Injured or Killed Patients

(NOTE: Information is not available to guarantee that all of these cases would be relevant under S.2349 subsections (2a) which exempts cases where a manufacturer withheld or misrepresented information from the FDA, and (2c) which exempts cases where the defendant failed to use reasonable care to comply with FDA regulations. However, this fact sheet provides some examples of dangerous drugs and devices sold with FDA approval in the past, and demonstrates that FDA approval is no guarantee of safety.)

- In a 1996 New Jersey case (*Coddington v. Laser Inc.*), a doctor prescribed the drug Theospan 65, a sustained release form of Theophylline, for a 22-month old child diagnosed with bronchitis. A few days later the child suffered a violent seizure which resulted in brain-damage.

  The plaintiffs produced evidence to show that doctors were never informed by the drug manufacturers of revised FDA guidelines for theophylline, including warnings that it was not safe for children under 5 years old.

  The case was eventually settled for $3.5 million.

- An Arkansas family sued the manufacturers of the Airco Ventilator, a medical device designed to assist patients with breathing during surgery, after a family member suffered fatal brain and lung damage as a result of being connected to the device (*Airco, Inc. v. Simmons First National Bank, Guardian, et al.).*

  The jury awarded the family $3 million in punitive damages after it was decided that the product was "grossly in violation of safety engineering principles and never should have been on the market." The decision was upheld by the Arkansas Supreme Court which stated that "the manufacturer knew...the product was so deadly it should never have been on the market."

  After the case, Airco submitted a medical device alert through the FDA warning doctors of the potential misuse of the product.

- In 1991 the FDA granted approval for Orcolon, a synthetic gel injected directly into the eye, designed to steady the eyeball during cataract surgery, despite the fact that in clinical trials it created dangerously high eye pressure. At the FDA's request, the product was pulled from the market that same year, after it had caused partial blindness in at least 100 people. A year later there had been an additional 170 reports of adverse reactions.

- In 1995 the FDA granted clearance for 10 manufacturers to market pedicle screws, used electively in conjunction with spinal fusion surgery to attach metal plates to patients'

vertebrae, to promote "off-label" uses of the device. The use of pedicle screws in spinal fusion surgery can significantly increase complications, creating neural damage, infection and the need for additional surgery.

More than 3,000 lawsuits against implant manufacturers have been filed claiming injured patients were not informed of the risks, off-label use, and investigational status of pedicle screw systems.

- Beginning in 1977, a series of pacemaker leads (components of a cardiac pacemaker) manufactured by Medtronic were approved under the FDA's 510(k) process - a procedure that only requires manufacturers to demonstrate that their devices are substantially equivalent to devices on the market prior to the enactment of the 1976 Medical Device Amendments.

  By 1984 reports of product failure surfaced in one of the Medtronic Models which caused medical reaction ranging from light-headedness to death. Three years later, the FDA requested that Medtronic issue a safety alert for additional lead models.

  This lead to a U.S. Supreme Court decision that manufacturers of medical devices can be sued in products liability cases. The suits are not preempted by the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (*Medtronic, Inc. v. Lohr).*

- In an Oklahoma Supreme Court case (*Edwards v. Basel Pharmaceuticals*) a plaintiff died of cardiac arrest after smoking cigarettes while wearing two nicotine patches. The warning on the patch, which met FDA requirements, referred to fainting as a result of nicotine overdose. It did not mention heart problems. The state Supreme Court decided that a drug manufacturer can be sued in products liability even though its warning complied with FDA requirements.

- A man who required an emergency liver transplant after drinking several glasses of wine and taking Extra-Strength Tylenol was awarded $350,000 in punitive damages. The jury found that the manufacturer did not give the FDA eight years of case reports until after the FDA had decided not to require a warning about alcohol. The manufacturer also wrote a letter to hospitals stating that Tylenol and alcohol could not cause liver damage (*Benedi v. McNeil-P.P.C., Inc.).*

Sources:

- *Medical Device Safety: 10 Reasons to Strengthen Not Weaken the FDA.* Public Citizen's Congress Watch, June 1997.

- *Lawyers Weekly USA* on the web at: http://www.lweekly.com

Consumers Union
Publisher of Consumer Reports

Public Citizen
Congress Watch

HOW S. 687 AND H.R. 1910 WOULD HARM WOMEN

S. 687 and H.R. 1910 are billed as bringing "fairness" to the product liability system. However, the legislation is anything but fair to consumers and its effects would be particularly harmful to women. Women have been the disproportionate victims of dangerously defective drugs and medical devices such as DES, silicone breast implants, and the Copper-7 and Dalkon Shield IUDs. Women, therefore, would suffer tremendously if these bills became law since the legislation would protect manufacturers of defective pre-approved drugs and medical devices from liability for punitive damages and relieve guilty manufacturers of joint responsibility for injuries such as loss of fertility and disfigurement where the injuries result primarily in non-economic loss.

THE LEGISLATION'S "FDA EXCUSE" WOULD SHIELD MANUFACTURERS OF DANGEROUS AND DEFECTIVE DRUGS AND MEDICAL DEVICES MARKETED TO WOMEN

○ The bill includes an "FDA excuse" (Section 203(b) in S.687 and section 6(1)(A) of H.R. 1910) which would protect manufacturers of dangerous drugs and medical devices approved by the Food and Drug Administration and marketed to women from liability for punitive damages no matter how egregious the wrongdoing of the manufacturer unless the victim can show that the drug maker defrauded the FDA.

Enactment of this provision would simply be a disaster for women's health. This provision could protect the manufacturers of some of the most notorious products which have wreaked havoc on women. For example, the "FDA excuse" would most likely shield the manufacturers of DES. Between 1947 and 1971, approximately 10 million mothers, daughters and sons were exposed to DES in the United States. DES mothers are at increased risk of breast cancer. DES daughters have increased risk of vaginal and cervical cancer and pregnancy complications. DES daughters and sons have increased rates of infertility.

The "FDA excuse" could also operate to protect manufacturers of products such as the Copper-7 IUD. Thousands of women suffered serious pelvic infections, loss of fertility and removal of internal reproductive organs from use of this FDA-approved device.

○ The "FDA excuse" would undermine the important public safety function of punitive damage awards.

Although punitive damages are seldom awarded, in cases in which they have been deemed appropriate, the defective product is often removed from the market or made safe. Examples of products marketed to women which were removed from the market, improved or availability was restricted as a direct result of punitive damage awards include the Dalkon Shield and Copper-7 IUDs, silicone breast implants and high-estrogen contraceptives.

○ **The "FDA Excuse" would establish inadequate FDA regulations as the standard of care for manufacturers of drugs and medical devices.**

FDA pre-market approval and standards set by the agency are intended to function as minimum safety standards. In recent months, FDA itself has pointed out the inadequacy of its current medical device regulation. Medical devices are responsible for approximately 53 deaths and over 1,000 serious injuries every year. FDA has concluded that its requirements for the design and use of medical devices are horribly inadequate and have led to many deaths and injuries. The FDA has put forth new proposed rules to increase FDA oversight of medical device development. The industry has strenuously resisted more stringent regulation while continuing to fight for protection from civil liability.[1]

The lack of adequate FDA oversight has allowed products injurious to women to be mass-marketed. Because FDA did not exercise pre-market approval of medical devices until 1976, two million women received silicone breast implants without any evidence that they were safe or any appreciation of the serious risk of auto-immune dysfunction caused by the devices. Evidence now indicates that some children breast fed by women with implants also suffer from auto-immune dysfunction. The availability of silicone breast implants was restricted only after a California court found Dow Corning liable for punitive damages.

THE BILLS' BAR ON JOINT AND SEVERAL LIABILITY FOR SO-CALLED "NON-ECONOMIC" DAMAGES WOULD DENY WOMEN FAIR COMPENSATION

○ **S. 687 and H.R. 1910 would abolish the long-standing doctrine of joint and several liability for "non-economic" damages that says where more than one defendant is responsible for causing injury but not all can contribute to the award the plaintiff is allowed to fully recover from the solvent wrongdoers.**

The current system punishes guilty parties and makes the innocent victim whole.

"Non-economic" damages compensate for losses other than out-of-pocket expenses such as medical bills and lost wages. "Non-economic" damages include pain and suffering for victims who suffer horrible disfigurement or loss of fertility. Such damages are particularly important to women. Women victims of products such as DES, Dalkon Shield and Copper-7 IUDs, and silicone breast implants suffer injuries such as loss of fertility and miscarriage which do not carry high economic price tags but take a tremendous toll on mental health and quality of life. These are real losses that do not deserve to be relegated to second-class status. Proponents of the bar on joint and several liability for non-economic damages point out that women could still be compensated for expenses such as child care. Of what good is such compensation to a women who can bear no children?

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[1] As reported in the *Washington Post* Friday, November 19, 1993

TESTIMONY OF LUCINDA M. FINLEY

PROFESSOR OF LAW, SUNY AT BUFFALO LAW SCHOOL

BEFORE THE COMMITTEE ON THE JUDICIARY

OF THE U.S.SENATE

ON

THE "FDA DEFENSE" FROM PUNITIVE DAMAGES IN S. 672

104TH CONG., 1ST SESS.

JULY 26, 1995

Mr. Chairman, and members of the Committee, I thank you for the opportunity to present my views on the so-called "FDA defense" provisions of S. 672, the Civil Justice Fairness Act of 1995. I am Professor Lucinda Finley, a Professor of Law at the State University of New York at Buffalo School of Law. My teaching and research areas include tort law and toxic torts. I am a past Chair of the Torts and Compensation Systems Section of the Association of American Law Schools, and I am currently working on a Tort Law casebook. In particular, my research has concentrated on the impact of damages recovery provisions on women, and on pharmaceutical products and medical devices that cause reproductive injuries. I appear before you today as an independent professor -- I am not representing the interests of any particular group or industry that might be affected by changes in product liability law. Rather, I am testifying because my research into the implications of tort damages principles on women gives me concern that the FDA defense from punitive damages may have adverse consequences for women's health.

A. Proposals to Limit Punitive Damages are Based on Fears Refuted by Empirical Evidence

The premises on which S. 672's proposals to cut back on punitive damages are based are not supported by the growing body of empirical research on punitive damages. Research from disinterested sources such as academic researchers[1], the GAO[2], and the ABA[3], arrives at similar

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[1] See Michael Rustad, In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data, 78 Iowa L. Rev. 1 (1992); Thomas Koenig and Michael Rustad, Demystifying Punitive Damages in Product Liability Cases: A Survey of a Quarter Century of verdicts (Roscoe Pound Foundation, 1991); S. Daniels and J. Martin, Myth and Reality in Punitive Damages, 75 Minn. L. Rev. 1 (1990) (authors are researchers at American Bar Foundation); Peterson, Sharma & Stanley, Punitive Damages: Empirical Findings (Rand Inst. for Civil Justice, Report R-3311-1CJ).

conclusions:

-- Apart from asbestos cases, in other products liability cases, including drug and medical device cases, the frequency of punitive damages awards since 1980 is decreasing.[4]

--The impression that punitive damages are routinely awarded in huge amounts that bear no relationship to compensatory awards is a false one, fueled by the tendency of the media and the business community to feature a few mega-awards, without mentioning that those awards are often reduced later by the trial court or an appellate court. When punitive damages awards since 1965 are controlled for inflation, there has been little change in the median size of awards, and the ratio of awards is only slightly more than the amount of compensatory damages.

--The overwhelming majority of plaintiffs who received punitive damages suffered catastrophic injury or death.

--When punitive damages are imposed, they are attributable to severe manufacturer misconduct that constitutes flagrant disregard of safety. Three out of four product liability punitive damages awards involve failure to warn of well-known dangers, or the failure to adopt inexpensive remedies, after marketing or regulatory approval, for known serious dangers. In most of these cases high corporate management had knowledge of the health hazards and made conscious decisions to do nothing to improve safety or actively to suppress information of the

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[2] GAO, Product Liability: Verdicts and Case Resolution in Five States (Sept. 1989).

[3] Report of the Special ABA Committee on Punitive Damages: A Constructive Examination (ABA 1986).

[4] Only 15% of the punitive damage awards in all the products liability cases studied by Professor Rustad came in cases involving drugs or medical devices. Rustad, In Defense of Punitive Damages, 78 Iowa L. Rev. 1, 47 (1992).

hazards or to falsify data.[5]

In light of the mounting empirical evidence that punitive damages awards are not increasing, and are awarded only in a few instances of flagrant disregard for safety, those who would insulate a drug or device manufacturer from punitive damages must be able to answer satisfactorily the following question: why should a manufacturer of a drug or medical device whose behavior meets the standard in S. 672 for punitive damages -- conscious, flagrant indifference to human safety -- be insulated from punitive damages because a regulatory agency with limited resources and often slow response time previously approved marketing the drug or medical device? Or, to put the question another way, why should a person who is injured by a drug or medical device whose manufacturer has engaged in conscious, flagrant, indifference to human safety not receive punitive damages, when a person injured by another type of product whose manufacturer had been equally indifferent to safety would receive punitive damages?

While S.672 would still permit punitive damages when the drug or medical device manufacturer has withheld information from the FDA or misrepresented information to the agency, these are not the only situations that may demonstrate conscious disregard of human safety. Consider the situation where a manufacturer of an approved drug submits information about subsequent adverse reactions to the FDA, but fails to warn physicians and engages in a misleading advertising campaign denying that there are any problems. The FDA then fails to act in the face of the mounting reports of serious problems, and the manufacturer continues to deny

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[5] See Rustad, 78 Iowa L. Rev. at 66, 67 - 75.

to physicians and the public that there are any reasons for concern.[6] Or, the manufacturer knows that there is a readily available and relatively inexpensive change that can be made to the device, such as changing the tail string on the Dalkon Shield IUD, or a change in the components of the drug that will greatly reduce the problem identified by the mounting adverse incident reports, but the manufacturer fails to take the corrective measure. Or, consider the scenario where subsequent testing or adverse incident reports demonstrate that the product causes far greater harm than medical benefit, yet the FDA does not act promptly to withdraw approval, and the manufacturer takes no voluntary action to cease marketing the drug or device.

These scenarios demonstrate that a manufacturer may comply with FDA reporting requirements and still, vis-a-vis doctors and the public, engage in flagrant disregard of human safety. These scenarios also demonstrate that the FDA is not always a perfect watchdog for the safety of drugs and devices, for reasons I develop in the next section of this written testimony. While S. 687 does still permit punitive damages if the manufacturer of the drug or device has falsified information given to the FDA, or failed to report required information, or has submitted misleading information by, for example, greatly downplaying risks or failing to mention adverse studies, as the above scenarios illustrate these are not the only situations that might meet the standards for punitive damages. So, why, in the scenarios described above, all of which involve behavior that should be strongly deterred, should the drug or device manufacturer be insulated

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[6] This scenario is drawn from the examples of the Dalkon Shield IUD and silicone gel breast implant devices. Even though these devices did not have to receive FDA pre-market approval, the post-marketing conduct of covering up evidence of harm, failing to take cost-effective corrective measures, and misrepresenting safety to physicians and the consuming public could easily be repeated with an FDA-approved drug or device. Prior FDA approval would hardly serve as a bar or deterrent to this sort of post-marketing misconduct.

from punitive damages? Why isn't the standard of conscious, flagrant disregard for human safety enough protection for the pharmaceutical industry, as it is for other industries?

An answer that is frequently given by advocates of insulating drug and medical device manufacturers from punitive damages is that manufacturers' fears and perceptions of runaway punitive damages may discourage them from bringing potentially lifesaving drugs to market. Members of Congress, as responsible makers of public policy, must carefully examine the validity of such claims.[7] A recent Rand Institute for Civil Justice Report, [8] suggests that these perceptions are fueled by only three examples that are oft-repeated and distorted or blown out of proportion with each retelling. The study also concludes that the distorted perceptions about the magnitude and frequency of punitive damages are not likely to be overcome by liability policy reform. Education, more empirical research, and more responsible reporting may be more effective ways to address the distorted perceptions than to alter product liability law in ways that may reduce incentives to pay greater attention to safety.

The empirical data about the frequency, amount and circumstances of punitive damages awards in products liability cases in general, and drug or medical device cases in particular speak

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[7] An example of the need to greet claims that punitive damages are discouraging the introduction of safe and useful new products with a healthy degree of skepticism is provided by testimony that Peter Huber, the well known author and critic of the tort system, gave to this Committee in 1990. Huber claimed that Monsanto refused to bring to market a safe asbestos substitute because of fears of the liability system. Hearings on S. 1400 before the Consumer Subcommittee of the Senate Comm. on Commerce, Science, and Transportation, 101st Cong., 2d Sess. 340 (1990). What Huber failed to reveal, however, is that test animals injected with this supposedly safe product developed sarcomas, and that Monsanto's claim that this was of little or no relevance to likely effects in humans was refuted by some eminent scientists and public health experts. See Rustad, supra, 78 Iowa L. Rev. at 78-79, n. 345.

[8] Garber, "Product Liability and the Economics of Pharmaceuticals and Medical Devices," Rand Institute for Civil Justice Report No. R-4285-ICJ 1993.

clearly to the fears of the potential innovator: if your company displays the basic level of regard for public health and safety that most manufacturers do indeed exhibit, and engages in scientifically adequate testing and follows up on evidence of risk, and does not commit fraud, falsify data or submit misleading summaries of data, and does not cover up mounting evidence of safety hazards and serious injuries, and does take inexpensive remedial or warning action in the face of mounting and compelling evidence of serious injuries, then your company does not have any reasonable fears of punitive damages awards.

B. The Proposal to Cut Off Punitive Damages in Most Instances of FDA Approval Eliminates an Important Safety Valve When Regulatory Oversight is Too Slow or Fails

One reason for the traditional tort rule that regulatory approval does not preempt tort liability is the recognition that regulatory agencies may themselves not always be the most effective guarantors of public safety, and that tort liability can serve as an important check, or additional safety valve, when the regulatory agency is strapped for resources, overwhelmed with other matters, or too slow to respond. For example, with breast implant devices, over the years of their increasing use, there was mounting evidence -- much of it gleaned from company documents through the discovery process in lawsuits-- that the manufacturers were aware that the implants could leak and rupture and that silicone leakage could have serious adverse health effects. Yet it was almost nine years after the first punitive damages verdict -- a verdict imposed because of the company's conscious failure to warn physicians or women of the known dangers and its misrepresentation of the product's safety in package inserts and promotional literature -- before the FDA convened an investigation of these devices.

In the case of the Dalkon Shield intrauterine device, the FDA in 1974 initially asked A.H.

Robins Co. to suspend marketing until the agency could review serious questions about the device's safety, but six months later the FDA allowed marketing to resume so long as Shields were registered and adverse effects were reported. Then, despite accumulating evidence of serious, sometimes fatal infections, septic abortions, perforated uteruses, and infertility, neither the FDA nor the manufacturer took any remedial action. A. H. Robins did not warn physicians, nor did it recall the product, even though it was aware that the risk to women increased the longer the device was in their bodies. Instead, the company issued press releases saying there was no reason for current users to have the device removed. It was not until ten years later, when some large punitive damages awards were issued by juries, and a federal judge strongly urged the company to contact doctors and women and remedy the danger, that the manufacturer offered to remove this deadly product from women's bodies.[9]

Another recent episode of mounting injury, a known danger, and regulatory inaction is provided by the Bjork-Shiley heart valves. The FDA approved the valves despite strong evidence of frequent breakage during clinical trials. Ten years after the FDA approval, the manufacturer had reported to the agency 248 deaths resulting from the predictable fractures of the valves. Still the FDA did nothing. This alarming situation prompted an investigation and scathing critique of the FDA by the House of Representatives Subcommittee of Oversight and Investigations of the Committee on Energy and Commerce. The report concluded that the FDA failed to heed its own staff's reports and warnings, failed actively to monitor the manufacturer and was lax in

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[9] See, e.g., Tetuan v. A. H. Robins, 241 Kan. 441, 738 P.2d 1210 (1987); N. Grant, The Selling of Contraception: The Dalkon Shield Case, Sexuality and Women's Autonomy (Ohio St. Univ. Press 1992); Richard B. Sobol, Bending the Law 10-22 (1991); M. Mintz, At Any Cost: Corporate Greed, Women, and the Dalkon Shield (N.Y. Pantheon Books 1985).

requiring it to submit information, abdicated the role of getting risk information out to doctors and patients to the manufacturer, and failed to monitor or require corrections in the misleading information distributed by the manufacturer. Staff Report, "Earn as You Learn: Shiley Inc.'s Breach of the Honor System and FDA's Failure in Medical Device Regulation," Staff Report No. 26-766, Subcommittee on Oversight and Investigations of the Comm. on Energy and Commerce, U.S. House of Representatives (February 1990).

Another sad example of regulatory failure is provided by the anti-arthritis drug Oraflex. The manufacturer Eli Lilly submitted favorable as well as unfavorable safety studies to the FDA. Due to a filing backlog in the FDA, however, FDA staff responsible for reviewing Oraflex were unaware of several clinical trial reports demonstrating serious adverse reactions to the drug. Shortly after the FDA approval, there were so many reports of such serious and sometimes fatal liver and kidney reactions that Eli Lilly had to withdraw the drug. This situation prompted a Congressional investigation, which criticized the FDA for its failure to review all the data submitted by Lilly as well as its approval of warning language submitted by Lilly that was directly contrary to adverse incident reports. House Comm. on Government Operations, "Deficiencies of FDA's Regulation of the New Drug Oraflex," H.R. Rep. 511, 98th Cong., 1st Sess. (1983).[10]

While there are certainly commendable instances in which the FDA has acted swiftly to prevent dangerous drugs or devices from injuring U.S. consumers, such as the FDA's refusal to

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[10] The failures of regulatory oversight with Oraflex and several other drugs are described in Daniel Sigelman, "Turning the Tables on Drug Companies: Exposing Deficiencies in FDA Regulation," TRIAL, March 1994 at p. 72. The author is a former counsel to the House Subcommittee on Human Resources and Intergovernmental Relations.

cave in to intense manufacturer pressure and approve thalidomide for use during pregnancy in the U.S.[11]. the instances recounted above, as well as others, illustrate the wisdom of the traditional tort approach of not automatically allowing regulatory approval to insulate manufacturers from liability for their flagrant misconduct. When the regulatory agency has proven inadequate to monitor, prevent, or correct the health threat caused by known dangers, then why should the manufacturer that has continued to market or failed to correct the dangerous drug or device be insulated from punitive damages? Why should the people injured by the continued use of the dangerous drug or device bear the burden of both the manufacturer's flagrant misconduct and the FDA's inadequacies or limited resources? Why should society be deprived of the fall back deterrent protection of punitive damages awards, which in several instances have finally been what has prompted adequate remedial action?

C. The Proposal to Curtail Punitive Damages When the FDA Has Approved a Drug or Device Presents Particularly Grave Risks to Women's Health

It is neither accidental nor coincidental that several of the instances of regulatory failure and flagrant corporate disregard for health and safety mentioned above concern products intended to be used in women's bodies or in connection with women's reproductive systems. Too many of the most tragic and preventable instances of unsafe drugs or devices have involved women's reproductive health: the FDA approved but ineffective drug D.E.S., which some have called one of the greatest public health disasters of the 20th century; the Dalkon Shield and Copper-7 IUDs; Rely super-absorbent tampons; Accutane, the FDA approved acne medication that caused severe birth defects when taken by pregnant women; Parlodel, an FDA approved lactation suppressant

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[11] See, e.g., Richard McFayden. "Thalidomide in America: A Brush with Tragedy." 11 Clio Medica 79 (1976).

that caused several maternal deaths from stroke or heart attack. There may be others predictably looming on the horizon. Many of the widely used infertility drugs, for example, despite warnings from the medical profession for the need for such testing, have not been adequately tested for possible adverse effects on any children conceived while using them, nor have they been tested for any extra health risks they may present to women already hormonally at risk because of their DES exposure, even though DES daughters are one of the largest consuming groups for infertility treatment.

Research has indicated that in several of these instances, manufacturers have been particularly lax about testing or about heeding signs of dangers or issuing warnings because women and women's health are devalued.[12] For example, in the case of the Dalkon Shield, complaints from women of severe bleeding, cramping, and searing pain were dismissed as not serious or as evidence of a woman's emotional problems, rather than as safety data that required careful investigation.[13] As indicated by the recent struggles to obtain more funding for research into women's health problems such as breast cancer, and to get women included in drug research and clinical trials, governmental entities also, unfortunately, have not always accorded women's health a high priority.

Thus for women, the tort system serves as an especially important back up or check for

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[12] See, e.g., D. Scully, Men Who Control Women's Health (Teachers College Press 1994); G. Corea, The Hidden Malpractice: How American Medicine Mistreats Women (Harper & Row updated ed. 1985); C. Muller, Health Care and Gender (Russell Sage 1990); R. Meyer, The Bitter Pill (Seaview Putnam 1983); D. Dutton, Worse Than the Disease: Pitfalls of Medical Progress (Cambridge Univ. Press 1988); M. Mintz, At Any Cost (Pantheon 1985); N. Grant, The Politics of Contraception (Ohio St. Univ. Press 1993).

[13] Mintz, supra; Grant, supra; K. Hicks, Surviving the Dalkon Shield (Teachers College Press 1994).

the sorts of invisibility or conscious neglect they sometimes suffer from medical product manufacturers or government agencies. The deterrent impact of punitive damages is sometimes all that women have to send a message to manufacturers that they must take women's health seriously and fully investigate immediate and long term risks, especially reproductive risks. In the case of several of the drugs or devices most dangerous to women's health, punitive damages have served as the necessary device for finally persuading manufacturers and the FDA to take remedial action.

For these reasons, punitive damages for flagrant disregard of health and safety in the context of drugs and medical devices are an important part of the overall scheme for protecting women's reproductive health. Even when a punitive damages claim does not go before a jury, the possibility of punitive sanctions can help encourage a swifter settlement that affords more adequate compensatory damages. The text of S. 672 states that the effect of punitive damages in raising settlement values has a detrimental effect on insurance or assets. There is absolutely no empirical support for this proposition; moreover, the bill fails to point out that even the augmented settlement value is still less than the full amount of compensatory damages that would be awarded at trial. Thus, the settlement effect of punitive damages is to make compensation for injured people more adequate, although less than complete. In the case of women's reproductive injuries, such as permanent infertility, increased settlement values send an important social signal that this is a very serious kind of harm, and one that must be given more consideration while drugs and devices are being tested and marketed. I hope that this Committee will conclude that women and their reproductive health are important enough to warrant leaving in place the deterrent role of punitive damages carefully developed by decades of tort law.

Recently, a group sponsored by the pharmaceutical industry , the Product Liability Coordinating Council (PLCC) has distributed a memo claiming that cutting back on punitive damages will help women's health because it will reduce drug manufacturers' fears of liability sufficiently so that they will do more research on women. This claim -- that cutting back on women's right to recover punitive damages from drug manufacturers that have previously demonstrated flagrant and conscious disregard for their safety will somehow help advance women's interests -- is both cynical and unsupported.[14] The reasons women have been excluded from medical research have very little to do with the tort system. Rather, women were excluded because of the assumption that men's bodies were the norm, and that the inclusion of women would complicate the data, or because of the view that including women would expand the required number of subjects and thus the cost of medical research, or because of fetal protective policies. See, e.g., V.W. Pinn, "Women's Health Research: Prescribing Change and Addressing the issues," 268 JAMA 1921-22 (1992); J.H. LaRosa and V.W. Pinn, "Gender Bias in Biomedical Research," Sept./Oct. 1993 JAMA 145; Report of the Public Health Service Task Force on Women's Health Issues, U.S. Dept. of HHS Pub. No. (PHS) 88-50206 (1988). It is not the

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[14] As an example of both the lack of support for the claim that tort law is what is keeping women out of medical research, and the cynicism of that claim, the two articles that the PLCC has been citing as supposed support for the claim that the current tort liability system forces manufacturers to exclude women from clinical trials, actually draw the opposite conclusion. Merkatz, Temple, et al., "Women in Clinical Trials of New Drugs," 329 New England Journal of Medicine 292, 295 (July 22, 1993) states: "A review of case law suggests that manufacturers have not faced substantial litigation by clinical trial participants. Liability litigation occurs mostly when an approved drug has been used in a population in whom it has not first been systematically tested." In other words, it is the exclusion of women from clinical trials that leads to liability, and not the other way around. Similarly, La Rosa and Pinn, "Gender Bias in Biomedical Research," Sept./Oct. 1993 JAMA at 149, caution about "the future costs from litigation, ... and personal suffering that could result if women are not included in studies." (emphasis in original).

inclusion of women in clinical trials that has led to liability, as the PLCC is suggesting, but rather it has been the failure to study the effects of drugs or devices on women that has led to liability. And now that NIH and FDA guidelines require the inclusion of women in medical research and clinical trials, the failure adequately to study the likely health effects of a drug or device on women is even more likely to be a factor in assessing liability for failure to test or warn. Thus, the exact opposite of the PLCC assertion that fear of liability is what keeps drug companies from adequately studying women's health is true: product liability law, including the possibility of punitive damages for flagrant disregard for women's health, is a strong factor in motivating a rational pharmaceutical company to study thoroughly the effects of drugs and devices on women.

D. The FDA Defense Would Not Allow Punitive Damages in Several Documented Instances of Serious Manufacturer Misconduct

In cases dealing with drugs or medical devices, there are several situations which have warranted punitive damages that would go unpunished and undeterred under S. 672 as currently drafted. For example, in the case of the Copper-7 intrauterine device, after FDA approval, the manufacturer became aware of reports of serious health problems suffered by women using the device. G.D. Searle failed to follow up on these reports, failed to conduct further testing, and engaged in an active advertising campaign designed to assuage any concerns doctors might have due to these adverse experiences. The advertising campaign was also designed to encourage doctors to use the device on precisely the group of women most at risk of serious or fatal infection or sterility.[15]

In the case of the Dalkon Shield and the Copper -7, while the FDA did nothing and the

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[15] See, e.g., Kociemba v. G.D. Searle & Co., 707 F. Supp. 1317 (D. Minn. 1989).

reports of dangers continued to accumulate, the manufacturers also undertook no additional warnings or remedial action such as efforts to get women to have the deadly devices removed. Similarly, in the case of breast implants, while the FDA did nothing in the face of mounting evidence of health risks and product failure, some manufacturers continued to sell and aggressively market the product without warning about the problems of leakage, rupture, and capsular contracture, and without warning physicians about the adverse studies. In other instances, while the FDA has approved a drug or device and issued guidelines for its marketing and the necessary warnings, manufacturers have knowingly failed to comply with the FDA guidelines and failed to provide the mandated warnings.[16]

S. 672 as currently drafted would not appear to allow punitive damages in these situations. For example, while it mentions withholding information from or misrepresenting data to the FDA, the bill says nothing about failure to comply with FDA guidelines or about callous inaction in the face of knowledge of danger or misrepresentation in advertising or information sent to physicians and consumers. Isn't this the sort of conduct that society wishes to deter and punish? Why should drug and medical device manufacturers who engage in this sort of gross disregard for human health and safety be insulated from punitive damages, when manufacturers of other sorts of products who show similar contempt for health and safety are appropriately punished?

If the Senate deems some sort of an FDA approval defense necessary, then S. 672 should be amended to allow punitive damages in the following situations: 1) when the defendant failed

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[16] See, e.g., Batteast v. Wyeth Laboratories, Inc., 526 N.E.2d 428 (Ill. App. 1988)($13 million in punitive damages assessed for intentional failure to provide warnings mandated by FDA about serious dangers, such s coma or death, of aminophylline suppositories for infants and small children).

to comply with any FDA requirement, including warning and labeling requirements; 2) when the defendant withheld from or misrepresented material health and safety and performance information to physicians or consumers; 3) when the defendant deliberately failed to adopt an inexpensive, cost-effective remedial measure that would have significantly reduced the danger or the risk to human life.

February 9, 1999

SENATE JUDICIARY COMMITTEE
SB 2349

CHAIRMAN STENEHJEM AND COMMITTEE MEMBERS:

My name is Jack McDonald. I'm proposing the following amendment on behalf of The North Dakota Trial Lawyers Association. The amendment was discussed during the hearing, and at that time it was our understanding the bill's sponsor, Sen. Grindberg, had no objection to it.

We respectfully request your **FAVORABLE CONSIDERATION** of this amendment. If you have any questions, I'll be happy to answer them. THANK YOU FOR YOUR TIME AND CONSIDERATION.

PROPOSED AMENDMENTS TO SB 2349

On page 2, after line 2, insert:

"d. Failed to warn or protect against a danger or hazard in the use, misuse or unintended use of any product or device, or failed to provide proper instructions for the use of any product or device."

Renumber accordingly

Greater North Dakota Association

Testimony in Support of SB 2349
House Judiciary Committee
March 9, 1999

Mr. Chairman, members of the committee:

My name is Joy Johnston. I am the Executive Director of the Manufacturers and Processors Division of the Greater North Dakota Association. Today I am testifying in favor of SB 2349 on behalf of GNDA, its divisions and the Economic Development Association of North Dakota.

The Greater North Dakota Association is the North Dakota Chamber of Commerce. GNDA is the voice of business and principal advocate for positive change for North Dakota.

The Economic Development Association of North Dakota, formerly known as the Industrial Development Association, has a membership of professional developers, banks, utility companies and other entities committed to enhancing the standard of living of North Dakotans by encouraging economic development opportunities. GNDA is a member of the Economic Development Association of North Dakota.

The manufacture of medical devices is an industry that North Dakota is attempting to attract to the state. Medical device manufacture is a target industry for North Dakota according to experts from the Enhancing Growing North Dakota Study commissioned by the North Dakota Department of Economic Development and Finance.

The study was conducted by Flour-Daniel and Arthur Anderson. The consultants held meetings throughout the state using the Vision 2000 model. Many of you participated in those community meetings. The consultants conducted interviews with North Dakota business owners, entrepreneurs who decided to start businesses in North Dakota, entrepreneurs who decided not to come to North Dakota after studying the business climate of the state and businesses who decided to leave North Dakota. The consultants analyzed the resources and barriers of North Dakota's economy. Using information that illustrates the economic trends of the globe and filtered to North Dakota, the study pinpointed some target industries that North Dakota was in the right position to take on as potentially successful ventures. Medical device manufacture is one.

North Dakotans in the Enhancing Growing North Dakota Progress Report were very honest about identifying what we want and what may be stopping us from achieving those goals. We know we need to diversify the economy in North Dakota. But diversification has to come by increasing the standard of living in North Dakota. More succinctly we don't just want jobs; we want good paying jobs. We also know we don't

have a large labor pool to draw from for those jobs. We acknowledge our education system is excellent, but we need to concentrate more in the high skilled technical areas.

How does SB 2349 factor into this?

SB 2349 extends the progressive pro-manufacturing business climate to the medical device manufacture industry. Medical device manufacturers are small companies in size of number of employees. North Dakota isn't looking for large factories. However, medical device manufacture companies use a high skilled, highly compensated workforce. North Dakota urban or rural could attract the medical device manufacture industry.

The North Dakota legislature has enacted some of the most progressive tort reform in the US. SB 2349 extends the same progressive reform to the medical device industry.

Section 2 of SB 2349 provides an extra consumer protection standard that is not listed in NDCC 32-03.2-11. There is no defense against exemplary damages under SB 2349 if the manufacturer failed to comply with the FDA's investigation and correction of defects in design or manufacture of a medical device if the failure to comply has caused the plaintiff harm.

The legislature provided the aircraft manufacture industry progressive product liability law in 1995. It provided aviation manufacturer products liability law under NDCC 28-01.4. It enabled the insurance industry to provide aftermarket coverage of tort exposure under North Dakota law at NDCC 26.1-48. North Dakota can point to new companies in the state because of the work by the legislature. Cirrus Industries in Grand Forks and Dakota Aero in Devils Lake are new ventures with high wage jobs.

SB 2349 can do the same for medical device manufacture. It provides limited punitive damage protection for a product manufacturer but does not eliminate the ability for a claim due to negligence by a company. Punitive damages are the damages awarded above and beyond actual damages and pain and suffering. These are the "punishment" damages for companies who do egregious acts or refuse to rectify something they know will injure people. SB 2349 disallows punitive damages for a company that complies with FDA regulations.

GNDA, its divisions and EDND urge the House Judiciary Committee to recommend a "do pass" to SB 2439.

Sec. 355. New drugs

- (a) Necessity of effective approval of application
  No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

- (b) Filing application; contents
  - (1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).
  - (2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include -
    - (A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section -
      - (i) that such patent information has not been filed,
      - (ii) that such patent has expired,
      - (iii) of the date on which such patent will expire, or
      - (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
    - (B) if with respect to the drug for which investigations

described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

- (3)
  - (A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to -
    - (i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and
    - (ii) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.
  - (B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.
  - (C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.
- (4)
  - (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.
  - (B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.
  - (C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except -
    - (i) with the written agreement of the sponsor or applicant; or
    - (ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

- (D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.
- (E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.
- (F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.
- (G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of title 42 (including all scientific and medical matters, chemistry, manufacturing, and controls).

- (c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order
  - (1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either -
    - (A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or
    - (B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.
  - (2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information

under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

- (3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:
  - (A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.
  - (B) If the applicant made a certification described in clause
    - (iii) of subsection (b)(2)(A) of this section, the approval may be made effective on the date certified under clause (iii).
  - (C) If the applicant made a certification described in clause
    - (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that -
      - (i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,
      - (ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or
      - (iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

      In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28 for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.
  - (D)

- (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b) of this section.
- (ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) of this section before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under subsection (b) of this section after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A) of this section. The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.
- (iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations

(other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

- (iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty [1] studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.
- (v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

- (4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the

drug.

- (d) Grounds for refusing application; approval of application; "substantial evidence" defined
  If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that
  - (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

- (e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health
  The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of

which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: Provided, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or

- (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or
    - (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

- (f) Revocation of order refusing, withdrawing or suspending approval of application
  Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

- (g) Service of orders
  Orders of the Secretary issued under this section shall be served
    - (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

- (h) Appeal from order
  An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United

States court of appeals or the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

- (i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary
  - (1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon -
    - (A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;
    - (B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and
    - (C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or

the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section.

- (2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including -
  - (A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and
  - (B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.
- (3)
  - (A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.
  - (B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that -

- (i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

- (ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).
  - (C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.
    - (4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is

not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

- (j) Abbreviated new drug applications
  - (1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.
  - (2)
    - (A) An abbreviated application for a new drug shall contain -

- (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

- (ii)
  - (I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;
  - (II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or
  - (III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

- (iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

- (iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the

application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

- (v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

- (vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

- (vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section -
    - (I) that such patent information has not been filed,
    - (II) that such patent has expired,
    - (III) of the date on which such patent will expire, or
    - (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

- (viii) if with respect to the listed drug referred to in clause

- (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use. The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

- (B)
    - (i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to -

- (I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

- (II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

- (ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

- (iii) If an application is amended to include a certification described in subparagraph (A)(vii) (IV), the notice required by clause (ii) shall be given when the amended application is submitted.
    - (C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds -

- (i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

- (ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

- (3)
    - (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.
    - (B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.
    - (C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the

testing begins, except -

- (i) with the written agreement of the sponsor or applicant; or
- (ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.
    - (D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.
    - (E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.
    - (F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.
    - (G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).
        - (4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds -
    - (A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;
    - (B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;
    - (C)
        - (i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;
        - (ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or
        - (iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show -
    - (I) that the other active ingredients are the same as the active ingredients of the listed drug, or
    - (II) that the different active ingredient is an active

ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title, or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

- (D)
  - (i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or
  - (ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);
- (E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;
- (F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;
- (G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;
- (H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;
- (I) the approval under subsection (c) of this section of the

listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

- (J) the application does not meet any other requirement of paragraph (2)(A); or
- (K) the application contains an untrue statement of material fact.
- (5)
  - (A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.
  - (B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

- (i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

- (ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

- (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that -
  - (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,
  - (II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall

be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or

- (III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

  In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

- (iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after -
  - (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
  - (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

    whichever is earlier.
  - (C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.
  - (D)
    - (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

- (ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.
- (iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.
- (iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.
- (v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.
    - (6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or

suspended -

- (A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or
- (B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

- (7)
  - (A)
    - (i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public -
  - (I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;
  - (II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and
  - (III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

- (ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

- (iii) When patent information submitted under subsection (b) or
  - (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.
    - (B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.
    - (C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list -

- (i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

- (ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons. A notice of the removal shall be published in the Federal Register.

- (8) For purposes of this subsection:
  - (A) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.
  - (B) A drug shall be considered to be bioequivalent to a listed drug if -

- (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

- (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.
  - (9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of -
    - (A) the name of the applicant,
    - (B) the name of the drug covered by the application,
    - (C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and
    - (D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment. The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.
      - (k) Records and reports; required information; regulations and orders; access to records
  - (1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar

information received or otherwise obtained by the Secretary.

- (2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.
  - (l) Public disclosure of safety and effectiveness data
    Safety and effectiveness data and information which has been submitted in an application under subsection (b) of this section for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown -
- (1) if no work is being or will be undertaken to have the application approved,
- (2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,
- (3) if approval of the application under subsection (c) of this section is withdrawn and all legal appeals have been exhausted,
- (4) if the Secretary has determined that such drug is not a new drug, or
- (5) upon the effective date of the approval of the first application under subsection (j) of this section which refers to such drug or upon the date upon which the approval of an application under subsection (j) of this section which refers to such drug could be made effective if such an application had been submitted.
  - (m) "Patent" defined
    For purposes of this section, the term "patent" means a patent issued by the Patent and Trademark Office of the Department of Commerce.
  - (n) Scientific advisory panels
- (1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under this section or section 262 of title 42, the Secretary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.
- (2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.
- (3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of -
  - (A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;
  - (B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;
  - (C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

- (D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

- (4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.
- (5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.
- (6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, for persons in the Government service employed intermittently.
- (7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.
- (8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

Footnotes

[1] So in original. Probably should be "bioavailability".