

NATIONAL ORTHOTICS MANUFACTURERS ASSOCIATION

**TESTIMONY BEFORE THE COMMITTEE ON PROFESSIONAL LICENSURE OF THE
PENNSYLVANIA HOUSE OF REPRESENTATIVES REGARDING H.B. 2015**

March 19, 2008, 10:00 AM

**418 Main Capitol Building
Harrisburg, PA**

My name is Richard Rafferty, and I am the Group Product Manager of EBI, LP dba Biomet, Inc., a manufacturer of orthotic devices. EBI is headquartered in Parsippany, New Jersey. We have over 1100 employees, many of whom are Pennsylvania residents. Today, I am testifying on behalf of the National Orthotic Manufacturers Association or "NOMA." I would like to begin by thanking the Committee for the opportunity to discuss House Bill 2015.

My focus today is on the importance of providing an exception under the licensing regime for representatives of orthotics manufacturers to measure and fit these devices under the supervision of a physician or other licensed health care professional. The Bill currently does not contain such an exception.

NOMA is a national trade association of FDA-regulated manufacturers of orthotic devices. Our members manufacture and sell thousands of devices in the Commonwealth, and we work alongside physicians and other health care professionals to provide orthotic devices to Pennsylvanians. In fact, approximately 50 of our manufacturers' representatives call Pennsylvania home.

NOMA's member companies produce a wide range of technologically advanced orthotic devices, and each of our members takes great pride in the high quality of its products. Our members make both "custom fitted"—that is, adapted from components that are adjusted as needed to fit the patient—or "custom fabricated" products, which means that the device was built specifically for a particular patient based on that patient's exact needs. Ultimately, our members' products benefit patients in Pennsylvania and the rest of the United States by providing a major therapeutic approach to a wide variety of diseases and disabilities.

My comments today are limited to the provisions of HB 2015 with respect to the practice of orthotics. NOMA has no position regarding the bills's applicability to prosthetics and pedorthics. NOMA opposes HB 2015 in its current form for two reasons. First, we would respectfully point out that the vast majority of states do not have a license requirement for orthotists. It is doubtful that patients benefit from the licensing requirements that are in effect in a few states. These licensing requirements tend to limit competition, reduce treatment options for physicians and drive up costs. Second, even if the state decides to adopt a licensing requirement, it should not apply to the kinds of activities in which NOMA's manufacturers' representatives are engaged.

In particular, we urge the legislature to add an amendment that allows manufacturers' representatives to measure, fit and adjust orthotics under the supervision of a physician or other licensed health care professional. This amendment would allow NOMA's representatives to

provide significant benefits to physicians and patients. The states that have adopted licensing requirements over the last few years, including Alabama, Oklahoma, Georgia, Tennessee, and Arkansas, have included such exemptions in their statutes.

Today, physicians in Pennsylvania must prescribe an orthotic device in order for the patient to have access to one. Although the physician is the only professional qualified to prescribe such a device, the patient has to be measured and fitted for the device as well. In order to measure and fit the device, physicians now have the option to refer patients to an independent orthotist, to rely upon their own staff, or to rely upon manufacturers' representatives to measure and fit patients for orthotic devices in the physician's office, usually during the same visit. Thus the choice for fitting the device currently rests with the physician. HB 2015 would take this choice away from physicians.

Allowing the patient to be measured and fitted in the physician's office can avoid a great deal of inconvenience and cost for the patient, particularly an elderly or disabled person, who might find it exceedingly difficult to travel from his or her physician's office to an orthotist's office, which might be located in another city. In deciding who should measure and fit a device, the physician plays the role of gatekeeper. If he feels that an orthotist needs to see the patient, he has the option to refer the patient to one. If she feels that the patient can have the device measured and fitted in the doctor's office, she has that option. Thus, the interests of the patient are protected under our proposed amendment.

NOMA members' representatives have completed extensive, specialized training, testing and quality assurance programs. They are required to develop an expertise in their products and to understand the safest and most effective ways to use them. However, they do not make clinical or medical decisions. Instead, they work under the supervision of a licensed physician or health care professional and provide the devices requested by the physician.

It is important to recognize that an orthotist's scope of practice under the current bill would be much broader than the activities of a manufacturer's representative contemplated by our proposed amendment. Under our proposed amendment, manufacturers' representatives would be limited to measuring, fitting and adjusting orthotics under the supervision of a licensed physician or other healthcare professional. On the other hand, a licensed orthotist could also evaluate, design, fabricate, assemble, and service orthotics, and such actions need not be supervised by anyone.

It is also important to keep in mind that there will be not be licensed orthotists in every community in Pennsylvania. Based on the information we have regarding certified orthotists, many communities, particularly in rural areas, have no certified orthotists. Thus, patients would have to travel to another city to find one. If the legislature imposes a licensing requirement on NOMA's manufacturing representatives, the overall effect will be to prevent them from providing services that now benefit physicians and patients. Some of them may not be able to obtain a license because of education requirements and even those who have the necessary educational requirements would be forced out of the marketplace for a significant period in order to comply with unnecessary and pointless licensing requirements.

We hope the Committee will include an exception to the proposed orthotist licensing requirement that allows manufacturers' representatives to measure, fit and adjust orthotics under

the supervision of a licensed physician or other healthcare professional. Such an exception would benefit patients and physicians in the Commonwealth, because it would allow our members to provide the low cost and high quality products and services that patients and health care providers have come to depend on.

Thank you for the opportunity to provide testimony before the Committee on this legislation. At this time, I would be happy to answer any questions you may have pertaining to my presentation.

[Please see attached letters from Pennsylvania physicians in support of an exception for manufacturers' representatives to measure and fit orthotic devices under the supervision of a physician or other healthcare professional.]

The Honorable P. Michael Sturia
Majority Chairman, Professional Licensure Committee
Pennsylvania House of Representatives
333 Main Capitol Building
P.O. Box 202096
Harrisburg, PA 17120-2096

Re: HB 2015—Prosthetist and Orthotist Licensure Requirements

Dear Chairman Sturia:

As you are aware, Representative Mario Scavello has introduced HB 2015, a bill that would require all orthotists, prosthetists and pedorthists in Pennsylvania to obtain a state license. I understand that your committee plans to have a hearing on HB 2015 in March. I am writing to express my support for a revision to the bill that would not require licensure for orthotics manufacturers' representatives, such as those who measure, fit and adjust orthotics for patients in my office. This exemption is important to ensure that Pennsylvanians have access to quality, low-cost orthotics and to preserve an important treatment option for physicians.

As a practicing orthopedic physician, I treat many of Pennsylvania's disabled and injured persons, and I have significant experience diagnosing those physical conditions that require the use of an orthotic device. As part of my practice, I rely on representatives of orthotics manufacturers to measure and fit patients for these devices in my office under my direction and supervision. These representatives are well-qualified to perform the relatively straightforward tasks of measuring and fitting devices. However, these representatives do not make any clinical or medical decisions and only provide those devices and services that I request. Given the nature of my patients' physical limitations, the ability to rely on representatives in my office means that physically impaired individuals can avoid the hardship associated with making several office trips, traveling farther to find a specified orthotist and waiting longer to receive much-needed orthotics. On the other hand, if I feel that it is necessary for the patient to see an orthotist, I have the option to refer them to one. Preserving these treatment options gives physicians flexibility in deciding what is the most appropriate approach for our patients.

My experience with these representatives has been very good, and I do not believe a licensing requirement for these individuals is needed. As such, I would like to express my strong support for including an exemption for manufacturers' representatives in any bill requiring the licensure of orthotists.

Sincerely,



Fredric Kleisbart, MD

The Honorable P. Michael Sturla
Majority Chairman, Professional Licensure Committee
Pennsylvania House of Representatives
333 Main Capitol Building
P.O. Box 202096
Harrisburg, PA 17120-2096

Re: House Bill No. 2015

Dear Chairman Sturla:

It has come to my attention that your committee plans to hold a hearing in March on a bill—House Bill 2015—that would require orthotists, prosthetists and pedorthists to obtain a Pennsylvania state license. As a practicing orthopedic physician in Pennsylvania, I wish to indicate my strong support for an exception for orthotics manufacturers' representatives to any requirement that orthotists be licensed by the state. In my practice, I treat those injuries and disabilities that require the use of an orthotic device and have become highly familiar with how these devices work. I depend upon manufacturers' representatives to measure, fit and adjust orthotics to my patients in my office under my supervision. I find these representatives to be well-qualified experts in how orthotics work and how they should be applied and fitted. They are skilled professionals who perform all tasks under my supervision. All clinical decisions are left to me, and only those devices that I prescribe are used.

When a patient presents a medical problem and I have determined that he or she requires an orthotic device, I write a prescription for the device and the representative measures, fits and adjusts the device for the patient right there in my office. Otherwise, my patient would be required to take the prescription to an orthotist, who could be many miles away or in another city altogether. Once the orthotist has measured my patient, he or she would order the device, have the patient wait several days for the device to arrive, and then require the patient to return for fitting and adjustment. As a result, a patient could make several trips to several offices for one device. Using manufacturers' representatives allows my patients to be treated for their injuries or disabilities directly in my office and has saved my patients countless hours of inconvenient and medically difficult travel to and from an orthotist. I still have the option, however, of sending a patient to an orthotist if I consider it to be medically necessary.

I have had only the best experiences with representatives of orthotics manufacturers, and I would ask that you support this helpful treatment option by exempting these representatives from any state orthotist licensure requirement. This will ensure that my disabled and injured patients receive the best, most convenient care.

Yours truly,

Parath Maenpaa MD
PARATH MAENPAA
MD

The Honorable P. Michael Sturla
Majority Chairman, Professional Licensure Committee
Pennsylvania House of Representatives
333 Main Capitol Building
P.O. Box 202096
Harrisburg, PA 17120-2096

Re: **House Bill 2015: An Act Regulating the Right to Practice Prosthetics,
Orthotics and Pedorthics**

Dear Chairman Sturla:

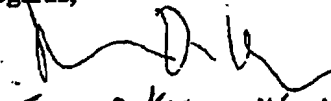
I understand that legislation has been introduced by Representative Mario Scavello (House Bill No. 2015) that would require all orthotists, prosthetists and pedorthists practicing in Pennsylvania to obtain a license from the state. I also understand that the Professional Licensure Committee intends to hold a hearing on this bill in March. I am writing to ask that you include an exemption from any licensure requirement that would permit representatives of orthotics manufacturers to measure, fit and adjust orthotics under the supervision of a physician or other healthcare professional without being licensed. I depend on these representatives to assist me in my practice, and I believe that exempting representatives from any licensure requirement would maintain a highly useful option that is beneficial to Pennsylvanians who require orthotics as treatment for their disabilities or injuries.

I am a practicing orthopedic physician, and many of my patients include individuals who are disabled or who suffer from musculoskeletal injuries. As part of my practice, I am very familiar with the treatment of those conditions that require orthoses as well as how such products should be applied and used by my patients. I use manufacturers' representatives in my office (under my supervision) to measure and fit patients for orthoses on a regular basis. I find these representatives to be very well-qualified and highly skilled in performing these tasks. Importantly, because all measuring or fitting performed by a representative is done under my supervision, I maintain responsibility for all clinical decisions with respect to the prescribing of any orthotic device.

I would also like to point out that the use of a manufacturer's representative in my office has saved many of my patients from making inconvenient and difficult trips to an orthotist's office in order to be fitted with an orthosis. Relying on representatives saves my patients a significant amount of time and allows them to avoid waiting to receive orthotics from an orthotist after an initial visit and fitting session. Notably, however, using a manufacturer's representative directly in my office allows me to retain the flexibility to determine the best treatment approach for my patients. If I feel that it is necessary in my medical opinion, I can still send my patients to an orthotist instead of using the manufacturer's representative.

In conclusion, I would like to express my support for exempting manufacturers' representatives from any licensure requirement for orthotists in an effort to ensure that physicians like myself retain the flexibility necessary to treat my disabled or injured patients.

Warm regards,


James J. Kelly, IV, MD

The Honorable P. Michael Sturla
Majority Chairman, Professional Licensure Committee
Pennsylvania House of Representatives
333 Main Capitol Building
P.O. Box 202096
Harrisburg, PA 17120-2096

Re: **House Bill 2015: An Act Regulating the Right to Practice Prosthetics,
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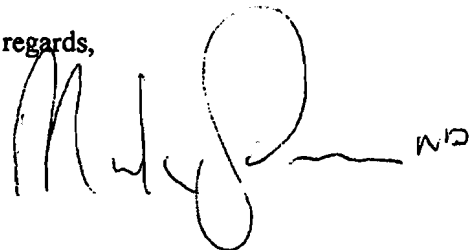
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In conclusion, I would like to express my support for exempting manufacturers' representatives from any licensure requirement for orthotists in an effort to ensure that physicians like myself retain the flexibility necessary to treat my disabled or injured patients.

Warm regards,

A handwritten signature in black ink, appearing to read "P. Michael Sturla", with a small "MS" monogram to the right.

The Honorable William F. Adolph, Jr.
Minority Chairman, Professional Licensure Committee
Pennsylvania House of Representatives
110 Ryan Office Building
P.O. Box 202165
Harrisburg, PA 17120-2165

Re: **House Bill 2015: An Act Regulating the Right to Practice Prosthetics,
Orthotics and Pedorthics**

Dear Chairman Adolph:

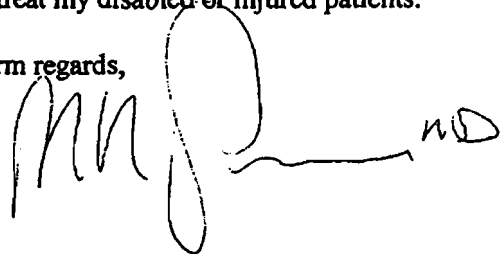
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I am a practicing orthopedic physician, and many of my patients include individuals who are disabled or who suffer from musculoskeletal injuries. As part of my practice, I am very familiar with the treatment of those conditions that require orthoses as well as how such products should be applied and used by my patients. I use manufacturers' representatives in my office (under my supervision) to measure and fit patients for orthoses on a regular basis. I find these representatives to be very well-qualified and highly skilled in performing these tasks. Importantly, because all measuring or fitting performed by a representative is done under my supervision, I maintain responsibility for all clinical decisions with respect to the prescribing of any orthotic device.

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In conclusion, I would like to express my support for exempting manufacturers' representatives from any licensure requirement for orthotists in an effort to ensure that physicians like myself retain the flexibility necessary to treat my disabled or injured patients.

Warm regards,

A handwritten signature in black ink, appearing to be 'WFA', with a long horizontal flourish extending to the right. The signature is written over the 'Warm regards,' text.

The Honorable William F. Adolph, Jr.
Minority Chairman, Professional Licensure Committee
Pennsylvania House of Representatives
110 Ryan Office Building
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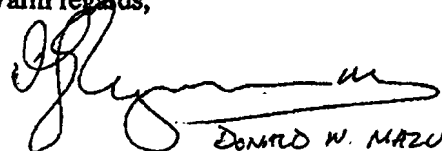
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I am a practicing orthopedic physician, and many of my patients include individuals who are disabled or who suffer from musculoskeletal injuries. As part of my practice, I am very familiar with the treatment of those conditions that require orthoses as well as how such products should be applied and used by my patients. I use manufacturers' representatives in my office (under my supervision) to measure and fit patients for orthoses on a regular basis. I find these representatives to be very well-qualified and highly skilled in performing these tasks. Importantly, because all measuring or fitting performed by a representative is done under my supervision, I maintain responsibility for all clinical decisions with respect to the prescribing of any orthotic device.

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In conclusion, I would like to express my support for exempting manufacturers' representatives from any licensure requirement for orthotists in an effort to ensure that physicians like myself retain the flexibility necessary to treat my disabled or injured patients.

Warm regards,


DONALD W. MAZUR MD

The Honorable William F. Adolph, Jr.
Minority Chairman, Professional Licensure Committee
Pennsylvania House of Representatives
110 Ryan Office Building
P.O. Box 202165
Harrisburg, PA 17120-2165

Re: Orthotist Licensure Requirements (HB 2015)

Dear Chairman Adolph:

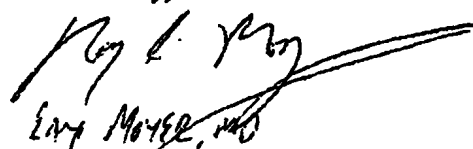
I understand that the Pennsylvania House of Representatives' Professional Licensure Committee intends to hold a hearing in March on House Bill No. 2015 (introduced last year by Representative Scavello) that, if enacted, would require orthotists, prosthetists and pedorthists in the state to obtain a license. I am a practicing orthopedic physician in Pennsylvania, and I am writing to express my support for the exemption of orthotics manufacturers' representatives from any state law that would require orthotists to be licensed. As part of my practice, I depend upon manufacturers' representatives to measure, adjust and fit orthotics to my patients, which include many Pennsylvanians suffering from musculoskeletal injuries or disabilities. These representatives, who operate in my office under my direct supervision, do not make any clinical assessments and give me a treatment option that provides my patients with the high-quality, convenient care.

As an orthopedic physician, I am highly familiar with the types of injuries and disabilities that require the use of an orthotic device. I am also highly familiar with how these devices work to treat musculoskeletal problems. I find representatives to be well-qualified experts who also have significant knowledge of how orthoses work and how they should be applied and fitted. They are skilled professionals who perform all measuring and fitting under my supervision and make no clinical decisions. In short, they provide only those devices that I have prescribed.

In addition, using representatives allows my patients to obtain treatment for their injuries or disabilities without traveling to an orthotist's office to fill a prescription that I have written for an orthotic device. Traditionally, to obtain an orthotic device, I would assess a patient and write a prescription for an orthosis. The patient would take this prescription to an orthotist's office to be measured for a device. This could take days and could require my patients to travel many miles away, sometimes to another county. After being measured, the orthotist would order the device, have the patient return at a later date and then fit and adjust the device to the patient. As a result, a patient would be required to make several trips to more than one office for a device. By using manufacturers' representatives, patients quickly obtain orthoses in my office without having to travel an inconvenient distance or wait a significant period of time. I still have the option, however, of sending a patient to an orthotist if I consider it to be medically necessary.

Based on these reasons, I would ask that you exempt manufacturers' representatives from any licensure requirement for orthotists in an effort to ensure that my disabled or injured patients receive the most convenient, most effective care.

Sincerely,


Eric Meyer, MD