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Measuring Economic Effects of Technical Barriers to Trade on U.S. Exporters

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Measuring Economic Effects of Technical Barriers to Trade on U.S. Exporters

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PREFACE

As international agreements have brought down traditional barriers to trade, such as tariffs, concern has grown about the possible economic effects of technical barriers to trade (TBTs). While there exists an international Agreement on Technical Barriers to Trade, definitions of what constitute TBTs tend to be amorphous and can be difficult to apply in practice. In addition, there is no established methodology for evaluating the economic effects of TBTs.

RAND undertook a study for the National Institute of Standards and Technology on the economic effects of TBTs. This document provides a definitional foundation for the analysis, presents results from preliminary assessments of the pharmaceutical and automotive industries, reviews the current state of measurement methodologies, and develops and applies a framework for estimating the costs of TBTs to U.S. exporters.

The document should be of interest to individuals engaged in collecting information on TBTs for government or industry purposes, economists interested in issues of international trade, current and potential U.S. exporters, and to anyone interested in evaluating the economic costs of TBTs.

This study is being performed under the auspices of RAND Science and Technology (S&T). RAND S&T conducts research and analysis that helps government and corporate decisionmakers address opportunities and challenges created by scientific innovation and rapid technological change. Our work stretches from emerging energy technologies to global environmental change to still other endeavors seeking a better understanding of the nation's scientific enterprise and how best to nurture it. Focal points of RAND S&T work include energy, the environment, information technology, aerospace issues, technology and economic development, bioethics, advanced materials, and "critical" technologies for industries and occupations.

RAND S&T serves a variety of clients, including federal, state, and local government agencies, foreign governments, foundations, and private organizations. Our team has a wide range of expertise and includes

physicists and geophysicists; chemists and geochemists; electrical, chemical, mechanical, and information technology engineers; biological and environmental scientists; and economists and other social scientists.

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SUMMARY

The research documented in this report explores means for determining the economic costs to U.S. exporters of technical barriers to trade (TBTs). Though TBTs – and allegations of TBTs – have grown more common as other tariff and non-tariff barriers to trade have decreased, the issues surrounding them are complex enough to make analysis a difficult task. The project we conducted was intended to provide a foundation for further development and exploitation.

TBTs arise from the intersection of two interests. Governments pass laws, issue regulations, and enforce measures for assuring compliance with these laws and regulations in order to pursue a variety of goals related to public welfare. Industries agree to sets of standards that facilitate the integration of products into networks and production processes, thereby increasing economic efficiency. These standards may also serve to help consumers to compare products and to assure them concerning product quality.

Yet, technical regulations, standards, and conformity assessment procedures (we refer to these collectively as "technical measures") may also affect international trade. The existence of technical measures could enhance the flow of goods by providing reassurance to potential foreign purchasers. More frequently, technical measures create additional hurdles for current and potential exporters to overcome by raising the costs of producing export-oriented goods. To the extent that such a measure or its application discriminates against foreign producers or is more trade restrictive than needed to fulfill a legitimate policy objective, it may constitute a TBT.

All members of the World Trade Organization (WTO) are bound by an Agreement on Technical Barriers to Trade. That agreement tries to ensure that technical measures do not create unnecessary obstacles to trade. However, it can be difficult to show conclusively that such technical measures are indeed discriminatory or not legitimately founded. The difficulty of assessing whether a technical measure is a

TBT underscores the need for more information and data on the role of technical measures in international trade, and for analytical tools to interpret those data.

This report presents results from a project intended to determine where such information lies, how it might be acquired, and how this information might be used to evaluate and estimate the economic effects of TBTs. It provides a definitional context and proposes criteria for identifying TBT-like practices. It also presents preliminary assessments of technical measures that may act as TBTs in two important U.S. export industries: pharmaceuticals and automotive products. These industry assessments seek evidence of TBT-like practices by relating the proposed criteria to allegations of questionable technical measures. The report then reviews the current state of practice in measuring the potential effects of TBT-like practices. We conclude by developing and applying a framework designed to calculate the upper bound costs to U.S. exporters resulting from an alleged TBT while also seeking to isolate the TBT effect from the wider assortment of effects usually included in other measuring systems.

DEFINITIONS

The WTO Agreement on Technical Barriers to Trade (the "Agreement") does not define "TBTs" per se. Rather, it defines acceptable behavior and specifies that technical measures must be applied in a non-discriminatory fashion. It recognizes the legitimacy of trade-affecting technical measures in some instances and sets ground rules for establishing and maintaining them. The TBT Agreement allows for diversity: members are encouraged, but not required to adopt international standards. The emphasis of the Agreement is on appropriate preparation, adoption, and application of regulations and standards and avoidance of unnecessary obstacles to trade. Unlike its companion WTO Agreement on the Application of Sanitary and Phytosanitary Measures, the TBT Agreement treats so-called "sound science" as an element for consideration, but not a fundamental basis for establishing policy. The absence of more rigorous requirements for risk assessment

under the TBT Agreement leaves considerable room for maneuver in determining the acceptability of regulations, standards, and conformity assessment procedures, including necessity.

To develop a practical definition of TBTs, we first limit the analysis to policy measures that fall under the purview of the TBT Agreement. Second, a TBT only exists or arises when a country's behavior is or becomes inconsistent with the terms of the TBT Agreement, e.g., if a technical regulation is discriminatory, if it is prepared, adopted or applied with a view to or with the effect of creating an unnecessary obstacle to international trade, or if it is more trade-restrictive than necessary.

In practice, it is often difficult to discern WTO-inconsistency. We can work toward developing a "checklist" to aid in TBT identification. The literature on TBTs suggests a set of questions:

- Is the measure or its enforcement purely cost-raising?
- Is the measure set at a level that is stronger than required to achieve a policy objective?
- Does the measure increase the profitability of domestic producers at the expense of foreign producers?
- Is a measure discriminatory in application or effect between domestic and foreign firms with respect to market access?
- Is the measure more disruptive to trade than other potentially available policy options?
- Does the measure mandate excessive caution in relation to reliable scientific measures of risk?

Alternatively, we may pose a series of outcome- and context-based questions:

- Is there a legitimate and defensible rationale for preparing, adopting and applying standards, conformity assessment procedures or technical regulations that are not based on international standards, recommendations and guides?

- Does the technical regulation, standard, or conformity assessment procedure apply equally to all suppliers regardless of national origin?
- Was the measure introduced after imports began to take an appreciable share of the local market?
- Were there domestic pressures or sources of influence leading to adoption of the regulation?
- Are the standards, conformity assessment procedures, or technical regulations unduly onerous with no opportunity for graduated application (e.g., take effect only above a reasonable number of units sold)?
- Is the net effect of the technical regulation, conformity assessment procedure or standard to prevent foreign entrants into a national market?

If the answers to several of these questions are affirmative, there is likely to be reason to engage in a more detailed investigation of whether the measure is having a deleterious effect on trade.

TWO INDUSTRIES: PHARMACEUTICALS AND AUTOMOTIVE PRODUCTS

Pharmaceutical Industry

The pharmaceutical industry by nature of its structure and output presents many preconditions for the emergence of TBTs. It is truly a global industry but one where governments also have a stake in having a large measure of local control. It is among the most highly regulated industries in all countries and the variety of its product offerings is great, making regulations truly complex. It produces high value added goods in much demand, hence a desire by others to obtain some portion of the resulting value stream for themselves. And because its products are all directed toward health, with attendant concerns about safety, the issue of defining regulatory legitimacy is far from easy.

A number of regulations and conformity assessment procedures in this industry have TBT-like characteristics. In particular, a number of

countries write regulations in such a manner that they appear to discriminate against innovative pharmaceuticals, an area in which the United States has a comparative advantage. In a number of instances, domestic manufacturers of pharmaceuticals, especially of generics, faced much less onerous regulatory approval procedures than importers of innovative drugs manufactured in the United States. In some countries, the speed of approval varies greatly between imported and domestically produced drugs. As many imported drugs are patented and patents have a limited life, speed of approval has a substantial impact on total export revenues over the life of the patent. In a number of countries, inspection procedures, requirements to test each lot imported, discriminatory requirements in terms of certification documentation and other conformity assessment procedures show characteristics of TBTs.

Automotive Industry

Although imports of automotive products usually get more media attention, in 2002 total automotive exports ran $76.5 billion or 11.2 percent or total U.S. exports.

There do appear to be a number of regulations in actual and potential U.S. automotive export markets that display TBT-like characteristics. Instances of possible product-related TBTs tend to be confined to medium-income developing countries with domestic automotive industries. By adopting their own regulations in whole or in part they make it more difficult for exports to penetrate domestic markets.

Regulations with TBT-like characteristics affecting processes were most common in the repair and service sector. Both Japan and Turkey have had regulations concerning repair services that seem unduly onerous for the public policy goals that they desire to achieve. A new potential source of TBTs may emerge from regulations on recycling in the EU. These regulations seem overly prescriptive.

Conformity assessment procedures seem to be the most numerous and tend to be the most widespread of potential TBTs to U.S. automotive exports. In some countries, an unholy alliance of customs officials and "private" certification and testing bodies has succeeded in creating conformity assessment procedures that are arbitrary and costly.

Trade in automotive products is an area where the U.S. Government will continue to find it useful to examine and monitor foreign regulations, standards, and conformity assessment procedures to ensure that they do not violate the TBT agreement.

METRICS AND MEASURES

To the extent that the pharmaceutical, automotive products, or any other industry presents evidence of TBT-like practices, the findings lead naturally to concern about effects. Quantifying the effects of TBTs poses significant challenges owing to both theoretical complexity and data scarcity. In the absence of a definitive approach to measurement, the choice of analytical framework may be driven in part by the underlying policy question.

A full reckoning would require a careful inspection of the positive and negative sides of the ledger to arrive at an overall assessment of the net effect of the measure on the economic well being or "welfare" of all market participants. A trade-affecting rule may impart effects through a simple shift of an exporter's cost curve, but it may also have broader market implications by altering the structure of domestic supply or demand.

A TBT may also convey some of the benefits associated with regulations and standards in general. For example, it may provide information or remove a safety hazard. But a strictly trade-oriented analysis would evaluate the effects of TBTs on costs, prices, and quantities, without consideration of the broader welfare implications; it might also evaluate the effects on a discrete subset of market participants, such as exporters.

However, even a narrow analysis entails complexities. The effects of TBTs can vary over time. For example, manufacturers incur a "one-time" cost when they retool production lines to meet the requirements of a new foreign regulation. They incur "recurring" costs when they certify each shipment's conformance with the regulation.

The literature describes four classes of empirical methodologies to help assess the effects of TBTs. We discuss these to better explain our eventual choice of approach:

Econometric analyses. Econometric models typically seek to explain trade flows in terms of available data on variables identified as important. Econometric approaches can provide insight into the broad relationships between technical measures and trade flows. The results of an econometric model can provide inputs to other types of analyses. However, the variables used in econometric analyses may be very crude. For example, some studies use the number of standards or regulations in a country as explanatory variables in econometric equations with no regard to the purpose or importance of the measure.

Partial equilibrium approaches. Partial equilibrium (PE) approaches can incorporate various effects, both positive and negative, to assess the net effects of particular technical measures on trade or welfare more generally. They rely on microeconomic representations of supply and demand in a specific industry or sector. They are "partial" in the sense that they do not capture spillover effects between sectors. But again, the requisite data may be hard to come by.

Computable general equilibrium (CGE) approaches. CGE approaches also hold the potential for incorporating positive and negative effects. Additionally, they can capture interactions across all sectors of an economy. However, they typically lack the capacity to accommodate the necessary details for industry-based, case study analyses.

Surveys. Descriptive statistics compiled via surveys can help fill information gaps, identify "diffuse" barriers, and provide insight into real-world issues. As in the case of an econometric analysis, they can provide data to inform other methodologies. They suffer from potential bias if firms think they may be able to influence government actions through the information they provide.

A FRAMEWORK FOR ASSESSING COSTS TO U.S. EXPORTERS

Drawing on the foregoing reviews of definitions, industry findings, and measurement methods, we develop and implement a trade-oriented PE

framework for assessing the costs of TBTs to U.S. exporters. As a foundation effort designed to be refined in later work, we sought first to provide an upper bound to the potential economic cost to U.S exporters while making certain we were measuring solely the effects from TBTs. The approach can be applied to any one of a number of industries, but it is intended for evaluating the effects of individual TBTs rather than aggregate effects.

The approach focuses on the additional cost to U.S. exporters, defining "additional" as the differential element or the part of the cost that applies only to producers residing outside the TBT-affected country. The approach does not account for the broader welfare implications of the TBT nor do we consider any of the potential benefits that a TBT could generate.

The approach is deliberately designed to emphasize accuracy and ease of practical application. As such, it requires relatively simple calculations using information on prices, quantities, and direct compliance costs along with some insight into manufacturers' responsiveness to changes in market prices. It carefully distinguishes between "one-time" and "recurring" costs and their different effects on firms' production and export decisions.

We use the approach to identify the upper bound on the costs to U.S. exporters, who may, in a limited set of circumstances, face a "worst-case" choice between the less costly of two options: (1) absorbing the full cost of a TBT, such as the costs of developing and implementing a new conformity assessment procedure or (2) pulling out of or never entering a TBT-affected market, absent a viable alternative. We estimate the costs – or losses – associated with both options. In this case, the upper bound is the lesser of the two. We conclude with a quantitative illustration by applying the methodology to an example from the automotive components industry.

CONCLUSIONS AND RECOMMENDATIONS

We found that federal agencies already gather a substantial amount of data on TBTs, some of which is readily available in extant databases.

Further, we did not find any especially helpful formal databases outside the governmental domain. In the two industries we examined we found no evidence of formal data gathering or collation on a comprehensive basis. Rather than attempt to collect new information -- likely to be of the same character as the government already collects -- it would be better for the appropriate federal agencies to use existing federal databases coupled with interviews with industry and government representatives to monitor foreign technical measures that may serve as TBTs.

Based on the availability of existing data and discussions with industry representatives, we have concluded that at this time independent surveys of industry and attempts to collate the responses into a new data facility are unlikely to be sufficiently fruitful to justify the requisite expenditures. The value of data collection efforts already underway in federal agencies could potentially be increased by providing technical guidance on the types of information necessary to identify and gauge the magnitude of alleged TBTs and providing a mechanism for assessing what this information means.

The project team was asked to provide recommendations resulting from the initial excursion represented by this project. Based on the results of the research conducted to date, we believe that implementing the following recommendations for continuing the research in any future project would provide the most additional value for NIST.

Recommendation 1: Consider the Experience of Other Industries

We recommend broadening the scope of the sectoral studies of specific U.S. industries to provide a more comprehensive overview of the prevalence and types of TBTs that cause the most concern and potential costs. This will provide better support for any results being viewed as representative. It is also an important step for attempting to provide an informed and authoritative estimate of aggregate costs. We suggest the following industries as worthy of attention:

- Electronics
- Electrical engineering
- Mechanical engineering

Recommendation 2: Build Upon Foundation Methodology

We recommend refining the methodology developed in this research to enhance its applicability to a wide range of sectors and ensure its fidelity for illuminating TBT effects within individual markets. This would involve a targeted search for the data necessary for generating approximations of TBT-related costs to U.S. exporters.

Recommendation 3: Explore Aggregation -- Cautiously

We recommend exploring the possibilities for aggregation in determining overall costs to U.S. exporters of TBTs – with a qualification. The goal would be to gain a better approximation of the costs faced by U.S. exporters across industrial sectors. Yet, attempts to do so must not reintroduce the fundamental theoretical and practical confusions this study has sought to surmount. The methodology we developed to calculate upper bounds costs of individual TBTs could not simply be "grossed up". A well-reasoned redrafting would be required.

In our two cases, automotive and pharmaceuticals, for the former there do appear to be grounds for claiming the existence of some TBT-like practices. The tasks of assessing where they lie and what they may cost U.S. exporters appear relatively straightforward. The pharmaceuticals industry, however, presents a richer variety of instances of alleged TBTs posing different kinds of analytical challenges. This provides two opposing guesses about what would be involved in an aggregation strategy for approximating TBT costs to U.S. exporters across sectors.

Recommendation 4: Embody TBT Knowledge in a User-Friendly Software Tool

We recommend encapsulating the knowledge gained in this research in a form that will provide an infratechnology for use by NIST and other federal agencies to provide an overarching framework within which to place such information, inform its collection, and suggest avenues for utilization. We propose creating an Excel-based software tool based upon the methodology to be further developed for calculating the bounds of possible costs stemming from any particular suspected or alleged TBT.

The goal is to provide for enhanced automaticity in assessment based on question-driven user protocols.

ABBREVIATIONS AND ACRONYMS

Symbol	Definition
CA	Conformity Assessment
CGE	Computable general equilibrium
DSB	Dispute Settlement Body
DSU	Dispute Settlement Understanding
ELV	End-of-Life [motor] Vehicle
EP	European Pharmacopoeia
EPA	United States Environmental Protection Agency
EU	European Union
FDA	United States Food and Drug Administration
GATT	General Agreement on Tariffs and Trade
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IPR	Intellectual property rights
IT	Information technology
ISO	International Organization for Standardization
MRA	Mutual recognition agreement
NAFTA	North America Free Trade Agreement
NHTSA	National Highway Traffic Safety Agency
NIST	National Institute of Standards and Technology
NGO	Non-governmental organization
NTAA	National Technology Transfer and Advancement Act
NTB	Non-tariff barrier
OEM	Original Equipment Manufacturer
PE	Partial equilibrium
PhRMA	Pharmaceutical Research and Manufacturers of America
SPS	Sanitary and phytosanitary
TBT	Technical barrier to trade
TRIPS	Trade Related Intellectual Property Agreement
UNECE	United Nations Economic Commission for Europe
USCAR	United States Council for Automotive Research
USTR	United States Trade Representative
WTO	World Trade Organization

I. THE NATURE AND PROBLEMS OF TECHNICAL BARRIERS TO TRADE

> *"The requirement announced [by Taiwan] in May 2001 to supply significant quantities of proprietary manufacturing ('validation') data as part of approval does not follow internationally accepted practice in this area....The requirements also treat local manufacturing in a different, more favorable, less onerous manner than foreign producers. ...Implementation of this requirement...[will] require every company to submit a minimum 50,000 pages of data per manufacturing facility per product. . . . Furthermore, and of particular concern, the ... sensitive, proprietary information will be reviewed by a third party . . . and as such protection of intellectual property becomes a concern for the industry. Failure to comply with this requirement will result in a product be*[ing] *removed from the market. . ."*[1]

PURPOSE OF THE STUDY

In a world where much is changing, one of the most visible arenas of change is trade among nations. The interest in trade policy has spread beyond the ranks of government officials and industry. Issues related to trade and its subsequent effects on economies, societies and cultures can literally bring people into the streets and create confrontations both political and, at times, physical.

This report is the result of a study undertaken for the National Institute of Standards and Technology (NIST) to examine one aspect of contemporary international trade, namely the role of so-called technical barriers to trade (TBTs). The research project was designed to assist NIST in its role of developing and disseminating infrastructural knowledge and technologies intended to support the activities of U.S. industries and of other agencies of the U.S. federal government. Applying this general charge to the area of trade, this research examines the issue of TBTs and develops through standards-related economic analyses the technical and methodological means for determining how they operate and to what effect. In this sense, the output from

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[1] Excerpt from submission of the Pharmaceutical Research and Manufacturers of America (PhRMA) for the "Special 301" Report on Intellectual Property Barriers — September 15, 2002 (http://www.phrma.org/international/special301/index.cfm)

this study is designed to inform not only NIST for purposes of planning and conducting its activities but also other interested parties and agencies that are confronting the issues surrounding TBTs.[2]

Further, under Article 10 of the World Trade Organization's (WTO) Agreement on TBTs, member states are obligated to establish national inquiry points to answer questions on regulations, standards, and conformity assessment raised by other members and their domestic interest communities. The inquiry point must also provide notification of any proposed technical regulations and conformity assessment procedures that may significantly affect trade. NIST is the central repository for standards-related information in the United States and under the TBT Agreement also serves as the U.S. Inquiry Point for technical measures concerning non-agricultural products. As such, it works with the private and public sectors to provide timely information and expertise on regulations, standards and conformity assessment.

A thorough understanding of the issues surrounding TBTs will help NIST in the performance of the crucial roles we have just discussed. The balance of this chapter will next provide a brief survey of the issues surrounding TBTs. It will conclude with an outline of the remaining chapters of this report.

THE RISE OF THE TECHNICAL BARRIERS TO TRADE ISSUE

The TBT issue has many facets and arises from the successes of efforts both to increase the volume of trade and to codify the rules for its conduct. On the one hand, there exist today powerful forces leading to the widening reach of global trade. Companies of even medium-scale may now be found carrying out operations in other countries. Where competition was once to be found locally or nationally today serious competitors for markets and contracts may often come from abroad. Perhaps most strongly, the idea of trade as mutually beneficial and

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[2] This is a theme consonant with several of the recommendations made in the National Research Council's 1995 report, *Standards, Conformity Assessment, and Trade into the 21st Century* (Washington: National Academy of Sciences).

enriching has gained a wider currency marking a pronounced change from the common perception that existed only a few decades before. The pressures, both autonomous and policy-driven, for increasing levels of international trade are great.

At the same time, there is domestic pressure for governments to take measures that address issues of health, workplace and home safety, environmental preservation, and labor protection beyond levels that had been seen previously. Government agencies routinely issue regulations, establish guidelines and adopt voluntary standards[3], and enforce measures for assuring compliance to pursue a variety of goals related to sustaining or improving public welfare.

Such technical measures[4] have the potential for affecting trade although the direction of the net effect may not be obvious. Unlike other non-tariff measures that create impediments to trade such as formal quotas or voluntary export restraints, formal economic theory recognizes that this class of potential impediments to trade does have the potential to enhance public welfare by providing public goods that might not otherwise be available. Technical measures, then, are justified as correctives to perceived market failures.

Technical measures may even be trade creating. The existence of technical measures may enhance the flow of goods by providing reassurance to potential foreign purchasers and by making imported goods closer substitutes for domestic analogues. The imposition of technical measures may not even necessarily affect exporters more adversely than importers. The imposition of measures concerning corporate average fuel economy in the United States, for example, was generally seen as

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[3] Strictly speaking, a regulation is a rule established by a government agency that has the force of law. Standards, on the other hand, are considered voluntary and often emanate from non-governmental bodies or market-driven forces. For the present, it is useful to speak of them together although the important policy and practical distinctions between the two will be highlighted in the course of this study.

[4] For convenience, in the following discussion we frequently use the term “technical measures” to encompass both regulations and standards as well as concomitant compliance assurance measures.

enhancing the position of Japanese exporters relative to domestic U.S. auto manufacturers.

On the other hand, governmental rule-making is often seen as creating an additional hurdle for potential exporters to overcome by forcing the potential exporter to make changes in products or processes to comply with regulations or by stipulating compliance testing before the exporters goods may be offered on the market. Whether enacted as discriminatory measures or merely having the effect of raising exporters' costs they are likely to affect trade.

The potential conflict between the increasing role of trade and the enhanced role for government measures is exacerbated because of the lack of a common view on what the specifics of these measures of regulatory governance should be. Technical measures and protections may have their origin in the findings of research. However, any regulatory body is ultimately operated through (and responds to) political processes so the technical measures may owe as much to cultural or social precepts as to science. Local conditions and needs, the playing out of the political process in each country, and differing levels of interpretation of scientific and other technical findings are all factors that could lead governments to adopt differing regulations, standards, and procedures for compliance. While some differences in regulations, standards, and conformity assessment procedures among countries are inevitable, to the extent that they discriminate against foreign producers or are more trade restrictive than needed to fulfill a legitimate policy objective, they may constitute a TBT.

If all market participants have to comply with a technical measure that appears to be designed to improve the common welfare, there is no a priori reason to consider it a TBT. However, there are many claims suggesting that technical rules couched as welfare measures but intended as instruments of policy to achieve other ends are becoming an increasingly important impediment to trade. That is, in addition to or under the cover of the internationally recognized legitimate purposes for enacting technical regulations, standards, and compliance procedures, there may be ulterior strategic purposes behind certain

measures – e.g., protecting domestic industries by imposing onerous costs on potential competitors from abroad or even effectively excluding them entirely by making the barriers to entry sufficiently high. This may be viewed in part as a natural concomitant of the reduced importance and legal standing of other means to protect trade or domestic markets. The allegation is that protection-seeking governments are replacing declining tariffs and quotas with technical measures to impede the sale of imported goods in domestic markets.

Unfortunately, while a technical measure may have a greater effect on exports to a given market than on domestic manufactures, it can be very difficult to show conclusively that the technical measure in question is not a legitimate means to protect consumers in the target market or is inherently discriminatory. Despite the existence of an international agreement, considerable uncertainty prevails. Even something as basic as defining precisely what constitutes a technical measure with no legitimate standing, therefore requiring modification or removal because it acts as a TBT, is left not fully resolved.[5] The difficulty in making an assessment of whether a technical measure serves as a TBT points up the need for more information and data on the role of technical measures in international trade and for analytical tools to interpret those data.

The lack of clarity surrounding TBTs and the multi-dimensional character of the issue leaves policy makers in a bind. The amount of technical detail attached to each potential instance of a TBT and the level of resources required to engage in and resolve any given problem are quite large. Yet, the question remains open: how much do TBTs enacted by U.S. trading partners cost U.S. exporters? The main agenda for this study is to develop the analytic means for addressing this issue.

OUTLINE OF THIS REPORT

The research in this report centers on reviewing and developing data sources, key concepts, and analytical tools for coming to a better

[5] This issue will be discussed at considerable length below.

understanding of the issues raised by TBTs. The discussion first provides a basic foundation on what is currently known about TBTs on the basis of policy statements, white papers and legal documents. This is laid out in the following chapter; it addresses the questions, "what is a technical barrier to trade?" and "how do we recognize a TBT when we see one?" The chapter proposes criteria for identifying TBT-like practices in foreign markets.

Next, the empirical dimensions of the TBT issue are explored through interviews with interlocutors from industry, trade associations, non-governmental bodies, U.S. government agency staff, and officials of foreign organizations. These interviews focused on TBT-related issues in two major U.S. exporting industries, pharmaceuticals and automotive products, to ensure the practical grounding of findings and recommendations. Using the operational definitions developed in the second chapter, chapters three and four provide initial assessments of conditions in these two industries. They use the proposed criteria to determine whether U.S. exporters actually encounter TBT-like trade impediments. To the extent that evidence of TBTs exists in these or any other industries, it calls naturally for an evaluation of economic effects.

Finally, the analytic dimension is explored in chapters five and six. Chapter five provides a discussion and analysis of the current state of metrics and measures derived from recent theoretical and empirical research on TBTs. It reviews the basic model types, including their benefits and limitations. Chapter six then develops a detailed framework for measuring the costs of TBTs to U.S. exporters. It presents an example of practical implementation, using the description of a proposed technical measure and data from the automotive components industry.

The final chapter, seven, provides a set of general findings and, based upon these findings, recommendations for further examination of the issues raised by TBTs.

We also attach four appendices providing definitions from the TBT Agreement, an annotated bibliography, a running inventory of existing databases on TBTs, and a list of interviewees and contacts.

II. WHAT DO WE KNOW ABOUT TBTs AND WHAT MUST BE LEARNED?

This chapter addresses issues of vocabulary, including TBT identification. It is a necessary precursor to later discussion of methodology and measures of economic cost. These themes are all closely related. Attention to vocabulary is not an academic exercise but a practical necessity. Definitions of "TBTs," technical regulations, standards, etc., matter for obvious reasons, such as legal consistency, but also for methodological development. How we define—or conceptualize—TBTs will have serious implications for how we identify them and assess their costs (Beghin and Bureau 2001).

THE WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE

The issue of TBTs has grown as a focus for international attention over the past two decades. The 1986-1994 Uruguay Round of General Agreement on Tariffs and Trade (GATT) negotiations led to the formation of the World Trade Organization (WTO). It also resulted in a specific multilateral Agreement on Technical Barriers to Trade (hereafter referred to as the "TBT Agreement" or "Agreement").

WTO members recognized the important contributions of technical measures to the efficient functioning of national economies and encouraged their development but were also cognizant that technical regulations, standards and conformity assessment procedures for products, processes and production methods (including terminology, symbols, packaging, marking and labeling requirements) may present obstacles to international trade. The TBT Agreement does not define "TBTs" per se. Rather, it defines acceptable behavior with respect to technical measures. The Agreement specifies that technical measures must be applied in a non-discriminatory fashion. However, it does not disallow trade-affecting regulations, standards, or assessment procedures. Instead, it recognizes their legitimacy in some instances and sets ground rules for establishing and maintaining them to avoid "unnecessary" obstacles to trade and discrimination against imported

products. In this way, the TBT Agreement implicitly defines TBTs indirectly as the failure to behave acceptably within the context of the Agreement.

The TBT Agreement builds on a long-standing plurilateral agreement under GATT.[6] Above all, it "tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles" to trade. Unlike its GATT predecessor, it applies to all members and extends coverage to processing and production methods. Moreover, the TBT Agreement requires that all member governments establish national enquiry points for timely information dissemination.

The WTO provides a general description of the TBT Agreement:

> The agreement recognizes countries' rights to adopt the standards[7] they consider appropriate—for example, for human, animal or plant life or health, for the protection of the environment or to meet other consumer interests. Moreover, members are not prevented from taking measures necessary to ensure their standards are met. In order to prevent too much diversity, the agreement encourages countries to use international standards where these are appropriate, but it does not require them to change their levels of protection as a result.

The Agreement sets out a code of good practice for the preparation, adoption and application of standards by central government bodies. It also includes provisions describing how local government and non-governmental bodies should apply their own regulations; normally they should use the same principles as apply to central governments.

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[6] The prior "plurilateral" agreement was negotiated under the 1973-79 Tokyo Round of the GATT. Plurilateral agreements do not apply to all WTO members, only signatories.

[7] In this description, the WTO does not delineate between *mandatory* "technical regulations" and *voluntary* "standards," as it does in the text and Annexes of the TBT agreement. Here, it uses "standards" more broadly, as a non-technical term, according to common English usage.

> The agreement says the procedures used to decide whether a product conforms to national standards have to be fair and equitable. It discourages any methods that would give domestically produced goods an unfair advantage. The agreement also encourages countries to recognize each other's testing procedures…[8]

Trade-affecting technical regulations, voluntary standards, and conformity assessment procedures stand apart from many other trade-distorting policy measures in that they hold the potential for enhancing efficiency and improving social welfare, for example by correcting market failures. For these reasons among others, WTO recognizes the legitimacy of such trade-affecting technical measures under certain circumstances. The WTO also recognizes that unique national circumstances may necessitate differences in policies across members. The TBT Agreement allows for diversity; WTO members are encouraged, but not required to adopt international standards. The emphasis of the Agreement is on appropriate preparation, adoption, and application of regulations and standards and avoidance of unnecessary obstacles to trade.

The TBT Agreement provides a highly relevant and useful frame of reference for identification and measurement, but still leaves ample room for interpretation. Moreover, owing to the possibility of efficiency enhancement, estimating the costs of these trade-affecting measures is more complex than in the case of tariffs and many other types of non-tariff barriers to trade.

WHAT ARE TBTS?

A TBT, like other non-tariff trade barriers (NTBs,) is defined partly in terms of what it is not (Deardorff and Stern, p. 4., 1997). The TBT Agreement defines mandatory "technical regulations," voluntary "standards," "conformity assessment procedures" and other key TBT-related terms in its Annex 1; it does not, however, explicitly define

[8] http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm8_e.htm#technical

"TBT" (see Appendix A for Annex 1 definitions). Instead, the Agreement defines acceptable behavior with respect to those regulations, standards, and assessment procedures, including provisions for nondiscrimination, minimum trade restrictiveness, and transparency. For example, regarding technical regulations—essentially, mandatory standards—and central governments, the TBT Agreement specifies:

> 2.1. Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.
>
> 2.2. Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.
>
> 2.3. Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.
>
> 2.4. Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an

> ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

As implied in paragraph 2.2, the TBT Agreement recognizes the legitimacy of technical regulations, standards, and conformity assessment procedures as domestic policy instruments for correcting market failures, internalizing externalities, protecting national security, etc. Thus, WTO members are permitted to establish and maintain some trade-affecting measures if they meet the agreed criteria of the TBT Agreement.

In paragraphs 2.4 and 2.5, WTO members are encouraged, but not required to adopt international standards. A country's regulations and standards may differ from internationally derived mechanisms if domestic conditions necessitate; unique national circumstances may require unique policy responses. However,

> Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph [2.2], and is in accordance with relevant international standards it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.[9]

The explicit presumption of acceptability may create an additional incentive to adopt international standards.

Examining the TBT Agreement in the light of the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures (the "SPS Agreement") demonstrates another way in which TBTs are defined partly by what they are not. The TBT Agreement applies to all industrial and agricultural products, but, as noted in Article 1, Paragraph 5 of the

[9] TBT Agreement, paragraph 2.5.

Agreement, it does not apply to SPS measures. In particular, the SPS Agreement covers any measures applied:[10]

- To protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food;
- To protect human life from plant- or animal-carried diseases;
- To protect animal or plant life from pests, diseases, or disease-causing organisms;
- To prevent or limit other damage to a country from the entry, establishment or spread of pests.

Clearly, these two areas of WTO doctrine cover related terrain. Not surprisingly, disputes involving one set of issues often involve the other. Of the 26 cases brought to the Dispute Settlement Body (DSB) for consultations between 1995 and 2000 that referenced provisions of either the TBT or SPS Agreements, 12 referenced provisions of both Agreements (Maskus and Wilson, 2001, Table 1.1, p. 8).[11]

How then do we define TBTs? First, TBT and SPS cross-referencing not withstanding, we limit our analysis to the elements of a policy measure that fall under the purview of the TBT Agreement. Second, recognizing that a trade-affecting regulation, standard, or assessment procedure, as defined in the TBT Agreement may be entirely permissible under the WTO, albeit potentially costly for U.S. firms, we identify two mutually exclusive, if elusive, subcategories of trade-affecting technical measures: WTO-consistent and WTO-inconsistent. For the purposes of this report, consistency with the WTO Agreement is the decisive factor: a TBT only exists or arises when a country's behavior is or becomes inconsistent with the terms of the TBT Agreement, e.g., if

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[10] These points appear in the WTO on-line questions and answers about the SPS Agreement, available at, http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm. The Agreement also covers sanitary and phytosanitary measures taken to protect the health of fish and wild fauna, as well as of forests and wild flora.

[11] See Maskus and Wilson (2001), "Quantifying the Impact of Technical Barriers to Trade: Can It Be Done?"

a technical measure is discriminatory, if it is prepared, adopted or applied with a view to or with the effect of creating an unnecessary obstacle to international trade, or if it is more trade-restrictive than necessary.

We define TBTs as WTO-inconsistent technical regulations, standards, or conformity assessment procedures, as covered under the TBT Agreement and, to the extent possible, we also confine our analysis to the particular aspect of the policy measure that makes it WTO-inconsistent. For example, a country may have a fully acceptable, albeit trade-affecting technical regulation, but a partially unacceptable conformity assessment procedure. Ideally, we would assess the cost of the unacceptable aspect of the conformity assessment procedure, not the entire regulatory package, unless the entire package would require modification to eliminate the objectionable aspect of the procedure. At the very least, we would try to separate the effects of the assessment procedure from the technical regulation.

In practice, however, it may be difficult to discern WTO-inconsistency. For example, what is an "unnecessary" obstacle to international trade? Necessity may be in the eye of the beholder. Comparing the provisions of the TBT and SPS Agreements reveals another potential source of difficulty in establishing "necessity," i.e., the lack of rigor in the TBT Agreement's requirements for risk assessment.

In the TBT Agreement, the "relevant elements of consideration" for assessing risks associated with the protection of human health or safety are, "inter alia: available scientific and technical information, related to processing technology or intended end-uses of products." In this setting, so-called "sound science" is merely an element for consideration and not a fundamental basis for establishing policy.

By contrast, the SPS Agreement requires that:

> 5.1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk

> assessment techniques developed by the relevant international organizations.
>
> 5.2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

Admittedly, so-called "sound science" is not a cure all, but the provisions of the SPS Agreement establish ground rules for a debate, at the very least.[12] The absence of more rigorous requirements for risk assessment under the TBT Agreement leaves considerable latitude in the determination of necessity, hence consistency. Further complicating the determination of consistency, Annex 1 of the TBT Agreement defines the term "international body", but not "international standards". Thus, the presumption of acceptability established in paragraph 2.5 is also undefined. Ultimately, a combination of WTO precedent, case law, and common sense regarding the context surrounding particular instances may be the answer.

From the perspective of U.S. industry, the consistency distinction may not be overly helpful in facilitating market entry. Even WTO-consistent technical measures may entail significant costs to U.S.

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[12] More generally, sound science is a regulatory prerequisite in the SPS Agreement, in Article 2, paragraph 2, "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5." Then in Article 5, paragraph 7, "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

exporters. However, such policy measures reside outside the scope of the TBT Agreement. Strictly speaking, they are not legally "actionable" and as a practical matter may be even less open to change than those under the purview of the TBT Agreement. The TBT Agreement applies to all WTO members and provides recourse through the DSB under the Dispute Settlement Understanding (DSU). As such, inconsistency becomes a "hook" for negotiations and may sometimes suggest an opportunity for gain on both sides—e.g., when externalities are at issue, the importer might be able to meet a legitimate policy objective at lower cost.

IF IT LOOKS LIKE A DUCK…

Practical difficulties notwithstanding, we can work toward developing a "checklist" for TBT identification. The first approach would be predicated on the language of the TBT Agreement itself. The second would be to take a more outcomes-oriented view to identifying TBTs as the origin of observable phenomena in the marketplace.

Several recent studies have addressed themselves to the TBT issue in detail. In doing so, their approach suggests, if only by inference, evaluation criteria based on an assessment of the provisions of the TBT Agreement. For example, Maskus and Wilson (2001, pp. 20-21) present guidelines for remedying protectionist technical measures:

- If the measure or its enforcement is purely cost-raising, it is inefficient and should be removed.
- If a measure is set at a level that is stronger than required to achieve a policy objective, and it increases domestic profits at the expense of foreign profits, it may have protectionist intent.
- If a measure is discriminatory in application or effect between domestic and foreign firms, the margin of discrimination could be viewed as unnecessary protection and removed.

- If a measure is not the one least disruptive to trade among available policies it may require modification.[13]
- If a measure mandates excessive caution in relation to reliable scientific measures of risk it may be considered protectionist.[14]

These guidelines suggest a framework for the evaluating the existence of TBTs as well.

In a similar vein, Baldwin (2001, p. 79) summarizes the content of the TBT Agreement in terms of five main principles:

- Most favored nation (MFN) treatment: treating all trading partners equally;
- National treatment: treating imported and locally-produced goods equally after they enter the market;
- The sham principle: the technical measure should not be "a disguised restriction" on international trade;
- The least-restrictive-means principle: the technical measure should accomplish its regulatory goal by means that are the least restrictive to trade; and
- The transparency principle, implemented through notice-and-comment periods on proposals for new trade-affecting measures and national points of inquiry.

Again, this offers a framework for constructing a process-oriented TBT "checklist" that compares actual practice to the ideal propounded in the TBT Agreement.

In discussing these principles, Baldwin also refers to the requirement for using international standards, but argues that it is

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[13] Maskus and Wilson do not specifically recommend modification or any other course of action; we have inferred the possibility from the text.

[14] Although the provisions for risk assessment in the TBT Agreement are not as rigorous as in the SPS Agreement, the TBT Agreement still calls for some consideration of risk.

largely nullified because it does not apply when an international standard would be "ineffective or inappropriate" in fulfilling a legitimate regulatory objective. As previously noted, attempts to enforce this requirement may be further complicated by the absence of a clear definition of an "international standard."

Checklists based upon the formal statements found in the TBT Agreement might be supplemented by additions based more on outcomes. This second direction also is based upon the statements in the TBT Agreement that while there are legitimate reasons for enacting technical measures that might have the effect of restricting trade, such measures should be non-discriminatory and their trade-restricting effects kept to a minimum. This approach would then suggest a series of questions that might be asked based on actual market effects to determine whether a TBT may exist:

- Is there a legitimate and defensible rationale for preparing, adopting and applying technical regulations, standards, and conformity assessment procedures that are not based on international standards, recommendations and guides?
- Does the technical regulation, standard, or conformity assessment procedure apply equally to all suppliers regardless of national origin?
- Was the measure introduced after imports began to take an appreciable share of the local market?
- Were there domestic pressures or sources of influence leading to adoption of the regulation?
- Are the standards, conformity assessment procedures, or technical regulations unduly onerous with no opportunity for graduated application (e.g., take effect only above a reasonable number of units sold?)
- Is the net effect of the technical regulation, conformity assessment procedure or standard to prevent foreign entrants into a national market?

If there are sufficient reasons based on the criteria above to find correspondence between technical measures and some of the effects noted, then this provides a reason for engaging in more detailed follow up. One might apply the more narrow tests to see if indeed a TBT exists according to the terms of the Agreement and take appropriate actions in response.

What becomes clear from this discussion is that the determination of whether a standard, conformity assessment procedure, or technical regulation serves as a TBT must generally be made on a case-by-case basis. Even if it is concluded that a TBT has occurred, there remains the question as to what its economic effect will be. Therefore, the question of how serious the problem of TBTs for U.S. exporters and the U.S. economy may be remains open. We need to explore both empirical and theoretical avenues to gain fuller insight into the core question of economic cost.

III. TBTS AND THE U.S. PHARMACEUTICALS INDUSTRY

INTRODUCTION

This chapter and the one that follows review TBT issues arising in two major U.S. export sectors, pharmaceuticals and automotive products. Following this introduction, the second section of this chapter gives a brief description of the organization of the industry and principal U.S. export markets. The next section takes a thematic approach to the major areas of TBT concern for U.S. firms. In both of the case study chapters, an economic rather than legal perspective informs the discussion. We do not seek to rule on whether a particular allegation of trade restriction, discrimination, or non-transparency constitutes a TBT. Rather, we draw attention to trade-affecting practices that display TBT-like characteristics. Following the thematic treatment, the fourth section presents an overview of selected noteworthy concerns about technical measures with TBT characteristics by geographic region. The final section then draws some conclusions and provides thoughts for how to build on this initial sectoral overview.

The discussion in this chapter derives largely from interviews with individuals in industry associations, government agencies and non-governmental organizations, and also draws on the available literature and data on TBTs in pharmaceuticals.[15] To the extent possible these sources were cross-checked against each other. However, there was no opportunity to speak with representatives of governments alleged to have engaged in practices that potentially constitute TBTs. Therefore, the results should be treated as indicative rather than conclusive, suggesting areas where there is sufficient evidence of serious barriers to warrant a more intensive investigation of the technical measure.

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[15] In particular, the leading industry association of the U.S. pharmaceuticals sector, the Pharmaceutical Manufacturing Association of America (PhRMA,), which, despite its name, includes the world's major manufacturers of innovative drug products among its members, provided considerable assistance. Staff at the Biotechnology Industry organization (BIO) also provided insights.

THE U.S. PHARMACEUTICAL INDUSTRY AND PHARMACEUTICAL EXPORTS

The "pharmaceutical" manufacturing sector may be divided several ways, leading to different conclusions about its size and industrial organization. For example, there is a distinction between drugs prepared in the fundamentally chemical engineering tradition that has prevailed since the last third of the 19th century and the emerging biotechnology sector where pharmaceutical preparations are derived from or produced by living organisms. The U.S. Census Bureau, for example, excludes the latter from its Current Industrial Report on the industry.[16] Yet, the share of biologics in the output of the drug industry is growing and is clearly on a sharp upward trajectory. In 1989, such products accounted for less than 1% of the total. In 2002 they were over 7% of total sales. More telling, today over a third of medicines in development are biotechnology products.[17] For some purposes, the industry may also include the manufacture of dietary supplements such as vitamins and veterinary preparations (see, e.g., Census Bureau, 2001). This chapter focuses solely on the production of prescription and over-the-counter medicines for human consumption, including biological preparations.

Even so defined, there are important distinctions within this sector. One of the most important is the relationship between the part of the industry that produces innovative pharmaceutical products and that which produces products based on generic formulations when drugs go off patent. This structural difference is rooted in the economics and regulation of pharmaceutical manufacturing.

Although the fixed costs for establishing a physical plant are not incommensurate with those in other industries, the marginal cost for

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[16] See, Census Bureau, 2001.

[17] Personal communication with Biotechnology Industry Organization staff. BIO is an industry association of approximately 1100 members. Its coverage extends to all fields of biotechnology, not pharmaceuticals alone. Among the pharmaceuticals manufacturing members, all but two are also members of PhRMA. Genentech, clearly an industry leader, is one of these two. The overlap in membership is clearly a manifestation of the tremendous investment costs involved in the application of biotechnology to pharmaceuticals.

producing an individual drug dose is generally small and sometimes negligible. At the same time, the costs for researching and developing products are quite substantial compared to most other industries. R&D programs can be expensive and each success must cover the costs of many research efforts that fail to produce immediately usable results. Beyond this, the pharmaceuticals market is one of the most highly regulated in both the United States and the world. While understandable, this means that even the preparations that emerge successfully from corporate R&D efforts must still pass into several clinical trial phases that routinely last several years. Few of the candidate drugs successfully emerge from trial to home market.[18] If they are to be exported they entail further delay during the process of being registered for legal sale by the appropriate regulatory body in the importing country. During the entire course of the trial period the clock is ticking on the drug manufacturer's patent protection.

When the patent protection on a drug lapses, the original innovator then faces competition – often beginning on the day after the protection rolls off -- from manufacturers of generic formulations of the drug product. The generic drug has the same active ingredients as the innovator and may or may not have the same formulation of inactive ingredients, depending in part on patents that may have been registered for the latter, that are also part of the drug product. There is overlap between manufacturers of innovative and generic pharmaceuticals, but generally speaking, most companies specialize in the production of one or the other. In 2003, it is estimated that patented drugs representing some $6.7 billion in worldwide sales will go off patent due to expiring patent terms. Possibly, two-thirds of all prescriptions around the world will have been filled by generics that year.[19]

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[18] Taking into account the expense involved in all the research, development and trials that fail to deliver an approved drug, the average cost for each successful drug brought to market is currently over $800 million. (PhRMA, private communication.)

[19] Cho, Man K. (2003). "Beyond the Borders: International Challenges and Opportunities", International Trade Administration, Department of Commerce, Presentation to the Annual Meeting of the Generics Pharmaceutical Association, 28 January.

The United States accounts for a disproportionately large share of all research-based producers of medicines and of global exports of these products. As the importance of the biotechnology sector grows, this preponderance is likely to become even more exaggerated.[20] Therefore, the trade in pharmaceuticals, while not necessarily typical of all innovation-based businesses, does have the potential for teaching lessons on how TBTs may affect U.S. manufacturing sectors that rely heavily on innovation and are looked to as likely export leaders. In the international division of labor, the advantage to U.S. exporters is likely to be in the realm of quality and innovation rather than cost of production. In this sense, the pharmaceutical industry presents an illustrative case of U.S. dominance of an innovation-led industry.

For 2002, the total value of shipments, a measure of total industry output, from the broadly defined U.S. manufacturing pharmaceuticals and medicines sector was $120.7 billion.[21] This figure also includes biological products, botanical preparations, and veterinary products. The more narrowly defined pharmaceutical preparation sub-sector accounted for $90.7 billion of this figure.[22]

U.S. exports of pharmaceutical preparations in 2002 were $17.3 billion.[23] For 2003, the estimate for total annual global sales of pharmaceuticals will most likely turn out to have been on the order of

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[20] Hurt and Morrione (2002) report based on industry figures that by 2005 the U.S. share of the global pharmaceuticals market could grow to well over half of the total due to the pace of innovation.

[21] Census Bureau (2002.) Note that this figure is an estimate derived from surveys. There are serious problems of comparability between the statistics available describing the structure of the U.S. industry, its size, and the volume and direction of outputs. The figures need to treated accordingly.

[22] This is the figure reported in Current Industrial Report, Census Bureau (2001).

[23] Bureau of Census data, Foreign Trade Statistics (http://www.census.gov/foreign-trade/statistics/product/enduse/exports/c0000.html). Note that this data series is reported using the 5-digit end-use classification, which are not fully consonant with data using either SIC or NAICS classifications. "Pharmaceutical preparations" in the end-use classification may not equate with the same nomenclature in the latter systems. Therefore it is difficult to determine precisely the percentage of total output represented by exports.

$435 billion. The combined markets of the United States, Canada, and Mexico, together account for 40 percent of these sales. Europe accounts for 25 percent. Western Europe remains the largest market for U.S. pharmaceutical exports followed by Japan and developing Asia.[24]

PHARMACEUTICAL INDUSTRY REGULATIONS AND STANDARDS AND POTENTIAL TBTS

Discussions with industry representatives and U.S. government representatives who track pharmaceutical industry issues yielded five principal areas potentially pertaining to TBTs for U.S. exporters of pharmaceutical products. Three fall clearly within the definition of TBT used in this study. These are: issues related to (1) conformity assessment and testing regulations; (2) transparency; and (3) regulations and standards. Two other issue areas were found to have ramifications that might be classified as posing technical barriers to trade. These are (4) intellectual property rights protection, particularly data exclusivity; and (5) market access, including drug registration and reimbursements in countries with single-payer health care. However, most intellectual property rights (IPR) issues fall under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the WTO. Market access problems, the core of the registration and reimbursement concerns, are also generally not covered by the TBT agreement. To the extent that these two issue areas may bear on or overlap with concerns about TBTs, we discuss them below. The initial section of this chapter concludes with a discussion of the efforts toward international harmonization of regulation in pharmaceuticals.

Conformity assessment and testing

The TBT Agreement specifically states that testing to ensure conformity with existing health and safety regulations in the importing country is an acceptable reason for regulation. Despite the continued progress of scientific investigation in this sector and considerable efforts to achieve harmonization of regulation and practice, this area is most often cited as being rich with examples of TBTs. Participants

[24] Cho (2003).

in harmonization processes typically agree that the safety, quality, and efficacy of pharmaceutical products are relevant to international regulation. What proves problematic is the practice of interpreting the science and applying it to regulatory concerns. The following discussion addresses several general areas of concern; the later section on regional differences includes specific country examples.

Demands for production data. A recent and growing practice has been for importing countries to require that potential exporters provide vast quantities of production quality and process data to regulatory agencies to receive permission to sell their products. Both Korea and Taiwan began this practice in early 2002 and other countries are beginning to follow suit. These data are generally generated around the time of Phase III clinical trials. The usual practice in the United States, owing to both the mass and extreme proprietary sensitivity of such data, is for FDA regulators to visit the manufacturer, review the data, and certify that the proposed production methods will consistently yield the chemical species desired at the appropriate level of quality.

The Taiwanese now insist that such data be physically produced and placed at the disposal of the government for the exporter to receive certificates of compliance to sell the drug in the country. This places foreign firms at a distinct disadvantage since the domestic firms need only submit to on-site visits.

In Korea, there are similar new requirements for additional information that have been deemed onerous by U.S. manufacturers. In this case, the discriminatory effect is apparently greater in that only innovative "new chemical entities" (almost entirely imports) are covered, not the local manufacture of generics.

There have already been purported instances of leaks of sensitive data to domestic generic manufacturers who are alleged to have now begun producing substitutes. Thus, IPR protection enters in and potentially raises trade concerns. More fundamentally, there appears to be little good reason to request such data in the first place. It would be a difficult enough task for the U.S. authorities to apply the expertise and resources necessary to make use of the amount of data being asked for. It is doubtful whether this task could be done more efficiently

elsewhere. IPR concerns notwithstanding, potential market entrants claim that the sole purpose served by such regulations is to erect a de facto discriminatory barrier to imports by raising the effective costs and reducing the benefits of attempting to enter the domestic market.

Testing procedures. Output from pharmaceutical production runs must be routinely tested for conformity with quality and safety regulations. This may be done either through self-certification by the manufacturer, if acceptable to the regulatory authorities, or by an independent testing process. U.S. pharmaceutical exporters claim that this process is sometimes fraught with devices such as long drawn out, costly, and redundant testing procedures to raise effective barriers to imports.

As an example, the European Union and the United States have a mutual recognition agreement on the certification of process quality information. However, several member states of the EU now require quality assurance testing at the border on a by-lot basis for non-EU pharmaceutical imports. This not only imposes greater costs but also entails at least two weeks time lost in testing by local government officials while each individual lot is held in storage. Self-certification is not permitted. This, coupled with the time required to gain official registration of a pharmaceutical product in the first place, is a concern. The industry association PhRMA claims that the single greatest source of loss to potential exporters is the time spent after the initial launch of a drug, before it may be offered for sale. In addition, even if the testing is done in a timely manner, the net effect is to raise the marginal cost of each lot of pharmaceutical imports. Testing may also increase exporters' fixed costs to the extent that compliance requires them to maintain a minimum additional level of staff in the importing country.

Testing requirements exist in other markets as well. In some, the procedures seem designed for inefficiency. Officially designated labs – sometimes only a single one – are permitted to conduct such testing. The labs may be in interior locales geographically removed from the main ports of entry. It is even suggested that in some countries testing for quality assurance on imports serves solely as an income generator. That

is, the agencies collect substantial fees for performing the testing. This business may be steered by less-than-scrupulous agency bureaucrats toward political or financial allies.

Again, the complaint is that this intrusive type of testing really has little scientific basis, especially when some countries require testing for every single lot imported. The trade limiting effects become even more accentuated by the seeming caprice that sometimes attends these procedures. The regulators in importing countries may change their testing specifications without any prior notification, a direct contravention of the TBT Agreement. This is in many ways the most onerous burden faced by potential exporters. Further, in some countries there do not even exist facilities for doing the type of testing required for advanced and innovative pharmaceuticals. The potential foreign supplier will itself be required to provide the testing equipment – which parenthetically also raises some serious IPR considerations.

Biological preparations. Before leaving the general discussion of conformity assessment and testing, we touch on an area that could prove problematic as a possible source of future difficulties. Differences in the regulations of biologic products and the biotechnology industry may pose challenges. For example, the EU has banned for inclusion in drug products any material from producers who have not been certified (by the country of origin) as being free of transmissible spongiform encephalopathy (TSE)[25] contaminations.[26] This includes the gelatin used to manufacture drug capsules. Because there is no such certification system in the United States, the ban prevents the inclusion of this material in pharmaceuticals offered for sale in Europe. Hence, the region suffering most from the outbreak and consequences of TSE and therefore most in need of imports is largely prevented from drawing upon a developed manufacturing region that has been completely clean of any

[25] TSE is the general category of disease caused by infectious agents of which the prion causing "Mad Cow Disease" (bovine spongiform encephalopathy) is one member.

[26] Commission Decision 97/534/EC

infection.[27] Such material cannot form a supply source because it is officially classed as a specified risk material.

International differences in the regulatory treatment of pharmaceuticals derived from biotechnology are also beginning to appear. New Zealand took a smallpox vaccine off the market because it is manufactured from a genetically modified organism. This vaccine is administered orally so it was considered a risk because it might be excreted into the environment. New Zealand's neighbor, Australia, has taken the opposite position.

There are special issues in the regulation of biologics that do not exist in the case of more traditional medicines. Among these, there is a need to demonstrate that the "cold chain" of adequate refrigeration between manufacture, transport, distribution, and end-point use has remained unbroken; shelf life issues are more of a concern; counterfeiting issues are a serious concern in some places because these are high value-added, high unit cost products.[28] The large number of regulatory issues may leave more room for TBT-like practices.

U.S. regulatory structures may pose additional challenges. In the United States, "traditional" drugs are regulated under the Food, Drug and Cosmetic Act. The key is that regulation is done on the basis of "end-specification". Thus, the focus is on the product; the major issues are quality and efficacy. The governing law for biotechnology medicines is the Public Health Service Act. This is not keyed on end-state specifications. Regulation is on the basis of process, purity, and identity. So if a biologic medicinal product, "B", is produced by process "P" using input "A", no part of this process may be changed and still maintain FDA approval. If the manufacturer wanted to use improved input "***A***" or process "***P***" to yield "B", the entire modified process would be required to pass through certification once more. This means that if some new requirements arise to qualify for recertification in a

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[27] This information is current as of November, 2003. One case of Creutzfeldt-Jakob disease, the human form of TSE, was noted in Florida but the victim in this case was a tourist visiting from the U.K.

[28] Counterfeiting usually takes the form of diluting doses. This is a large argument against re-importation because of compromises to the accountability chain.

region such as Europe, even if relatively minor, these could affect the ability to manufacture across the entire production line. This is why, for example, one can observe manufacturers who still use 1960s-era fermentation vessels so that they would not be required to recertify. Even a change in supplier could result in the U.S. Food and Drug Administration (FDA) deciding that this represents a significant enough modification to require recertification. Because the processes used to produce biologic products in essence define them, a generic biologic is currently an oxymoron from a U.S. regulatory point of view.

This aspect of the U.S. regulatory process may become more of an issue as the industry matures and patents begin to expire. In other words, a country seeking to boost – or protect – a nascent biotechnology industry would need only to introduce marginally different technical requirements to provide an entrée for other (presumably domestic) follow-on producers to enjoy a distinct advantage over the U.S. innovator. This makes the issue of sharing technical information and data exclusivity even more sensitive for the industry. Because the United States is the locus of the biotechnology industry and is likely to remain so, regulations stipulating the sharing of technical information would most likely impose the largest financial losses in terms of lost intellectual property rights on U.S. companies. If an importer changes its technical requirements, the U.S. innovator can become the next-generation supplier of its own product only by going through the whole approval process once again.[29] However, to the extent that a country changes a requirement for legitimate policy reasons and applies the change to all suppliers, it seems doubtful that the action would constitute a TBT.

Even as prosaic-seeming an issue as regulations determining what, in fact, is a biological medicine may have TBT-like characteristics.

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[29] In the United States, it currently takes 3-5 years for an innovator to get additional facilities up and running. To do so requires a Biologics License Application (BLA) for each facility. As a result there is no real trade in intermediate products for biologics manufacture as there is for other sectors of pharmaceutical manufacturing because of the regulatory focus on process. Firms producing biologics are "soup-to-nuts" manufacturers with closed value chains.

The matter is not straightforward. Aspirin, clearly, is a simple molecule and subject to specification control while a smallpox vaccine is a living product subject to process control. But finding the cutoff point for the vast array of prospective drug products that fall in between is not easy to do. Hence, the practice to date has been that whatever was done to make the first batch is considered to govern as long as successive batches are produced in the same way. But even this simple rule may come to be hard to administer in the future.

Transparency of Regulations

The high degree of regulation of the pharmaceutical trade, combined with the number of technical measures required to achieve this regulation, means that the issue of the transparency with which regulations are written and implemented is a major issue for potential U.S. exporters of pharmaceutical products. This is exacerbated by the multiplicity of different regulatory regimes around the globe and the great variation from country to country in the state of development of the institutional apparatus available for implementing the technical measures.

The TBT Agreement speaks at length about the need for transparency and communication to interested parties in establishing the rules regarding technical measures. Obligations for states to notify the other signatories of the TBT Agreement include, among others:

- Statement of means to be used for implementation and administration of the measures required by the Agreement as well as any subsequent changes (Article 15.2.)
- Notification of the technical measures for regulation and conformity assessment to be used by central and local authorities. This also includes the requirements to make advanced copies of such procedures available on request and to allow sufficient time for written comment (usually on the order of 45-60 days) as well as to publish the measures when formally adopted. (Articles 2.9; 2.10; 3.2; 5.6; 5.7; and 7.2).
- Notification of any bilateral or multilateral arrangements related to technical measures. (Article 10.7).

- Notification of acceptance or withdrawal from the Code of Good Practice. This lays down the structure for how governmental or NGO standardizing bodies should approach this process. Central government bodies are required to accept the Code and its provisions. Acceptance also means publication of the annual work program of any such body. (Annex 3).

In addition, WTO members are required to designate the government authority responsible for implementation of these notification obligations as well as to designate a formal enquiry point charged with responding to enquiries and providing documentation on proposed or adopted technical measures, location of notices published pursuant to the TBT Agreement, and information on membership in international or regional standardizing bodies and conformity assessment systems or in bilateral and multilateral arrangements. (Articles 10.1, 10.2, 10.3, 10.10 and 10.11.)

As might be expected, there is considerable variation in how well WTO members adhere to the various transparency obligations in practice. In the pharmaceuticals sector there are allegations of failure to establish functionally meaningful enquiry points, failure to publish regulations, failure to provide occasion and means for commenting before adoption, and certainly failure to adhere to published regulations in practice.

The failure to provide for transparency in the formulation and application of technical measures may have several effects on potential U.S. exporters. An unannounced change in technical measures may render previously successful exports unmarketable. There may be a period of adjustment that could have been eased with more notice as the products are reestablished for sale. Less dramatically, changes could add to costs as new testing and conformity assessment processes are suddenly brought into play. Again, the additional cost would come from whatever expedients were required in a short time frame to render products already in the export pipeline eligible for sale. Finally, the cumulative weight of a pervasive lack of transparency may raise doubts for potential exporters who then choose not to manufacture for sale into that market or to limit their exposure to this form of uncertainty. It

becomes difficult to develop a product and plan for its sales in an environment where there is fundamental doubt about the rules of the game.

Pharmacopoeias, standards, and regulatory enforcement

As discussed above, regulations are binding legal requirements set by governments. Standards are voluntary protocols, often established in the private sector by industry. Even though the pharmaceuticals sector is one of the most heavily regulated industries in the world, there is still a role for standards, but they are not divorced from regulatory enforcement. In the United States, some "standards" that make up pharmacopoeias have voluntary dimensions, but ultimately convey legal authority.

A pharmacopoeia consists of a set of standards for testing the quality of the components of drug products or of the drug products themselves. These standards are encapsulated in the form of individual monographs, each a complete protocol (including specification of testing procedures, materials, equipment, etc.) for establishing actual content and purity. The monographs may cover four basic formulations: active ingredients; the inactive ingredient components ("excipients") of a drug product such as the capsule, flavorings, inert material and so forth; the complete drug product (the active ingredients and excipients taken as a whole); or general procedures and protocols that may then be referred to in multiple individual monographs.

The purpose of a monograph is to set out standards for testing quality. They do not test for safety or efficacy. Neither do they test for bio-equivalence[30], per se. Nevertheless, dissolution or other performance tests may also be present in a monograph in the

[30] Bioequivalence refers to the need for generic formulations to demonstrate that the rate and extent to which active ingredient is delivered to the bloodstream is the equivalent of those for the innovator's formulation of a drug product. Assuming the active ingredient is the same, the concept of bioequivalence enters in with regards to the excipient aspects of the capsule, pill, or other product dose. These too may be patented and so the generic may be using a different formulation than the innovator's formulation.

pharmacopoeia but are rarely administered as such. Instead, these may be aspects of the testing for quality and purity.

The U.S. Pharmacopoeia (USP) is a private NGO established in 1820 by a group of physicians. It is the only pharmacopoeia in the world that is not part of the government. In the United States, drug innovators provide information on a voluntary basis. Then volunteer experts from industry, government, or academia check the information for technical details. After being checked the information is entered into the pharmacopoeia as a monograph that then becomes the reference standard for the subject of that monograph.

The biggest problem faced by USP is for the innovators to be forthcoming with this information. The manufacturers' reluctance to do so stems from concerns that this will provide eventual competitors producing generic products with useful information. On the other hand, this is balanced by the advantage that comes from the fact that the first one to register a monograph with USP then defines the test standard that all others must follow. If a monograph exists, then all who produce the entity that is the subject of the monograph must use the exact protocols contained in the monograph. The USP is specifically mentioned as the sole appropriate reference in the Food, Drug and Cosmetics Act. That is, the USP monograph becomes the legal basis for establishing non-conformity with standards for quality.[31] If no public USP monograph exists because the proprietary concerns outweigh this potential benefit, then in the United States the FDA will set out the specifications for purity and quality on a private basis. Thus, the FDA is responsible for private standards for quality assurance.

There are about 30 or more pharmacopoeias in existence throughout the world, but several are no longer active, e.g., the French, Spanish, Italian, etc. pharmacopoeias have been superseded by the European Pharmacopoeia (officially the European Pharmacopoeia Commission residing in Strasbourg, France.) But there are active pharmacopoeias in China,

[31] That is, when it becomes a legal matter of prosecuting non-conformity the USP reference monograph is definitive. However, a manufacturer may choose to claim compliance based upon another set of monograph procedures and market a drug on that basis.

India, Russia, Brazil and many other large export market countries. Pharmacopoeias are still coming into existence in places such as Vietnam and the Philippines. Such countries develop them largely to provide assistance to local industry. Canada is an example of a country without its own pharmacopoeia that recognizes USP, EP and several others as being equally valid for testing within Canada.

USP is often asked to develop a monograph for foreign drug manufacturers because USP is regarded in many areas as the "gold standard". It may be referred to even before local pharmacopoeias are consulted because it often is the key to being able to export successfully.

In the United States, pharmaceutical manufacturers self certify their compliance with USP standards. This is supplemented by spot checks and visits to facilities by FDA. FDA also has in place a policy that provides for national treatment in that foreign "drug sponsors" (manufacturers) may also self-certify conformity. It is the responsibility of the drug sponsor to produce data to satisfy FDA's criteria. This limited national treatment is only for the drug sponsor, not any foreign conformity assessment body.

Self-certification is rarely the rule abroad. The fact that in addition to the USP there also exist the European Pharmacopoeia (EP), the Japanese, and so forth, means that there is considerable complication in the case of exports. The principal difficulty is that in addition to meeting own-country standards for quality, the exporter must also meet the standards set in the country of importation. In the case of Europe and Japan, not only must the standards be met but the local testing protocols must be used as well. This type of testing must always be performed on a per lot basis. Since 1989, there has been a Pharmacopoeia Discussion Group between the United States, EU and Japan, operating in parallel to the other efforts at harmonization, discussed below. This body attempts to find areas where harmonization between pharmacopoeias may be accomplished. The efforts have focused on monographs for excipients and general procedures. The effort has not succeeded to date in addressing active ingredients or drug products. Even so, the effort, in common with other harmonization efforts in the

pharmaceuticals sector, is routinely described as being very slow and laborious.

Standards related to quality appear to inflict costs and complications on potential U.S. exporters who must expend resources to meet distinct criteria in at least three separate markets, but they do not obviously constitute TBTs. The standards are intended to apply to domestic and foreign producers alike. That having been said, there is at least one specific instance where these standards may have presented TBT-like attributes. In the case of the excipient sucrose, the EP effectively eliminates U.S. manufacturers from the European market. While U.S. sugar producers use both cane and beets as a raw material, Europeans use the latter exclusively. The EP reference standard is beet-derived sucrose. This means that sucrose as produced by industrial processes in U.S. firms has a different refractive index than that specified in the EP standard and so is precluded from sale for pharmacological purposes in Europe (and other regions applying the EP standard). This issue has been subject of long standing conversations between U.S. and European trade representatives but apparently still remains in effect.

There certainly exists a possibility that standards embodied in other pharmacopoeias could disadvantage U.S. exporters and protect domestic industries. It is not unknown even in the U.S. domestic market to have an innovator provide data for a USP monograph that has an intent, in part, to establish "lock out" criteria that will frustrate attempts by generics manufacturers to compete. However, no specific instance of a similar intent being enacted overseas to lock out a potential U.S. exporter came to the attention of this report's authors during the course of this overview.

Intellectual Property Rights Protection and TBTs

IPR protection concerns and TBT considerations may overlap. However, to the extent that proprietary data delivery requirements mandated by importing country regulations lead to loss of control over intellectual property, they would be governed by the TRIPS Agreement. The TRIPS Agreement requires governments requesting such data delivery

to make sure that information gained from importers is shared only with the appropriate parties within the government. TRIPS 39(3) states that regulatory bodies may not disclose commercially sensitive information unfairly.

Nevertheless, in some countries there appears to be leakage from the system. Exporters claim that their proprietary data routinely receives insufficient protection. They also face discriminatory requests to disclose information, owing to technical requirements that local firms can satisfy by other means. In many instances this appears to be a function of underdeveloped regulatory institutions. In some countries, however, it is alleged that the regulatory process in general and the requirement for proprietary data in particular is used to promote domestic industrial development and keep out imports.

Discriminatory demands for proprietary data coupled with leakage potentially impose a different set of costs on exporters than is usually focused on in the TBT literature. Attempts to estimate the cost of TBTs, like our own, usually focus on the loss of markets or the additional costs to the exporter of complying with the TBT. In this instance, the cost stems from the potential loss of intellectual property not the loss of the export market. Because facing these regulatory strictures may have a chilling effect on incentives to export, the potential reduction in exports is not due to an increase in production costs but rather the potential loss of an asset. Some U.S. firms have reportedly made decisions on a case-by-case basis not to export specific pharmaceutical products to markets where there are issues with data exclusivity. They fear that a launch in some countries will mean that they will soon find themselves competing with the local manufacturers of generics. This constitutes an opportunity cost in lost sales that is not governed by TRIPS. The regulations that lead to lost sales in some instances do have TBT characteristics.

Registration and reimbursement

The U.S. pharmaceutical industry is very concerned about reimbursement practices and price controls in export markets. Many countries have some sort of national health insurance that provides

partial or complete reimbursement for drugs. Under these systems, pharmaceuticals must be registered for approval for them to be dispensed and their costs then reimbursed by the appropriate public authority, which, in turn, is funded from the state treasury or a national health insurance fund.

Given the prevailing institutional arrangements, national health insurance authorities are monopsonistic buyers in most countries for most purposes.[32] The principal industry trade group, PhRMA, argues that this power is used both to restrict entry to certain classes of drugs and to introduce systems of effective price control.[33] In a number of countries, although framed in terms of general application, registration appears to discriminate against innovative drug products, which are principally imports and often from the United States, while not affecting locally produced generics. In some cases, registration is withheld because regulatory bodies are faced with political, institutional or social choice issues. To the extent that imported drugs are discriminated against in the registration process, registration processes may act as TBTs.

One of the complicating factors in registration is the issue of price. All health care systems are facing cost pressures. Cost pressures may lead to purposeful foot-dragging in registering drugs out of a desire to keep potentially expensive treatments off the approved list. In some instances, price differentials between innovative drugs and other, probably less effective substitutes make it difficult to determine whether registration procedures are discriminatory and hence have TBT characteristics.

Harmonization of Regulations

The process of achieving harmonization is conducted as part of the activities and meetings of the WHO-sponsored International Conference of

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[32] It should be noted, however, that even in nations with all-encompassing single-payer systems there is still often a market for imported pharmaceuticals in private transactions. However, the requirement for patients to pay the full retail price for these drugs make them practically inaccessible to much of the population.

[33] Interveiws with PhRMA staff.

Drug Regulatory Authorities and also of the body generally known as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The latter began in 1991 as an ongoing process for scientific and technical discussions of testing procedures required to ensure and assess safety, quality and efficacy. The participants are the three major regulatory authorities in the United States, Japan, and the EU as well as the major industry association from each region.

The ICH process is an exercise in harmonization by aggregation. That is, the process occurs incrementally. The body gathers attendees who compare the regulatory procedures each applies in one narrow area. If there is no institutional memory of how a particular practice originated, the participants look at the results from different approaches to see if there is any difference in the way alternative practices might lead to regulatory outcomes and scientific conclusions. The result in this one area then becomes a set of tests acceptable to all regulators. The process is then repeated in the next area for consideration. The process is by its nature a slow and rather expensive one. Only a limited number of areas can be addressed. And from the perspective of TBT-generating activities, even though there is now pretty wide consensus on areas of regulatory relevance the real concerns often arise from the realm of interpretation.

Mutual recognition agreements (MRAs) have been pursued as a means for addressing the differences in interpretation. Despite initial optimism, the generally held view is that they have proven of dubious value in practice. They are long and difficult to negotiate in part because the sides come from such very different perspectives. In the case of the development of the drug annex to the U.S.-EU MRA, it became clear that mutual recognition could imply almost anything. Apparently, the EU sought total equivalence in approach, focusing on procedures. In contrast, the United States sought agreement on policy goals and qualifying systems, focusing on results. The two views are hard to reconcile and made more difficult by such practical matters as the lack of copies of relevant standards and the differing regulatory and institutional traditions.

REGIONAL PERSPECTIVE ON TBTS IN PHARMACEUTICALS

What follows should be viewed as a presentation of regulations, standards, or conformity assessment procedures that display TBT-like characteristics. The discussion is based largely on interviews with representatives of U.S. industry and with U.S. government personnel. Special 301 filings by PhRMA with the Office of the U.S. Trade Representative also provided inputs.[34] The treatment highlights "episodes" and concerns from the standpoint of TBTs. It is not a definitive catalogue of documented instances of TBTs. Neither should presentation of allegations of potential TBTs be construed as conclusive demonstration of TBTs in fact.

Countries fall into three groups when viewed from the perspective of standards and regulations that may give rise to TBTs. The first tier consists principally of developed industrial countries that produce their own regulations. The United States, the countries of the European Union, and Japan are the most important members of this group. Each produces a complete system of regulatory measures. These institutions are often adopted as the model for another group of countries, the Tier III countries. These, in turn, tend to be developing market countries lacking the means or the need for developing regulatory systems distinctly their own. Tier II countries tend to be large developing countries or dynamic emerging economies. These are countries where elements of one or more Tier I regulatory systems may provide a basis for deriving a separate national policy of regulations, standards, and conformity assessments with the addition of a considerable number of local elements. These tend to be the most troubling for exporters because of their unique combination of regulatory elements.

Tier I Countries

Japan. Japan is a highly industrialized country with an aging population. It has several domestic pharmaceutical firms, but only six that could be classed as global companies and all are of relatively

[34] The Special 301 provisions are principally addressed to IPR issues. However, the PhRMA submissions also contain documented allegations of market barriers and restrictive practices alleged to be in place in specific countries.

small scale compared with the largest firms in the United States or in Europe. The rest of the firms in Japan concentrate solely on the manufacture of generic drugs.

As in many other countries, the government in Japan tries to reduce prices on the most expensive drugs. To achieve this policy goal, reimbursement for new drugs is linked to the price of an older, pre-existing drug to which it is officially paired. The reimbursable price for the new drug therefore fails to capture or reward the value of innovation. Further, the price remains linked not only to that of the specific older drug but also to the life cycle of that drug as well. If the old drug goes off patent and its price subsequently drops, the price of the new drug is also forced down. So the only reimbursement possible is at the old rate even if there is a radically new or vastly more effective drug. Given the industrial organization of the domestic pharmaceuticals industry, the result is to place the greatest burden – either in the form of lower prices or foregone sales because of the differential between what the buyer would pay and how much the reimbursement would cover -- on the producers of innovative drugs who most often come from abroad.

Local social objectives may also give rise to technical measures with TBT-like attributes. In Japan, as in Europe, the precautionary principle often holds more sway in informing policy than does the cost-benefit approach to safety regulations. The Japanese are now reportedly constructing a system that applies only to drug manufacturing innovators. It will require considerably greater information disclosure than is required at present and then at least a portion of this information will be disclosed externally. They are also considering changing the way in which they intend to assess safety. The presumption will be that new pharmaceuticals are unsafe and that the burden of proving a negative – that is, that any given drug is not unsafe – will fall on the manufacturer before a drug may be offered for sale. The argument, albeit speculative, is that this regulatory posture, if adopted, lacks scientific merit and may create a situation in which

innovative foreign manufacturers face greater regulatory hurdles than domestic manufacturers of generic drugs.[35]

European Union. Within the EU there is no formal Single Market for pharmaceuticals. As a result, exporters experience a patchwork of policies, processes, and measures. Safety and efficacy is within the competence of the European Commission, but healthcare provision and drug reimbursements remain within the competence of individual countries. However, once a drug is on the market in one country the product may move freely across borders. This means that price is arbitraged to some extent with the market price set by the national regulatory regime that yields the lowest price.

The issue of whether any particular practice regarding pharmaceutical regulations, standards, or conformity assessment is discriminatory is not an easy one in the EU setting. In most cases, European innovators face the same conditions, as would a potential U.S. exporter. Thus, discrimination is a subtle matter in that it is presented as an issue of innovative versus generic products rather than foreign versus domestic.

Some U.S. firms argue that members of the EU prefer to discuss and clarify particular regulatory issues in the context of the WTO and other multilateral forums. It is sometimes difficult to obtain engagement on a bilateral basis, despite the bilateral nature of some practices, such as conformity assessment testing. This inherently slows down a process that is felt by some to be in itself a serious trade restricting force. Again, the claim is that the innovative pharmaceuticals bear the brunt and are hit first.

One further cause for concern with regulation is that the United Kingdom has recently pioneered an additional approval step that is beginning to diffuse elsewhere on the continent. In addition to testing a new drug for safety, effectiveness, and quality, there is now a need to evaluate cost-effectiveness at the time of proposed country launch. This has introduced an effect known colloquially as "NICE Blight" after the National Institute for Clinical Excellence, the authoritative entity

[35] Interview with PhRMA staff.

in the United Kingdom. While a drug is being evaluated in this regard it effectively halts most doctor prescriptions. Physicians will wait for the results to come in. Then, after there is approval on the basis of cost effectiveness there is a further step – receiving approval for reimbursement. This introduces an additional sometimes quite lengthy delay in market entry. This delay entails direct costs and foregone sales but, it is also feared, prepares the path for more accelerated follow-on by generics. Further study would be required to ascertain whether this should be viewed as a regulatory issue per se or just an extension of the processes for reimbursement approval.

Other Europe. The nations of Central and Eastern Europe are all working toward eventual full membership in the EU, which would place them in the ranks of the Tier I category. However, they are still all in a state of transit to establishing the full range of EU regulations. At present, these countries are to varying degrees alleged to pursue delaying tactics in approvals for reimbursements. It is not the usual practice to routinely update reimbursement lists – officially. Yet, allegations have been made that nevertheless local copies and generics manage to get on the lists. In the instance of Poland, according to the 2003 Special 301 filing submitted to the Office of the U.S. Trade Representative (USTR) by PhRMA, no innovative products have been included in the reimbursement system for four years while the government appears willing to register patent-violating domestic direct copies of U.S. products in only a matter of months.

In Poland, even if an innovative drug makes it to the reimbursement list, there exists a formulary that has the effect of providing a further restriction on what can be prescribed directly and by whom. These are alleged to be non-transparent and discriminatory. The practice continues even though the formularies were declared illegal by the regulatory Office for Health Insurance Supervision.

Croatia provides another example. In this country every batch of drugs shipped is subject to analysis by a single government testing authority. This adds one month to the time of each shipment.

Tier II

The Tier II countries are in many respects the most problematic for U.S. exporters. These countries have chosen to produce their own sets of regulations, standards, and conformity assessment procedures for pharmaceuticals. In many cases, these technical measures amalgamate and draw heavily from those in force in Tier I countries. But there are a considerable number of local elements present as well. Generally speaking, it is in this region that there are the most allegations of regulations, standards, and conformity assessment procedures being used to serve other policy purposes. By the nature of the choice made by these nations to craft their own regulations, there are also allegations of considerable difficulty with transparency. Some specific instances are cited below.

Developing Asia. The governments in the Asia-Pacific region have originated several practices that display TBT-like characteristics and are said to be increasingly resistant to U.S. government overtures. Korea, along with Taiwan, is most often cited as operating in a manner that is discriminatory. There is an onerous process of quality assurance and testing that applies only to innovative (imported) pharmaceuticals and not to (domestic) generics.

PhRMA's Special 301 submissions charge Taiwan as presenting a sweeping array of TBT-like practices: regulations and conformity assessment procedures are reportedly discriminatory, non-transparent, and not scientifically grounded. Taiwan, too, has demanded that extensive production process data be made available before registration of imported innovative drug products. There is serious question of whether the expertise even exists within Taiwanese regulatory agencies to examine such information.

China has been working to improve its system of regulation and appears to be willing to introduce changes in accord with WTO practice. Yet, concerns have arisen among potential exporters. Generally, it has been charged that China will institute across-the-board changes in its testing specifications without prior notification. Such notification is required under the TBT Agreement. This is in many ways the most onerous potential TBT in the eyes of many U.S. manufacturers.

Following the lead of Japan, China now also requires what amounts to entire repetition of Stage III testing procedures of innovative pharmaceuticals entering into the country. The origin of the practice is the claimed necessity to ascertain the safety and efficacy of pharmaceutical products for the metabolisms of Asian populations. (There is no known scientific basis for such a broad requirement. ICH has concluded that there are few if any major differences between populations and what population differences exist can be quite adequately treated by constructing single studies to explore all such issues.) This requirement means that new drugs are required to be subjected to an entire new critical trials process. The net effect is an additional three year delay in time-to-market and perhaps as much as $100 million in extra costs. This practice is now proliferating in the region.

Other economies of Southeast Asia present a similar roster of problems arising from regulatory institutions and processes. The Association of Southeast Asian Nations (ASEAN) has engaged in a harmonization process to produce common guidelines, e.g. for drug stability requirements. Yet, they have harmonized on regulatory protocols that are not consistent with ICH accords or WTO requirements. In effect, this harmonization has resulted in the setting of two regulatory protocols; this in itself confuses and countervails the move toward harmonization. Again, the claim is that there is not much ambiguity or controversy on the science involved in this area. The market in drug products in many respects presents less room for interpretation than, for example, does trade in food because one is dealing with known and very well defined chemical entities. So when deviations appear, it is possible to make an inference that in the absence of a scientific basis for such measures other purposes may be being served.

Middle East. In this region, IPR issues are paramount among trade concerns, but concerns about alleged TBT-like practices have also come to the fore in Special 301 filings with USTR.

Turkey[36] is frequently the target of allegations running the full range of pharmaceutical export problems. Every box of imported drugs is inspected and tested; there is a bio-equivalency requirement applied only to innovative drugs and not to generics, quite the opposite of what one might expect; there is no practice of data exclusivity stemming from a regulatory agency stance that accepts no obligation to protect the large amounts of data authorities insist be provided, etc.

Israel is another country in the region that does not provide data exclusivity. This is alleged to benefit, if only indirectly, the local generics manufacturers some of whom are also quite successful exporters. An Israeli firm, TEVA Pharmaceuticals, is the fastest growing manufacturer in the world and makes only generics.

It is worth noting that two countries in the region, Saudi Arabia and Lebanon, are not WTO signatories. The latter has traditionally served as an entrepôt for the region, a port of entry where considerable transshipment occurs. It may be regaining this role in recent years, hence possessing a possible importance beyond the size of its domestic market.

Latin America. Because of the proximity to the United States and the existence of the North American Free Trade Agreement (NAFTA) it is useful to discuss the case of Mexico in a bit more detail. Mexico also represents the largest single market in Latin America for pharmaceuticals sales (on the order of $6 billion in 2003). In many ways it is emblematic of the type of issue that arises in Latin America with U.S. pharmaceutical exports.

The fundamental issues revolve around the drug registration process. All drugs must be registered, however, the way they are treated differs considerably. In Mexico there are three main types of drugs. The first category represents the innovative drugs that are new to the market. The second category is that of the generic drugs. The third is a category peculiar to Latin America called *similares*,

[36] Turkey is usually categorized with European countries rather than those in the Middle East. However, from the perspective of TBTs the industry finds it convenient to place it in the latter category as many of its practices are common elsewhere in the Middle East, but are not common in Europe.

described below. Whereas tests of bio-equivalency are required for the innovative drugs in order to be registered, many of the generics do not require such testing if the innovative drug that is being copied has already been registered. This is an instance of differential treatment. There are intellectual property issues that also arise because the registration process does not ask for patent information on the part of the firm asking for registration. Also, registrations have been made on the basis of stolen data obtained during the registration of innovative drugs.

Unlike generics, *similares* are not necessarily the same chemical entities as the innovative drugs that are usually copied by generics or if the same they are present in concentrations other than the concentrations that appear either in the generic composition or the original pharmaceutical that is being copied. These latter represent a potential danger because of lack of adequate regulation, lack of scientific understanding of the basis for their claims of efficacy, and the growing concern over developing resistance of many disease-causing bacteria to antibiotics. For this reason, they are viewed as having the potential not only to compete in the market for either innovative or generic drug products but to also destroy the market for future sales of the originals to which they are intended to be similar. In fact, the Mexican government is seeking, over a period of five years or so, to phase them out. On the other hand, the *similares* represent a very large market in Mexico; Mexican manufacturers have been actively lobbying the Mexican government to preserve their markets.

There is also a lack of homologation between the U.S. and Mexican registration processes. In many respects the Mexican process is more rigorous in the sense that there are requirements for registration of products that would not require registration in the United States. Not only medicines and allopathic drugs are required to be registered with the Health Ministry, but in common with most of the world outside the United States, vitamins and herbal medicines also require registration by the Health Ministry before receiving an import permit. All of these are considered to be medical products. Herbal remedies, including

supplements, go through a different registration process, the so-called Alpha Code process that then also yields the required import permit.

The Ministry of Health has a monopoly on the laboratories qualified to do bio-equivalency and other conformity assessment testing. The testing is a combination of providing written data to the government and having physical tests done in laboratories in Mexico. These laboratories are not necessarily only in Mexico City. They are all over the country but all are under the exclusive control of the Ministry of Health.

The only entities allowed to register medicines, drugs, and health products in Mexico are those that actually have manufacturing facilities in the country. Therefore, it is not simply a matter of registering these types of potential imports; the exporter must find a local partner who is willing to provide the auspices for the registration under Mexican law. The Mexican Ministry of Health has refused to allow importation of output from facilities that are outside of Mexico. NAFTA has changed things in that it is now possible for U.S. firms to receive national treatment in the sense of being able to submit bids for local tenders offered by the government. But they still need to be registered to submit tenders and that registration process requires a physical presence in Mexico. Mexican authorities claim that there is a need to have a facility in Mexico because otherwise they would have no recourse for liability issues if the facility were outside the country. The official U.S. response to this is that there needs to be national treatment for U.S. firms under NAFTA.

As an illustration, the manufacturer who produces a generic form of a popular, over-the-counter treatment for upset stomach for sale by several mass-market U.S. retail chains wanted to sell into the Mexican market. Even though several of these U.S. chains have a presence in Mexico, they are not permitted to buy a product that they routinely stock in the United States. This product must be registered and in order to be registered the manufacturer must have connection with a local Mexican pharmaceutical firm.

In spite of this apparent strictness, the Mexican system is riddled with anomalies. For example, registration made today is currently valid

for life. Some registrations go back 50 or more years. The registration could even be resold legitimately on the secondary market. There may be change of manufacturers or changes in the plants being used to produce registered drugs but there is no need to retest bio-equivalency under Mexican law.

Interestingly, in the realm of pharmaceuticals the Mexican authorities rarely refer to the health and safety exceptions provisions of the TBT Agreement or even recognize its relevance to the regulatory issues with which they deal. This may be due, in part, to a larger problem of communication between Mexican agencies. For example, the Ministry of Health, which has jurisdiction over imports of pharmaceuticals, and the Ministry of *Economía* (industry) appear to have little coordination on regulatory issues. In compliance with the TBT Agreement there is an official enquiry point, the Director General for Standards. But it has been charged that it is not very active, has not really been a powerful force in collecting information, and is not in tune with the actual rulings by regulatory agencies.

The transparency issue is raised by how new proposed technical regulations are often treated in Mexico. Most such new regulations in the health sector, for example, are not reported according to the reporting requirements of the TBT Agreement because they are not formally considered to be regulations by Mexico. Rather, they are issued as presidential orders. So notification procedures are not followed and no comment period is offered. This is said to create a climate unfriendly to foreign suppliers. A regulation will be announced and will be effective almost immediately. This situation of overnight adoption arises because the Mexican government wants to avoid strategic non-compliance during any latent period. They do not want, for example, a firm to dump a drug on the market in anticipation of a regulation going into effect at a later time that would ban it. This is true across all sectors, not just pharmaceuticals. For example, currently the Ministry of Health is working on a best manufacturing norm for nutritional substances. When this is completed, it will take effect the next day.

Other countries in Latin America present conditions similar to those found in Mexico. Examples of other actions that have the characteristics of potential TBTs include:

- In Ecuador, local manufacturers are given special treatment and procurement of domestic generics, by law, must constitute no less than 20 percent of total sales with government institutions being required to purchase only domestic generics.
- Venezuela requires individual packaging and dosing by the manufacturer for each and every patient prescribed. That is, the manufacturer must provide packages in the dimensions required by the physicians in their prescriptions. This serves to impose additional costs without a clear health or safety reason.
- Brazil represents a market with $4-5 billion in annual pharmaceutical sales. It has recently proposed a procedure for potential drug importers to first submit data and analyses on cost effectiveness. The authorities will not engage in quality and conformity assurance testing if the product does not first pass this hurdle. The procedures and criteria for passage are alleged not to be based on recognized scientific data.[37]

  Also in Brazil, generics are alleged to pass the bio-equivalency testing too easily and often inappropriately. The claim is that the testing of generics is not sufficiently rigorous because they have better access to and a different process from that applied to the innovative pharmaceuticals.

  Finally, in Brazil there is a tremendous backlog of process patents. This appears to many to be purposeful. There is no wait for any other form of chemical entity. All are processed in a timely manner. The exception is for pharmaceuticals. In 2002, Brazil approved 2 out of 18,000 drug patent applications. Meanwhile, while the innovative pharmaceutical remains patent pending, the generics and copies do manage to get registered for reimbursement.
- The countries of Central America have embarked on an effort to harmonize their regulations with respect to pharmaceuticals. Critics

[37] The problem of cost effectiveness testing is one of long standing in pharmaceuticals. See Luce, 1993.

charge they have deliberately chosen to harmonize on an older, lower quality set of standards. This will favor local manufacturers who cannot meet higher standards set elsewhere. Several of the Central American states also formally require procedures applied only to imports.

Tier III

By definition, the countries falling into this group are those who have chosen not to establish their own codes for regulation and conformity assessment testing but have instead adopted one of the major bodies of technical measures as their own. Typically, these are the regulations of the United States, Japan, or, most commonly, the EU. This does not, however, mean that difficulties with TBT-like characteristics do not arise in implementation.

To pick one example, Canada will accept either the U.S. or EU standards as being sufficient for meeting the regulations administered by Health Canada, the relevant regulatory body. Yet, PhRMA has cited some potentially TBT-like practices in its 2003 Special 301 submission to the USTR.

The allegations include purposefully slow registration processes for new products and unduly favorable treatment for domestically produced generics. In 2001 the average time for drug approval was nearly two years, seven months longer than the U.S. FDA's average approval time and well over the one year that Health Canada has set as its own goal. In addition, there is considerable variation across Canada's provinces on when and which pharmaceuticals appear in the official formularies. Among other charges, it is alleged that despite formal written regulations generics receive more favorable treatment than the innovative pharmaceuticals of which they are copies to the point that some generics have been approved even while the original drug product was still on patent. If true, this illustrates that being a Tier III country does not necessarily mean that there is an absence of issues that bear the characteristics of TBTs.

CONCLUSIONS

The pharmaceuticals industry by nature of its structure and output presents many preconditions for the emergence of TBTs. It is truly a global industry but one where governments also have a stake in having a large measure of local control. It is among the most highly regulated industries in any country and the variety of its product offerings is great, making the regulations truly complex. It produces high value added goods in much demand, hence an incentive for others to either control costs or to obtain some portion of the resulting value stream for themselves. And because its products are all directed toward improvements in health, with attendant concerns about safety, the issue of defining regulatory legitimacy is far from easy. Almost unique among internationally traded products, measures that might have the character of TBTs may be regarded as stands on principle by the officials and agencies that promulgate them.

Clearly, not all alleged TBTs are TBTs in fact and law. A significant number of alleged TBTs result from perceptions by U.S. exporter firms of being picked on – even if the regulatory agency in question is using the same standards and procedures used by FDA. The perception can also arise because the regulations may be dissimilar to those in the United States even though they are fully proper under the TBT Agreement.[38] Potential U.S. exporters discover they are dealing with a regulatory environment that is unfamiliar and where they are required to comply with more stringent requirements than they are used to on the U.S. domestic market. Consequently, complaints are brought alleging TBTs.

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[38] As an example, this issue often arises in the case of nutritional supplements. These are often placed in the drug category by the regulatory agencies of many countries. The U.S. position is that there should be a scientifically sound reason to do so; otherwise they should be treated as a food. This last, however, is not an obligation under the WTO rules. The U.S. does regulate nutritional supplements on the same basis as food, but this is in contrast with other countries where they are regulated on the same legal basis as drugs. This is not, therefore, necessarily a case of a TBT as much as problem of misaligned expectation and lack of experience.

The evidence, however, does suggest that some countries may emplace measures, both systematic and episodic, that appear prompted by health, fiscal, industrial, or foreign policy concerns -- or stem even from personal considerations -- that differentially and unnecessarily affect either the ability of U.S. firms to export or the cost of doing so.

Although regulations are written to cover general cases, the argument made in particular by the industry association of innovative pharmaceuticals manufacturers, PhRMA, is that de facto discrimination exists because regulations are written in such a manner that they only affect innovative pharmaceuticals. This is of particular concern from the perspective of the U.S. industry because the bulk of on-patent products have been developed in the United States. By the nature of the industry, technical measures that discriminate against new products would necessarily have most effect on this major U.S. product group.[39] Such regulations are couched in terms of protection for domestic populations but these goals are often conflated with an interest in promoting generics (because they are cheaper and the national health systems usually are the purchasers) as well as promoting local industry to keep the expended funds within the country.[40]

The welfare losses from this practice may be extensive but are hard to quantify. To the extent that such TBT-like results ensue, they might be viewed as providing a free ride for local generics manufacturers at the potential cost of reducing the local benefits to innovation and the incentives to develop the capacity to do domestic R&D. There is a further welfare cost to the extent that the local population is denied

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[39] Even when a drug is brought out by a non-U.S. manufacturer, in a great number of cases it is the product of research and development carried forward in the U.S.

[40] To make the issue even more complex, it may well be that the actual pills being regulated come from U.S. factories operating in China, Taiwan, Korea, etc. So these are not really exports in the fullest sense of the word. But in these cases it is the effort embodied in the drug product that has been exported. The trade restricting or discrimination argument becomes harder to make because pharmaceuticals are an intellectual property-intensive, high fixed cost, minimal marginal cost product. The idea embodied in the form of these products is being affected by regulations and practices that bar its full realization in the form of exports.

access to potentially helpful drug products either because they have been denied entry to the market through one or several technical measures or because knowing the indirect efforts of the local authorities to see generic versions of blockbuster drugs be developed locally, potential exporters choose not to go into this market and engender the creation of serious competitors. Finally, there is the more global potential welfare loss of lost innovation. Industry representatives argue that in spite of the apparently healthy returns to innovation presently enjoyed by pharmaceutical innovators, if it were not for the U.S. market the incentives for innovation would be most problematic. If external markets are restricted and the returns to be gained rendered lower through policy measures, the industry questions whether the U.S. market would remain large enough to compensate for the rising costs of drug discovery and marketing. But the issue may be more complex. It could be argued that it is not the size of the market necessarily as much as the number of innovating competitors that is crucial. Addressing this question in detail is beyond the scope of this study.

The principal effects of TBTs may take the form of increased recurring costs associated with regulatory compliance; one-time costs, perhaps resulting from the need to change manufacturing processes; and the opportunity costs associated with lost or reduced sales, perhaps as a result of a country's regulations or de facto processes raising unacceptable risks to potential exporters. The data on these costs and economic burdens exist but only at the level of the individual firm.

The leading industry association, PhRMA, does not do systematic collection of data on TBTs. They do focus attention on priority markets such as China, Korea, Taiwan, Brazil, and Mexico. There is active monitoring of regulations and new regulatory issues in these most sensitive markets, but only passive monitoring of other markets. Further, member firms develop their own direct information systems. So there does exist a well-established network for making inquiries, just no formal database. There is a great interest on the part of the industry to see more active and intensive monitoring and data collection on a case-by-case basis, but this is not something that is possible at

the industry association level. By their nature, steps to comprehend and accord with technical measures and undertake the requisite associated costs are experienced on a firm-by-firm basis. Such information is considered proprietary. Having an industry association collect such information could expose it to potential anti-trust concerns. Hence, obtaining these data from industry organizations is not feasible because many avoid collecting them as a matter of prudent practice.

At the U.S. government level, FDA maintains no files or databases on foreign regulations, standards, or conformity assessment procedures with TBT-like characteristics. Further, there is no information available from FDA that would allow for a calculation of economic effects of TBTs. The agency is specifically enjoined from collecting any information whatsoever on profits, costs, and revenues from firms in the industry.

The U.S. Department of Commerce recently began to maintain a case database of TBTs. However, it is not used to do aggregate analysis on the basis of systematic searches. Rather, it is intended as a resource for Special 301 investigations. The trade officials that are located in country, at the various U.S. trade missions, can be of assistance in gauging the general accuracy of these estimates, but there, too, there is no independent calculation of costs. Firms that make use of these services provide their own estimates of costs and loss. It is these that the Department of Commerce relies upon.

For these reasons, one conclusion of this chapter is that data for assessing the economic effects from TBTs on U.S. pharmaceuticals exporters would need to come from those exporters directly.

The issue of TBTs in pharmaceuticals also appears to differ from the situation in the automotive industry, the subject of the next chapter, in several respects. Whereas the latter industry produces a great variety of motor vehicles, the vehicles and their constituent components are utilized by and large to provide transport services for goods, people, or both over the common road grid. Pharmaceuticals, on the other hand, are more heterogeneous products. They may, for example, be used to treat symptoms, provide prophylactic protection, or ensure

the efficacy of other treatments. And they do not travel the same "road" within the body. Rather, they are targeted toward different body systems and operate in widely different ways. Further, there are not strict analogues in the automotive sector to the problems such as regulatory non-transparency and discriminatory registration practices, ostensibly on technical grounds, that are the principal sources of complaint in pharmaceuticals.

These factors make it difficult to provide an authoritative check list of alleged TBTs in the pharmaceuticals sector. Yet, even so, a cursory check of the specific instances discussed in this chapter does provide some insights. Based on these examples, Table 3.1 provides some suggestion as to where TBTs might occur.

Table 3.1: Patterns of TBT-like Measures in Pharmaceuticals

Measure	Europe	East Asia	Latin America	Rest of World	Total
Product	3	2	1	1	7
Process	0	2	0	0	2
Conformity Assessment Procedures	2	1	3	1	7
Total	5	5	4	2	16

The Table is a simple mapping of the instances of TBTs derived from the source material used in this chapter's discussion onto the three broad categories of technical measures. Clearly, it cannot be claimed to be definitive, merely suggestive. It indicates that issues of TBTs related to regulation of process is not a preponderant problem with the exception of the onerous data requirements on processes that are part of some registration protocols. On the other hand, issues of conformity assessment are prevalent. This represents an inversion of the concerns that exist in the automotive industry as discussed in the next chapter. TBTs arising from technical measures with respect to products are also a cause for concern in this sector. It is also worth noting that the

weight of alleged TBTs falls in the developed market regions of Europe and East Asia.

IV. TBTS AND THE U.S. AUTOMOTIVE INDUSTRY

INTRODUCTION

Like the pharmaceutical industry, the automotive industry provides a fruitful field of study for assessing the effect of technical barriers to trade on U.S. exports. Almost every country imposes regulations on motor vehicles that affect safety, emissions, and other items of public interest. Although the automotive industry is a global one, product standards vary by country or region. Further, the industry is politically and economically important so governments frequently seek to protect it from competition from imports. The combination of numerous, complex regulations, differing standards, and protectionistic pressures makes the automotive industry an especially inviting target for the application of TBTs.

The automotive industry is also worthy of study because of its importance to the U.S. economy. In 2001, total industry shipments ran $427.2 billion (Table 4.1); the automotive industry directly accounted for 1.1 percent of GDP.[41] The industry is also an important exporter. In 2001 and 2002, respectively, total automotive exports ran $73.5 and $76.5 billion, 10.2 and 11.2 percent of total U.S. exports. The 2001 figure was equal to 17.2 percent of total industry shipments.[42]

To evaluate the effects of TBTs on the U.S. automotive industry, we first briefly describe the structure of the U.S. and global automotive industry. The purpose of this discussion is to identify industry characteristics that make the application of TBTs more or less difficult. This is followed by a discussion of differences in international approaches to regulations, standards, and conformity

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[41] Census Bureau, Annual Survey of Manufactures, Table 2: Statistics for Industry Groups and Industries, December 20, 2002, p. 43.

[42] For the purposes of this study, automotive exports are defined as passenger cars, trucks, buses, and special purpose vehicles, and automotive components (end use trade code numbers 30000, 30100, 30200, 30210, 30230). We have chosen not to include automotive tires and tubes (30220) in this discussion.

assessment procedures that might affect U.S. exports. Then, using the checklist developed in Chapter II, we examine regulations, standards, and conformity assessment procedures throughout the world so as to identify measures that have characteristics of TBTs. We then explain how these measures may affect U.S. automotive exports. We conclude with an analysis of the most frequent types of measures adopted that have TBT-like characteristics.

Table 4.1: Value of U.S. Automotive Industry Shipments in 2001

(billion $'s)

Category	Shipments	Percent of Total Shipments
Cars and light duty vehicles	203.5	47.6
Heavy duty trucks	12.6	3.0
Parts, including bodies and trailers	211.0	49.4
Total	427.2	100.0

Source: Annual Survey of Manufacturers, U.S. Census Bureau, Dec. 20, 2002

THE U.S. AND GLOBAL AUTOMOTIVE INDUSTRIES

The structure of an industry may have an appreciable effect on firms' responses to differing regulations and standards in export markets and hence the effects of TBTs. For example, because sales volumes tend to be larger, big multinational corporations are more apt than smaller national companies to have the resources for responding to the introduction of a TBT by developing products according to different standards or to invest in production facilities in the country that has created a TBT. Smaller companies lack these resources and are usually faced with either adapting existing products to comply with foreign regulations and standards or abandoning the export market. The U.S. automotive industry consists of companies at both ends of this spectrum.

The automotive industry may be divided into three main groups of companies:

1. Original equipment manufacturers (OEMs) of light duty vehicles (cars and light trucks);
2. OEMs of commercial motor vehicles and trailers; and
3. Automotive component manufacturers.

The U.S. and global markets for light duty vehicles are dominated by a relatively few OEMs.[43] Eighteen companies account for over 90 percent of worldwide production, of which the top five account for well over one half.[44] As a result of corporate alliances and equity stakes among the leading manufacturers, the industry is even more concentrated than these numbers indicate: the top 18 manufactures fall into only nine truly independent groups. The top five companies include two manufacturers headquartered in the United States: General Motors and Ford, the two largest companies in terms of global sales. They are followed by Toyota, Volkswagen, and DaimlerChrysler. All five of these companies have production facilities in all major global markets.

Markets for commercial vehicles (excluding light duty vehicles) are much smaller and more fragmented than that for passenger cars. For example, in 2001, U.S. manufacturers' shipments of heavy trucks were only about 6 percent of the value of shipments of light duty vehicles.[45] Even though the market for commercial vehicles is much smaller than for light duty vehicles, the number of significant manufacturers, both in the United States and abroad, is larger. Globally, the industry is split into a small group of multinational manufacturers of medium and heavy trucks, which include DaimlerChrysler, Scania, Volvo, and Paccar,

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[43] For a various useful overview of the U.S. industry see: *The Road Ahead for the U.S. Auto Industry*, Office of Automotive Affairs, International Trade Administration, U.S. Department of Commerce, April 2003, http://www.ita.doc.gov/td/auto/2003roadahead.pdf.

[44] *Ward's World Motor Vehicle Data 2001*, Ward's Communications, Southfield, Michigan, 2001, p. 230-231.

[45] Census Bureau, Annual Survey of Manufactures, Table 2: Statistics for Industry Groups and Industries, December 20, 2002, p. 43.

a U.S. manufacturer. However, a number of other large manufacturers in Europe, Japan, and North America do not have a global manufacturing presence, for example, the U.S. manufacturer, Navistar. Smaller, independent domestic manufacturers are common, especially in developing countries. Bus manufacturers, in particular, tend to be focused on local markets.

In the United States and throughout the world, automotive components manufacturers form a much larger, more diverse group than OEMs of light duty or commercial vehicles. In the United States, there are about 5,000 components manufacturers, of which more than 500 are controlled by foreign firms.[46] Globally, the industry consists of tens of thousands of manufacturers. Both the domestic and global industry consists of several large multinational companies known as Tier 1 suppliers, followed by dozens of smaller, but still sizeable Tier 2 suppliers, and thousands of smaller companies that provide subcomponents and parts. In the United States, the largest 100 components manufacturers (the tier one and two suppliers) account for the vast majority of sales.

The composition of the industry has changed over time. Historically, OEMs produced a very large share of components in-house. Over the past two decades, OEMs, especially in North America, have divested components divisions and now rely much more on outside Tier I component suppliers than in the past. For example, General Motors has divested itself of Delphi while Ford has shed Visteon, both now Tier I suppliers. This same process has also taken place in Europe and Japan, although the degree of dependence on outside suppliers varies from company to company in all three regions.

Component manufacturers sell into two separate markets: sales to OEMs for installation on new vehicles and aftermarket sales to dealers, garages, and vehicle owners that are sold through a large variety of wholesale and retail outlets. Sales to OEMs dominate although

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[46] U.S. Department of Commerce, U.S. Industry and Trade Outlook 2000, Chapter 37 Automotive Parts, 2000; p. 37-1, http://www.outlook.gov/.

aftermarket sales are also sizeable. Total shipments by U.S. components manufacturers to both OEMs and the aftermarket ran $211 billion in 2001.

Exports of automotive components and parts are significantly more important than exports of finished vehicles. As shown in Table 4.2, in 2002, exports of parts and components, excluding tires, accounted for 62 percent of total automotive exports while components accounted for a little less than half of total industry output. Viewed another way, in 2001, exports of parts were equivalent to 22.8 percent of total U.S. output of automotive parts while exports of finished vehicles (cars and trucks) were equivalent to 11.7 percent of total output of finished vehicles.

Table 4.2: U.S. Automotive Industry Exports in 2002

(billion $'s)

Category	Total	Non-NAFTA
Cars	20.5	7.3
Trucks, Buses, and Special Purpose Vehicles	8.3	1.1
Parts	47.6	10.4
Total	76.5	18.7

Source: Annual Survey of Manufacturers, U.S. Census Bureau, Dec. 20, 2002

REGULATIONS IN THE AUTOMOTIVE INDUSTRY

TBTs stem from differences in regulations, standards, or conformity assessment procedures that serve to discriminate against exporters or are more trade restrictive than needed to fulfill a legitimate policy objective. In order to identify and assess potential TBTs in the automotive industry, it is useful to first describe the types of regulations, standards, and conformity assessment procedures facing U.S.

exporters of automotive products in major markets and explain how they differ from U.S. practices.

The UNECE and North American Regulatory Divide

U.S. exporters of automotive products face a world market that is roughly divided into two, previously three, major geographic regions in terms of technical regulations and standards affecting motor vehicles. In North America, the United States and Canada have adopted very similar technical regulations on safety and emissions. The U.S., Canadian and Mexican motor vehicle industries are extremely integrated; with some minor exceptions, standards are virtually identical.[47] Europe has adopted a core set of common technical regulations for motor vehicles under the auspices of the United Nations Economic Commission for Europe (UNECE). Like the North American industry, the European automotive industry also has a common set of standards, but one that differs from those in North America. Finally, Japan has had different technical regulations and somewhat different standards than either North America or Europe. However, in 1998 Japan became a signatory to the UNECE agreement: Japanese technical regulations are now being modified to correspond with UNECE regulations.

U.S. Regulations

In the United States, regulations affecting the design and construction of motor vehicles and automotive components are primarily set by the federal government although some state governments, most notably California's, have adopted their own regulations concerning emissions, fuel economy, and recycling tires among other issues.

1. Safety

[47] The North American market is less unified than the European market in terms of technical regulations. Although the Mexican automotive industry generally uses the same standards as in the United States and Canada, the United States imposes far more safety regulations on motor vehicles than does Mexico. The United States and Mexico also use different conformity assessment procedures to ensure compliance with regulations.

Regulations concerning motor vehicle safety are issued by the National Highway Traffic Safety Administration (NHTSA), part of the U.S. Department of Transportation under Title 49 of the United States Code, Chapter 301, Motor Vehicle Safety. Manufacturers of motor vehicles and components ensure that their products conform to these requirements and certify to NHTSA that they are in compliance. NHTSA regulations are written in terms of minimum safety performance requirements for motor vehicles or items of motor vehicle equipment. As long as manufacturers achieve the goals set by these requirements they are not constrained in terms of the designs or production processes they choose to employ.

NHTSA safety regulations generally fall into the following categories:

- Crash avoidance (controls and displays, braking systems, lighting systems, windshield wipers and defrosters, tires, etc.)
- Crashworthiness (restraints, air bags, windows glass, locks, seats, vehicle structure, etc.)
- Post-crash protection (fuel system integrity, flammability, etc.)[48]

2. Fuel Economy

NHTSA is also responsible for collecting information and enforcing U.S. regulations on corporate average fuel economy (CAFE). In the United States, the government establishes separate minimum average fuel consumption levels per distance traveled for the passenger car and light truck fleets. If average fuel economy of a manufacturer's fleet falls below specified levels, the manufacturer is liable for a tax per vehicle that increases to the extent the manufacturer misses the minimum. NHTSA establishes measures of fuel economy and enforces this legislation.[49]

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[48] National Highway Traffic Safety Administration, *Federal Motor Vehicle Safety Standards and Regulations*, August 2001, http://www.nhtsa.dot.gov/cars/rules/standards/safstan2.htm.

[49] National Highway Traffic Safety Administration, *Federal Motor Vehicle Safety Standards and Regulations*, August 2001, http://www.nhtsa.dot.gov/cars/rules/standards/safstan2.htm.

3. Emissions

A third major area of regulations affecting motor vehicles in the United States concerns emissions. The Environmental Protection Agency (EPA) is responsible for regulating tailpipe emissions of pollutants from motor vehicles. The EPA sets regulatory limits in terms of how much pollution motor vehicles may emit. Theoretically, manufacturers then decide how to ensure that emissions fall under these limits. In practice, manufacturers usually converge on the technology that most efficiently meets the regulatory limits. The limits, in turn, are determined on the basis of available technologies. The manufacturers, not EPA, test their vehicles under EPA guidelines and inform EPA of the test results. EPA ensures compliance by periodically conducting its own tests of vehicles.[50]

UNECE Regulations

1. The UNECE Agreement

As the result of international efforts to harmonize regulations and provide mutual recognition of conformity assessment procedures, Europe has developed a regulatory system that is generally applicable across that continent and is becoming increasingly accepted in other regions of the world as well. In 1949, the Convention on Road Traffic was adopted in Geneva. In 1952, the Working Party on Construction of Vehicles was set up by the Inland Transport Committee under this convention.[51] Initiatives by the Working Party to harmonize regulations on vehicle construction affecting safety led to negotiations on a treaty to harmonize regulations on motor vehicles. In 1958, a treaty was signed under the auspices of the UNECE entitled "Agreement Concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts, which Can be Fitted and/or be Used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of These Prescriptions." This treaty has become

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[50] Environmental Protection Agency, *Automobile Emissions: An Overview*, Fact Sheet OMS-5, EPA 400-F-92-007, August 1994, http://www.epa.gov/otaq/05-autos.htm

[51] The United States was a founding member of the Working Party on Construction of Vehicles.

the basis for creating common motor vehicle and component regulations in Europe and now beyond and for mutual recognition of certification. The agreement has been revised twice, most recently in 1995. Currently, 36 countries and the EU are signatories to Revision 2 of the UNECE treaty.

Until 1998, only European states had adopted common regulations under the agreement. However, in 1998, Japan not only became a signatory, but became the first non-European member to decide to make its regulations conform to those accepted by UNECE. Australia, New Zealand, and South Africa have signed since 2000. Because of these moves, regulations agreed to under the UNECE treaty are becoming the most commonly adopted both in and outside of Europe.

The national governments of the UNECE signatories can and do adopt additional regulations that must be met by motor vehicles and automotive components before they may be sold within their borders. However, signatories to UNECE agree that they will abide by all commonly agreed regulations. As of May 2003, UNECE had agreed to 114 regulations concerning motor vehicles and components. These fall within the following groups:

- Lights, directional signals, and reflectors;
- Electrical systems, including electromagnetic compatibility;
- Noise;
- Safety protection equipment, including door latches, seat belts, seats, airbags, and motorcycle helmets;
- Brakes;
- Safety glass and mirrors;
- Horns and other warning devices;
- Tires;
- Flammability;
- Crashworthiness and general construction, including specific components such as steering columns and interiors;

- Vehicle design in terms of exterior protrusions and clearance;
- Coupling devices, e.g., trailer hitches;
- Emissions of pollutants;
- Measurement of fuel consumption and engine power;
- Theft protection measures;
- Instrumentation and location of controls.

2. The EU and the UNECE Agreement

Although the UNECE sponsors the agreement, it is not a regulatory agency. Proposed regulations are first developed and in many instances adopted by agencies and ministries responsible for vehicle safety and emissions in the member states. In most member states, these agencies are located under the ministries of transportation. For EU member states, the largest and most important group of countries that are signatory to UNECE, the European Commission has become a major participant in this process. The European Commission has now become the primary source of regulations on motor vehicles in Europe.

As in the United States, the European Commission divides authority for regulations affecting safety and those affecting the environment between different agencies or, in the European Commission's case, directorates. Within the European Commission, the Directorate-General Enterprise is responsible for regulations concerning motor vehicle safety.

To some extent the European Commission takes a back seat to the UNECE in matters of safety regulation. The EU only became a signatory to the UNECE agreement in 1998. Because the UNECE agreement preceded EU involvement in vehicle safety issues, many EU regulations affecting safety have been developed under the auspices of the UNECE and adopted by the EU rather than vice versa.[52] This reflects the major roles

[52] *Automotive Industry: Regulatory Framework*, Enterprise Directorate, European Commission,

played by the ministries of transport in the member country states in the development of these regulations and the broader membership of the UNECE than of the EU.

In contrast, the European Commission has spearheaded the introduction of regulations to reduce the emission of pollutants from motor vehicles. Directorate-General Environment is in charge of regulating motor vehicle emissions. Emissions are regulated under Directive 70/220/EEC (for light vehicles) and 88/77/EC (for heavy vehicles) and by amendments to those directives.[53]

The EU has also adopted regulations concerning the disposal and recycling of motor vehicles. Japan has adopted regulations to this effect as well, but most other countries, including the United States, do not have regulations concerning recycling vehicles, although regulations on disposing of or recycling tires are common.

Other Countries' Regulations

Writing regulations on motor vehicle safety or emissions levels can be an expensive process if conducted on the basis of extensive research on crashworthiness and emissions technologies. Countries with large automotive manufacturing industries such as the major West European countries, Japan, and the United States have had the resources, private and public, to engage in this type of research. Poorer countries or countries without a large automotive industry have had fewer resources or less motivation to engage in the research needed to develop scientifically-based regulations. These countries tend to adopt or adapt UNECE, U.S., or in some cases Japanese regulations or accept vehicles produced by major motor vehicle manufacturers from countries that use these regulations.

Some medium-income industrializing countries that have domestic automotive industries have created their own systems of regulations,

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http://europa.eu.int/comm/enterprise/automotive/pagesbackground/regulatoryframework.htm

[53] Environment and Transport: Road Vehicles, Directorate for the Environment, European Commission, http://europa.eu.int/comm/environment/air/transport.htm

often by stipulating that manufacturers comply with additional regulations than those issued by the United States or the UNECE. For example, Russia imposes regulations concerning vehicle construction in addition to UNECE regulations. Some countries have adopted regulations from both the United States and the UNECE. For example, China, where the regulatory system is in flux, sometimes uses elements of both. These mixed cases tend to be difficult markets for U.S. OEMs as none of their standard models, even if designed to be produced for both North American and UNECE markets, meet the regulatory requirements of these countries. The small potential volumes of exports to these various markets make the costs of adapting products to conform to their regulatory requirements an inhibiting consideration. These mixed systems often effectively function as technical barriers to trade.

Harmonization of Regulations

As noted above, the Working Party on Construction of Vehicles (WP. 29), set up in 1952, was the original forum in which signatories agreed to work to harmonize automotive regulations. In addition to UNECE member states, the United States and Canada have also participated in WP.29 from its inception. Building on the work of WP.29, in 1998, the Global Agreement on Harmonization of Vehicle Regulations was signed. The agreement was deemed necessary because of the importance of ensuring that vehicles are safe, limiting environmental degradation caused by motor vehicles, and combating vehicle theft through technological innovation. In addition to the European Community, initial signatories included Canada, the United States, Japan, Russia, China, the Republic of Korea, and South Africa, among other major automobile producing nations.

Discussions concerning harmonization of regulations now take place within the World Forum for Harmonization of Vehicle Regulations (WP.29), the new title given the Working Party on Construction of Vehicles (WP. 29). Discussions on harmonization are conducted within six working groups: the Working Party on Pollution and Energy (GRPE), the Working Party on General Safety Provisions (GRSG), the Working Party on Brakes and Running Gear (GRRF), the Working Party on Lighting and Light-

Signaling (GRE), the Working Party on Passive Safety (GRSP), and the Working Party on Noise (GRB). Discussions not only focus on the harmonization of regulations affecting vehicle components, but also on the harmonization and mutual recognition of conformity assessment procedures.[54] Although progress has been made on harmonization of regulations, differences in regulatory goals and systems are such that complete international harmonization is highly unlikely in the near future.

STANDARDS IN THE AUTOMOTIVE INDUSTRY

As set out in Chapter II, standards are rules, guidelines, or characteristics for products or manufacturing processes approved by a recognized body. Compliance with standards, in contrast to regulations, is not legally mandatory. Standards are adopted to improve economic efficiency by facilitating the integration of products and processes and by providing market participants with information about products. In the case of the automotive industry, however, regulations are more typically directed at the achievement of public policy goals such as improving safety or reducing emissions of pollutants. Because of their voluntary nature, standards tend to be drafted by committees of stakeholders under the umbrella of non-governmental institutions, like the American National Standards Institute (ANSI) in the United States, the *Deutsches Institut fur Normung e.V.* (DIN) in Germany, the British Standards Institute in the United Kingdom and the *Association francaise de nomalisation* (AFNOR) in France, not by government agencies. However, in some instances government bodies, like the Japanese Industrial Standards Committee, part of the Japanese Ministry of Economy, Trade and Industry, are responsible for issuing standards.

These institutions, public and private, either set up standard drafting committees themselves or rely on specialized industry associations to conduct these activities. For example, the German

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[54] Economic Commission for Europe, *World Forum for Harmonization of Vehicle Regulations (WP.29): How it Works, How to Join It*, United Nations, New York and Geneva, 2002, http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29pub/wp29pub2002e.pdf.

Association of the Automotive Industry (VDA) is integrally involved in staffing and setting the agenda of the German Automotive Standards Committee (FAKRA) of DIN, the German standards body. Standards drafted by standard-setting committees such as FAKRA are subjected to public review and then adopted, often by consensus, by the presiding bodies of the national standards setting institutions.

In the automotive industry, the national standard setting bodies of the countries with the largest automotive manufacturing industries are the most important. In the United States, this organization is the Society of Automotive Engineers International(SAE International). SAE International organizes and runs technical standards committees that set automotive industry standards in the United States and elsewhere in the world. It publishes a number of publications to inform the industry and the public about standards; it also conducts some standards-related research. It has affiliates in Brazil and India and cooperative arrangements with other organizations involved in setting automotive industry standards, such as FISITA (*Fédération Internationale des Sociétés d'Ingénieurs des Techniques de l'Automobile*), a European organization. FISITA is another international organization of automotive engineers, with 32 member societies active in 32 countries.

As noted above, FAKRA, a committee under DIN, is the forum in which automotive standards are drawn up in Germany. Because of the importance of the German industry, FAKRA has a substantial influence on European, and therefore global, standards. FAKRA draws up standards for the automotive industry pertaining to terminology, testing, component and vehicle dimensions, interfaces, body structures and complete equipment. FAKRA represents DIN in the Road Vehicle Committee (ISO/TC 22) of the International Organization for Standardization (ISO) and also on 5 other ISO or CEN committees dealing with transport issues. In Japan, the Society of Automotive Engineers of Japan (JSAE) performs a similar role in setting standards under the Japanese Automotive Standards Organization (JASO).

Harmonization of Standards

In many respects, harmonization of standards in the automotive industry has moved more quickly than harmonization of regulations. All the major motor vehicle manufacturing countries are members of ISO committee TC 22 Road Vehicles. The automotive industry standards setting bodies participate in this committee through their nation's official representative, a national standards body. For example, ANSI is the U.S. representative to ISO. TC 22 and related committees have agreed on 536 ISO standards that pertain to the automotive industry. In addition, through the ISO 9000 certification of manufacturing processes programs, OEMs have benefited from an internationally accepted standard of manufacturing processes pertaining to automotive components, permitting them to shop for components from a wide-range of suppliers, confident that manufacturing processes are of a requisite quality. ISO 9000 has contributed to forestalling technical barriers to trade based on differing standards concerning manufacturing processes by establishing widely accepted international standards for automotive industry production processes.

Contributing to the harmonization of automotive industry standards, most OEMs now design "world" vehicles based on common components and hence standards. Through this process, the industry has pushed the development of common international standards for components.

CONFORMITY ASSESSMENT PROCEDURES

Within the global automotive industry, there are two general approaches to conformity assessment of products and processes with regulations: self-certification and type approval. The United States, Canada and some other countries use self-certification. Under self-certification, the manufacturer attests to the regulatory authority that the vehicle or component is designed to meet regulatory requirements. Regulatory agencies may spot check vehicles and components upon or after introduction to the market. Manufacturers are also responsible for collecting and providing to regulatory agencies information on after-sale performance to ensure the part or vehicle performs as specified. If the product fails to meet regulatory requirements, the manufacturer

has to issue a recall and modify the vehicle or part to ensure that it does so. In addition, self-certification creates legal liabilities for the manufacturer, making it vulnerable to civil law suits on the part of aggrieved customers.

The EU uses the other primary approach to conformity assessment: type approval. Under type approval, manufacturers have to procure a certificate of type approval before the product may be sold within the EU. They must first submit the product to be tested to an accredited testing organization to ensure that it meets government regulatory requirements. In recent years, the EU, under the "New Approach," has been moving towards more performance-based testing. However, in some instances, regulations determine design specifications that must be met. After the testing agency completes its tests, the manufacturer submits the test results to the appropriate government agency, which then decides whether to issue a certificate that the product conforms to regulations.[55] A certificate of type approval extended by any national authority of one EU member state must be recognized by all other EU member states.

Type approval tends to be more widespread than self-certification. In addition to Europe, Japan, and Mexico, most other Asian and Latin American countries practice type approval. Under the UNECE agreement, signatories agree to recognize type approvals provided by certified bodies in all other signatory states as well. This agreement provides very substantial cost savings to manufacturers. Not only do they only need to obtain one type approval for a particular product in a UNECE member state, they can also shop around for the lowest cost testing organizations. Historically, because obtaining type approval was mandatory and in many countries only one organization was certified to conduct tests, testing organizations were not very cost sensitive. Mutual recognition introduced competition into this activity. In some instances, testing organizations created TBTs by discriminating against

[55] Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles, Official Journal L 076 , 06/04/1970 P. 0001 – 0022.

imported goods through differential testing procedures or differential pricing structures. Mutual recognition serves to diminish this avenue for the application of TBTs.

In contrast to UNECE signatories, countries that are not signatories to UNECE may insist that manufacturers of finished vehicles or parts obtain type approvals from a domestic agency, replicating procedures that the manufacturer had already undertaken for UNECE markets.

DOES THE NORTH AMERICAN-UNECE DIVIDE CREATE TBTS?

Even though differences in regulations and standards between UNECE and North American markets impede trade by forcing manufacturers to make design changes to meet the demands of the two different regimes, in general these differences do not have the characteristics of TBTs as defined under the TBT agreement. The U.S., Canadian, and UNECE regulations are generally accepted as having been adopted to protect human life and health or for reasons of environmental protection. These regulations do not discriminate between imported and domestically produced vehicles and components, key provisos of the TBT agreement. Standards in the EU, North America, and Japan tend to be internationally recognized. Consequently, the "Great Divide" in the automotive industry may be cumbersome and costly for U.S. exporters, but in most respects the measures creating the divide fall outside the bounds of the TBT agreement.

The divide does impose costs. U.S. OEMs and component suppliers (as well as their European and Asian counterparts) have structured their businesses in accordance with this divide. U.S. OEMs have set up subsidiaries or alliances in Europe and Japan to manufacture vehicles that are in compliance with the UNECE and Japanese regulatory systems. Historically, the European and Japanese manufacturers have adjusted production lines to manufacture vehicles for export that are consistent with North American regulations. More recently, most major European and Japanese manufacturers have adopted the model of their U.S. competitors and acquired subsidiaries in North America to manufacture products for the North American market.

Component suppliers have followed a somewhat different strategy to cope with differing regulations and standards in these regions. Tier 1 suppliers have often followed the OEMs and set up plants close to major assembly operations. However, they also remain major exporters in as much as production of certain components may be more efficiently consolidated in a few plants. Tier 2 and Tier 3 suppliers have tended to export rather than site plants abroad. They adapt their products to the requirements of the various markets.

Although these differences in technical regulations and standards do not appear to meet the definition of TBTs, export data do raise the question of whether they have had a significant effect on U.S. exports of automotive products. Over three-quarters of total U.S. automotive exports and 65 percent of U.S. vehicle exports are exported to the NAFTA market (Figure 4.1). By way of comparison, 37.9 percent of all U.S. exports, including automotive, go to NAFTA countries.

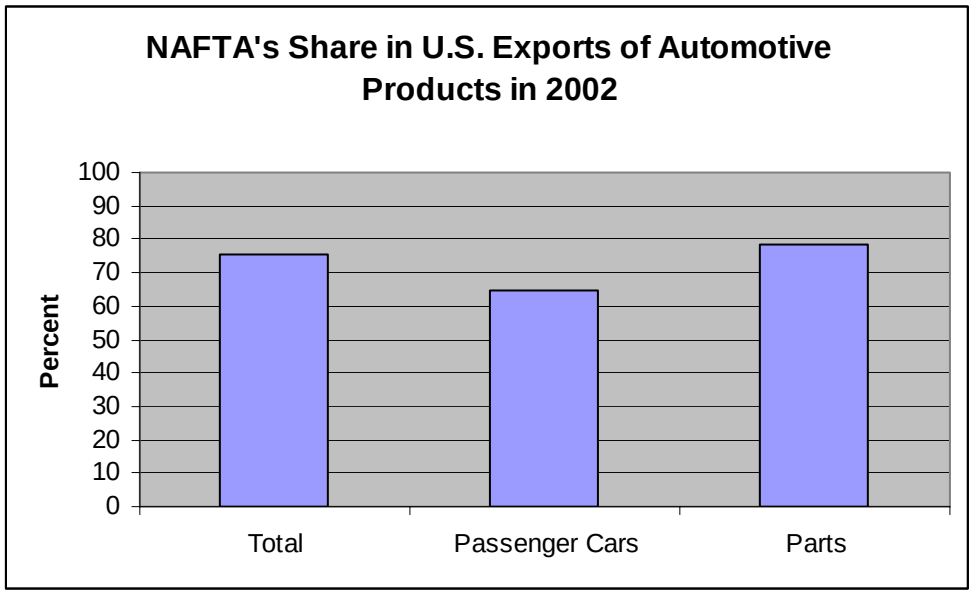

Figure 4.1-NAFTA's Share in U.S. Exports of Automotive Products

Differences in regulations and standards have not stopped U.S. automotive exports to non-NAFTA countries, however. Despite the design, tooling, and production costs of manufacturing vehicles and parts to meet regulations and standards other than those used in North America,

exports of automotive products outside of North America are substantial (Table 4.2). U.S. exports of passenger cars to non-NAFTA markets ran $7.25 billion in 2002, a third of the total; parts exports ran $10.4 billion.

Similar regulations and standards are not the only determinant of exports, however. Industrial structure and ownership also have an important influence on the destination of exports. The largest non-NAFTA U.S. automotive export markets are Germany and Japan, the two largest car-manufacturing nations outside the United States. Although traditional U.S. manufacturers also export finished vehicles to these markets, in recent years, most U.S. passenger car exports to Germany and Japan have come from plants that are located in the United States but owned by German and Japanese manufacturers. These foreign-owned manufacturers design vehicles and production processes so that vehicles can be manufactured to conform to European or Japanese regulations as well as U.S. regulations.

Design decisions that make it possible to manufacture the same model for UNECE and NAFTA markets are implemented by U.S. manufacturers as well as their European and Japanese competitors. For example, when Chrysler was still an independent company, it designed the Neon so that it could be manufactured for right-hand drive markets like Japan and the United Kingdom, as well as left-hand drive markets. The modifications in design these decisions entail can be quite substantial.

The substantial volumes of automotive exports to non-NAFTA markets suggest that the dominance of NAFTA automotive export markets is not just due to similar automotive regulations and standards. Rather, a key reason why NAFTA export markets are so important is the organization of the North American automotive industry, which in turn has been heavily influenced by North American trade policies, including NAFTA. The Canadian and U.S. automotive industries became closely integrated through the U.S.-Canada Automotive Pact, which lasted nearly three decades. NAFTA, which came into force on January 1, 1994, has superseded the pact. Initially, even under NAFTA trade in automotive products with Mexico continued to be subject to Mexican tariffs.

However, Mexico reduced tariffs on motor vehicles and automotive components very sharply in 1994 and subsequent years and finally eliminated all remaining tariffs on January 1, 2003. Trade in automotive products among NAFTA signatories is now duty-free.

Through the reduction of tariffs and other barriers to trade, NAFTA has encouraged automotive manufacturers to choose manufacturing sites in NAFTA countries on the basis of comparative advantage. As a consequence, labor-intensive processes have migrated to Mexico, while manufacturing of other components has been concentrated in the United States and Canada. Decisions on the location of automotive industry plants have in turn contributed to large increases in trade in automotive components within the region. In light of the growth of intra-NAFTA trade in automotive products since the signing of the agreement and the existence of substantial exports to non-NAFTA countries, the predominance of NAFTA markets for U.S. automotive exporters has to be ascribed to reductions in traditional barriers to trade and the organization of the North American automotive industry, not just common technical regulations or standards.

TECHNICAL MEASURES WITH TBT-LIKE CHARACTERISTICS IN THE AUTOMOTIVE SECTOR

In this section, we identify regulations, standards, and conformity assessment procedures imposed by various countries that may affect U.S. automotive exports. We then use the checklist developed in Chapter II to identify those measures that have TBT-like characteristics.

Data

In contrast to the use of tariffs and quotas, where the WTO is frequently called upon to adjudicate disputes, countries have very rarely made formal complaints under the TBT agreement. Countries do inform each other of pending regulations that might be considered TBTs. This provides an avenue through which trading partners can register objections and potentially forestall regulations that would act as TBTs. However, the TBT agreement has not generally triggered dispute settlement procedures through the WTO.

Because of the paucity of formal WTO disputes concerning TBTs, the list of specific measures that have been designated as such by the WTO is very short. Therefore, we have used a broader net to create a list of potential TBTs facing U.S. exporters of automotive products. This list has been compiled from information drawn from interviews with civil servants of the U.S. government, the Russian government, and the European Commission, representatives of U.S. automotive manufacturers, representatives of automotive industry associations, and documents such as *Compilation of World Motor Vehicle Import Requirements*, the *2003 National Trade Estimate Report on Foreign Trade Barriers*, "Market Access for Non-Agricultural Products: Indicative List of Key Non-Tariff Barriers", Minutes of Regular Meetings of the TBT Committee, and various reports from the WTO concerning implementation of the TBT agreement.[56]

The list is indicative, not definitive. We do not intend to make a judgment that these technical measures are, in fact, WTO inconsistent; rather, in our view these measures have some TBT-like attributes that may warrant further consideration.

The measures are grouped into three categories: technical measures pertaining to products; technical measures pertaining to production processes, and conformity assessment procedures. For each, we first describe the measure and then explain how it might serve to act as a TBT to U.S. exporters of automotive products. We then aggregate these measures to identify the most common forms and countries in which they occur. In the following chapter, we take one such measure and use it to demonstrate a method for estimating the potential economic costs to U.S. exporters that it could engender.

Automotive Products

Some examples of regulations on automotive products that have characteristics of TBTs include the following:

- Australia

[56] At http://www.ita.doc.gov/auto and http://www.ustr.gov/reports/nte/2003/index.htm, and http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm, respectively.

Although Australia joined UNECE in 2000, it has its own set of Australian Design Rules (ADRs). Australia does seek to reduce the impact of most ADRs on international trade. The ADRs use UNECE vehicle categories and are harmonized to a considerable extent with international standards.[57] Moreover, some rules, such as the stipulation that all imported vehicles be configured or reconfigured for right hand drive have obvious safety implications. However, others such ADR 45 ("Lighting & Light-signaling Devices not covered by ECE Regulations") impose additional requirements on manufacturers, that could have characteristics of TBTs, to the extent that they are more trade restrictive than necessary to improve vehicle safety. This regulation might be perceived as imposing requirements on manufacturers while not significantly affecting assurance of safe lighting.

- Brazil

Brazil bans imports of automobiles with diesel engines.[58] The ostensible rationale appears to be to reduce harmful emissions from diesel exhaust. However, sales of automobiles with diesel engines are permitted in all other sizeable automobile markets. Governments in these countries have found satisfactory means of controlling emissions from diesel engines other than sales bans. Thus, Brazil's ban has TBT-like attributes.

- China

China has been said to follow a mix and match approach by combining regulations from the UNECE and the United States as it creates its own system of regulations of motor vehicles. For example, the Chinese authorities have explored the adoption of North American regulations concerning emissions controls but UNECE regulations concerning safety equipment. This approach imposes significant burdens on foreign, including U.S., manufacturers because the costs of altering vehicles to meet these different specifications can be very high. In short, the mix

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[57] "Transport Regulation, Vehicle Transport, The Australian Design Rules," Department of Transport and Regional Services, http://www.dotars.gov.au/transreg/str_adrindx.htm.

[58] International Trade Administration, *Compilation of World Motor Vehicle Import Requirements*, U.S. Department of Commerce, August 2001, http://www.ita.doc.gov/auto, p. 13.

of regulations that have been adopted by China to regulate motor vehicles has had some characteristics of TBTs.

- Pakistan and the Philippines

A large number of countries, including Pakistan and the Philippines, levy disproportionate excise taxes or tariffs on vehicles with higher engine displacements. In Pakistan, for example, tariffs on passenger cars equipped with engines smaller than 1,000 ccs run 100 percent of the vehicle's value whereas cars equipped with engines more than 1,800 ccs in capacity incur a tariff of 265 percent.[59] In the Philippines, excise taxes are also levied on the basis of engine capacity. Vehicles with gasoline engines below 1,600 ccs incur a 15 percent tax; those above 2,700 cc incur a 100 percent rate.[60] The U.S. government argues that these tariff and excise tax rates create market distortions and serve to discriminate against exporters of vehicles with larger engine capacities.[61]

Countries that levy disproportionate taxes and tariffs on vehicles in terms of engine capacity reject the argument that these taxes serve as TBTs. They argue that differential taxes serve other public policy objectives such as restraining consumption of imported fuels or contributing to lower levels of emissions of carbon dioxide or conventional pollutants.

- Russia

Russia is a signatory to the UNECE agreement. In addition to UNECE regulations, Russia imposes five additional requirements that motor vehicles must meet to be sold in the country. These pertain to interior noise levels, interior air quality, ventilation and heating, and stability and handling. The fifth requirement pertains to front visibility, but is not always enforced. These requirements do not

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[59] International Trade Administration, *Compilation of World Motor Vehicle Import Requirements*, U.S. Department of Commerce, August 2001, http://www.ita.doc.gov/auto, p. 55.

[60] International Trade Administration, *Compilation of World Motor Vehicle Import Requirements*, U.S. Department of Commerce, August 2001, http://www.ita.doc.gov/auto, p. 70.

[61] Ibid, p. 70.

violate international agreements since UNECE does not preclude additional requirements. Moreover, Russia is not yet bound by the TBT agreement as it is not yet member of the WTO, although it is negotiating entry. These requirements do, however, have characteristics of TBTs. First, it is not clear that the additional regulatory requirements are necessary from the point of view of safety, environmental protection, or other rationales listed for regulations in the TBT agreement. In addition, potential exporters have charged that the regulations are applied in a discriminatory fashion: imported vehicles are held to higher standards than domestically produced vehicles.

- South Korea

South Korea has adopted its own regulations for headlamps and other components that differ from UNECE and North American regulations. Prior to 1998, South Korea did not accept headlamps that met UNECE or North American regulations, but did not meet South Korean regulations. Since 1998, South Korea has been adapting its regulations on lighting to better conform with UNECE regulations, but South Korean regulations concerning safety and other equipment still differ from UNECE and North American regulations, creating an impediment to trade.[62]

- Taiwan

Like Brazil, Taiwan bans imports of automobiles with diesel engines, with the exception of sport utility vehicles.[63] It also bans imports of cars with two-stroke engines. As in the case of Brazil, the ban on cars with diesel engines has TBT-like characteristics as alternative, less trade distorting measures for controlling emissions from vehicles are available and employed by others. Moreover, as Taiwan allows imports of diesel-powered trucks, the ban on diesel-powered cars seems inconsistent from the point of view of environmental policy.

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[62] International Trade Administration, *Compilation of World Motor Vehicle Import Requirements*, U.S. Department of Commerce, August 2001, http://www.ita.doc.gov/auto, p. 46-47.

[63] International Trade Administration, *Compilation of World Motor Vehicle Import Requirements*, U.S. Department of Commerce, August 2001, http://www.ita.doc.gov/auto, p. 45.

Automotive Manufacturing and Repair Processes

In general, governments do not regulate the processes by which motor vehicles and automotive components are manufactured. Automotive production processes do not pose the same potential threats to human health that processes in the pharmaceutical or food industries potentially do. Of course, automotive plants are subject to the same worker safety and plant emissions regulations that are imposed on other manufacturing plants within a country. In addition, some countries regulate the disposal and repair of motor vehicles. In some instances, regulations affecting these processes may have characteristics of TBTs.

- European Union

EU directives on recycling end-of-life vehicles (ELVs) may have TBT-like characteristics. As noted above, the EU has adopted a directive (EC Directive 2000/53/EC) on the disposal of ELVs that came into force on October 21, 2000. The Directive stipulates that by January 1, 2006, on average a minimum of 85 percent of ELVs by weight must be recycled and recovered, and a minimum of 80 percent by weight on average must be reused or recycled. The difference between the two concepts is that recovery may involve burning materials for the latent heat energy while recycling involves using the material again. Reuse involves reusing or renovating the part. By January 1, 2015, 95 percent of vehicles by weight must be recycled or recovered and 85 percent reused or recycled. The Directive makes manufacturers responsible for achieving these goals, potentially posing problems for exporters to the EU.

The regulations have been criticized for being unduly prescriptive: alternative, less prescriptive regulatory approaches could potentially achieve the same policy goal. To the extent that other, less prescriptive regulatory approaches are available, the regulations have TBT-like attributes. Adding to the concern, the average costs to exporters of adhering to the regulations, to the extent exporters to the EU market are affected, are likely to be substantially greater than for domestic producers because of economies of scale.

- Japan

In 1995, the United States and Japan signed the U.S.-Japan Automotive Framework Agreement. Among other goals, the agreement was designed to reduce technical barriers to trade to U.S. exports of aftermarket products to Japan. Japan has had a complex system of regulations and standards that affect aftermarket sales. The Japanese Ministry of Transport has created seven classifications of parts that are deemed "critical." Parts on the "critical parts list" may only be repaired at garages that are certified or if repaired elsewhere, have to be inspected at a certified garage. Because of the costs of training mechanics and certification, a large share of certified garages consist of dealer service centers or repair facilities directly tied to original parts manufacturers. These facilities generally only use original equipment parts, i.e., parts manufactured by the manufacturer or its direct suppliers.

Before the 1995 agreement, garages had to be certified for the repair of "critical parts" in all seven groups, if they were to be certified for the repair of any parts listed as "critical". Since the 1995 agreement, Japan has made it possible for garages to be certified for individual groups of components, reducing the costs of training and certification for smaller, independent garages. It has also removed a number of products from the "critical list," including shock absorbers and struts.[64]

Despite these changes, the Japanese system of certification of garages presents some TBT-like characteristics. The regulations discriminate in favor of domestic manufacturers because certified garages tend to be affiliated with Japanese OEMs or original parts manufacturers. As Japanese parts manufacturers supply domestic producers, the regulations serve to discriminate against foreign exporters of aftermarket parts that are not original equipment as these companies are not providers to the Japanese OEMs. Although the system is defended on the basis of its contribution to automotive safety, it

[64] "APAC Calls for New Treaty in Japan," AAIA 2000. *Aftermarket Insider*, vol. 3 at http://www.apaa.org/International/Trade_Agreements/Trade_Agreements.asp#Japan.

seems plausible that the same safety levels could be achieved with a less onerous system as they are elsewhere in the world. U.S. manufacturers argue that a number of components included on the critical parts list do not need to be classified as such.

- Turkey

Turkey imposes a regulation stipulating that companies planning to export to Turkey more than 75 units must obtain a Maintenance, Repair and Service Certificate from the Turkish Ministry of Industry and Commerce prior to importation. To obtain the certificate, the exporter is obliged to establish at least 20 service stations in seven designated geographic regions, of which at least one is to be operated by the exporter itself, and to maintain a sufficient supply of spare parts. Each of these service stations must obtain quality certificates from the Turkish Institute of Standards.

This regulation displays some TBT-like attributes. It does not seem necessary on the basis of reasons of safety or the environment. It also seems to discriminate among exporters and between exporters and domestic producers: Exporters of smaller quantities of vehicles to Turkey would have more difficulty in defraying the costs of developing a service network than exporters or domestic manufacturers who sell larger quantities of vehicles.

Conformity Assessment Procedures

- Mexico

In contrast to Canada and the United States, which use self-certification, Mexico uses type approval for conformity assessment. U.S. exporters of automobile components have reported some difficulties with obtaining type approvals from Mexico.

In addition, exporters to Mexico of some automotive parts have to apply to the Secretariat of Finance and Public Credit (SHCP) and be listed on a special industry register, otherwise they are not permitted to import the part. From a regulatory point of view, the registry requirement does not seem necessary. U.S. exporters have complained that when products are added to the list, the registration requirement

becomes immediately applicable, which can lead to costly delays while the exporter registers with the SHCP.[65]

- Russia

Russian conformity assessment procedures for finished motor vehicles and components have characteristics of TBTs. Although the UNECE agreement stipulates mutual recognition of certification procedures, in the event that a country like Russia imposes additional regulatory requirements, the UNECE agreement on mutual recognition applies only to those components like brakes or window glass that are covered in the agreement, not to the whole vehicle. Consequently, Russia requires additional testing and certification before Gosstandart, the regulatory authority, will issue a domestic certificate for the entire vehicle.

Testing and certification of the entire vehicle is expensive and time-consuming, costing between $3,000 - $20,000, depending on the period for which the certificate is to apply, the number of vehicles the manufacturer plans to export to Russia, and the extent to which the vehicle has been certified by other UNECE signatories. For example, the Russian certification agency, in accordance with the UNECE agreement, will accept certificates issued by an accredited agency from an EU member state concerning brakes and crashworthiness, but will still require certification of the whole vehicle by a Russian laboratory.[66]

Potential exporters to Russia complain that the process can entail demands for bribes and that employees of the certification agency will deliberately slow the process in an attempt to receive bribes or additional payments. Component manufacturers also find this procedure a barrier to trade as even small shipments of low-cost products will engender a demand for certification. Because initial orders are often in small volumes, the cost, delay, and expense of certification has dissuaded some exporters from selling into this market. In addition, Russian regulatory and customs authorities reportedly exercise a great deal of discretion concerning the applicability of type approval. At

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[65] United States Trade Representative, *2003 National Trade Estimate Report on Foreign Trade Barriers*, p. 274.

[66] Communication from Alexander Kansky, Russian automotive expert, U.S. Department of Commerce.

times, Russian authorities have demanded that each individual model or product variant receive separate certification. In the mid-1990s, one U.S. truck manufacturer was reportedly requested to obtain separate type approvals for vehicle differences as minor as different colors.[67] Domestic Russian manufacturers faced no such demands.

- South Korea

Vehicle homologation procedures are one of the major impediments to access to the Korean market. Imports of vehicles are held up for customs inspections and there is little transparency or consistency in customs procedures.[68] Safety compliance tests have to be performed in South Korea for all vehicles sold in quantities of 2,500 or more. Prior to 2001, virtually all imported vehicles had to go through this conformity assessment procedure. South Korea also imposes documentation requirements on imported vehicles to certify that they meet Korean standards for which there are U.S. or UNECE equivalents. Although South Korea has streamlined a number of these procedures and shifted from type approval to self-certification in 2002, the remaining procedures still present TBT-like characteristics.

- Venezuela

The Venezuelan government operates a standards office with the acronym COVENIN that establishes obligatory standards for some products sold in Venezuela. Venezuelan customs has demanded that exporters provide an official certificate to the effect that the product to be imported complies with these standards. In some instances the standards imposed by COVENIN were not the same as in the exporting country or, as in the case of the United States, no official institution could certify adherence to standards as the creation and observance of standards is a private-sector activity in the United States.

At one time, these Venezuelan conformity assessment procedures constituted a significant barrier to trade, but COVENIN now appears to accept a form of self-certification in which the manufacturer states

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[67] Communication with the author from U.S. Russian truck manufacturer representative.

[68] *2003 National Trade Estimate Report on Foreign Trade Barriers*, http://www.ustr.gov/reports/nte/2003/index.htm, p. 258.

that the product meets established standards. However, if the potential exporter is unable to provide any type of certification, COVENIN demands that quality tests be performed by a Venezuelan laboratory, an expensive, time-consuming process. In the case of automotive components, COVENIN has set obligatory standards for batteries, safety belts and anchors, McPherson struts, brake parts, spark plugs and a number of other items, some of which do not appear related to safety or environmental concerns.[69]

CONCLUSIONS

Drawing on survey and interview data that were extensive, albeit not exhaustive, we have identified fifteen regulations, standards, and conformity assessment procedures in U.S. automotive export markets that display TBT-like characteristics. We have found the largest number of instances of potential product-related TBTs in medium-income developing countries with domestic automotive industries. Latin American and East Asian countries figured most prominently within this group (Table 4.3).

Table 4.3: Instances of TBT-like Measures in the Automotive Sector

Measure	Europe	East Asia	Latin America	Rest of World	Total
Product	1	4	1	2	8
Process	1	1	0	1	3
Conformity Assessment Procedures	1	1	2	0	4
Total	3	6	3	3	15

[69] International Trade Administration, *Compilation of World Motor Vehicle Import Requirements*, U.S. Department of Commerce, August 2001, http://www.ita.doc.gov/auto, p. 30.

Regulations with TBT-like characteristics affecting processes were most common in the repair and service sector. Both Japan and Turkey have had regulations concerning repair services that seem unduly onerous for the public policy goals that they desire to achieve. New regulations on the disposal of End-of-Life vehicles like those that have been recently adopted by the EU have some TBT-like characteristics as some of these regulations seem very prescriptive.

In some countries, an unholy alliance of customs officials and "private" certification and testing bodies has succeeded in creating conformity assessment procedures that are arbitrary, costly and appear to discriminate against imports of automotive products. However, in our sample we have more instances of regulations affecting automotive products than conformity assessment procedures with TBT-like characteristics.

Based on the findings in this section we offer several recommendations consistent with those offered more generally in Chapter VII.

NIST does not need to set up its own, separate collection effort to identify TBTs. The U.S. government compiles a number of reports on market access problems confronting U.S. industry in general and the U.S. automotive industry in particular.[70] In addition, the TBT committee of the WTO publishes its minutes. These efforts have successfully netted a number of technical measures that have TBT-like characteristics. In our view, reviewing these reports and interviewing major exporters and industry associations are adequate steps for identifying most potential TBTs facing U.S. automotive exporters.

NIST should continue to monitor automotive export markets for instances of TBTs. As shown above, a number of countries have adopted technical measures and conformity assessment procedures concerning

[70] *Compilation of World Motor Vehicle Import Requirements*, *the 2003 National Trade Estimate Report on Foreign Trade Barriers*, "Market Access for Non-Agricultural Products: Indicative List of Key Non-Tariff Barriers", Minutes of Regular Meetings of the TBT Committee, and various reports from the WTO concerning implementation of the TBT agreement

automotive imports that have TBT-like characteristics. Automotive products are an important export, accounting for over one-tenth of total U.S. exports. Because of the prevalence of technical measures with TBT-like characteristics and the importance of this industry, NIST will continue to find it useful to examine and monitor foreign regulations, standards, and conformity assessment procedures affecting U.S. automotive exports to ensure that they do not violate the TBT agreement.

V. THE CURRENT STATE OF METRICS AND MEASURES

To the extent that the foregoing chapters present evidence of TBT-like practices, the question of effects arises naturally. If the U.S. pharmaceutical or automotive products industry, or any other U.S. industry, faces TBTs in a foreign market, how do we measure the economic effects? Who wins and who loses?

Two quotations suggest the difficulty of modeling the effects of TBTs on trade and welfare and the limits of the "state of the art" in this arena. Following a lengthy discussion of the difficulties of quantifying non-tariff barriers to trade (NTBs) generally, Deardorff and Stern (1997, p. 73) assert, "they [TBTs] are one of the most difficult NTBs imaginable to quantify." Maskus and Wilson (2001, p. vii) offer an even more sobering assessment:

> It is remarkable how little is known about the trade impact of technical barriers based on empirical data and analysis. Economists cannot say with confidence whether such restrictions tend to reduce trade by virtue of raising compliance costs or expand trade by increasing consumer confidence in the safety and quality of imported goods. Claims abound on both sides, about which little illumination is available from existing studies.

The combination of theoretical complexity and data scarcity makes efforts to model and measure TBTs that much more difficult. Unlike a tariff or quota, even a "bad" technical measure may have some redeeming features; for example, it may be overly trade restrictive, but it may also eliminate a safety hazard.[71] Several recent studies present,

[71] By and large, the literature on economic modeling and measurement does not distinguish consistently between technical regulations and standards as the TBT Agreement defines them. In this discussion, we adopt the definitions of the TBT Agreement; however, we also use the term "technical measures," to encompass any form of

assess, or apply methodologies for modeling and measuring the effects of NTBs, including TBTs, but no approach is or can be definitive. Each methodology offers its own pluses and minuses, depending on a number of factors, including the nature of the technical measure, the availability of data, and the goal of measurement. Among other major differences, some approaches look only at trade effects, without regard to any underlying market failures or externalities; others consider economic welfare more generally. Therefore, in the absence of any conclusive or definitive approach to measuring the economic effects of TBTs, care must be given on the one hand to prevent providing a distorted picture while at the same time crafting a method to illuminate the factors of most relevance for the policy issue of particular concern.

Maskus and Wilson (2001), Maskus, Otsuki, and Wilson (2001), and Beghin and Bureau (2001) provide comprehensive overviews of key economic issues relating to TBT modeling and measurement. We draw heavily from their findings and supplement them with insights from several other technical papers, including Roberts, Josling, and Orden's (1999) framework for analyzing technical barriers in agricultural markets and Deardorff and Stern's (1997) report on the measurement of a wide-range of NTBs, including TBTs.

Following Maskus and Wilson, we begin with a general discussion of the potential economic effects of technical measures, including TBTs. Next, we assess specific approaches to modeling and measuring those effects, addressing a variety of methodological challenges most typically relating to data availability and interpretation. We conclude in the following section with a discussion of how we intend to address modeling and measuring the effects of particular TBTs.

POTENTIAL ECONOMIC EFFECTS

Limiting the discussion of modeling and measurement to "TBTs," defined as "WTO-inconsistent technical regulations, standards, or conformity assessment procedures," narrows the range of analysis, but

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technical regulation, standard, or conformity assessment procedure that is covered under the TBT Agreement.

does not eliminate its complexities. Even a relatively simple exploration of added costs to U.S. exporters would likely pose substantial methodological challenges; a fuller — and arguably preferable — assessment would look beyond "compliance costs," to a broader range of economic considerations, involving supply, demand, and overall economic well-being.

A full reckoning of the potential economic effects of TBTs, requires a careful inspection of the positive and negative sides of the ledger; even a WTO-inconsistent technical measure may have some offsetting benefits. In cases involving a legitimate policy objective, a measure may work to discriminate against an imported good or raise costs more than necessary, but the measure may still remedy an actual problem, be it a safety hazard or other market failure. Moreover, a trade-affecting technical regulation, standard, or conformity assessment procedure, whether it is WTO consistent or inconsistent, may have broader market implications than a simple shift in an exporter's cost curve. Trade-affecting technical measures can affect the structure of the market and the basic configuration of domestic supply and demand curves. Their effects can also vary over time. Some effects are transient; others are long-lived. For example, a manufacturer incurs a "one-time" cost when it re-tools a production line to meet a new technical regulation; it incurs a "recurring" cost when it must certify each shipment's conformance to that regulation.

Setting WTO consistency aside, Maskus and Wilson (2001, pp. 17-18) explore the positive side of the ledger, that is, the legitimate need for technical measures and their ability to "facilitate production and exchange, reduce transactions costs, guarantee quality, and achieve the provision of public goods." Technical measures increase economic efficiency by:

- Improving the flow of information between suppliers and consumers about inherent product attributes;[72]

[72] The authors provide specific examples of the ways in which better information—through standardization—can improve how markets function, e.g., by reducing information asymmetries thereby helping to

- Increasing demand for complementary goods;
- Increasing the elasticity of substitution in demand between different versions of similar products;
- Promoting economies of scale;
- Acting as benchmarks for compatibility and performance;
- Promoting integration with global markets and technology diffusion;
- Overcoming market failures associated with public goods, such as human health and environmental protection.

Maskus and Wilson sum up as follows, "the essential point of standards is to support market development and facilitate transactions."[73] They note that the effects of technical measures may be both static and dynamic, especially with respect to technology diffusion and network industries.

On the negative side of the ledger, Maskus and Wilson (pp. 19-20) review some of the trade-related problems that can arise from technical measures, including those intended to address a legitimate policy objective: "The most straightforward problem is that costs of complying with standards may be higher for foreign firms than for domestic firms, implicitly erecting a trade barrier." The authors distinguish between "one-time" and "recurring" compliance costs.[74] They illustrate the

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overcome the "lemons problem" (Akerlof, 1970). They also cite the more-general benefits of reducing the costs of uncertainty that consumers face in assessing product attributes. Standardization may facilitate cross-product comparisons, thereby reducing search costs and other transactions costs.

[73] However, while addressing the legitimate uses of technical measures, the authors do not argue that they are necessarily the most efficient policy option.

[74] The authors present a possible trade-off between one-time and recurring costs. A firm may have the option to incur a large up-front cost, by investing in a flexible product platform, i.e., one that can be cheaply modified to meet export requirements in particular markets. Or, it may be able to spend less up-front for a more rigid, domestic-oriented product platform, but then face costly modifications for shipments out of country. They suggest that larger firms are better positioned to adopt the former strategy.

difference with a comparison of the one-time costs of product redesign and the recurring costs of continuous quality control and testing certification. Clearly, another source of recurring cost may be found in the efficiency loss of changing production technologies to meet a technical requirement, particularly if the change is market specific in a way that reduces economies of scale.[75] They also cite the possibility of "indirect" costs, e.g., the costs of making a change in product formulation in response to a labeling requirement on the part of a foreign government. Maskus and Wilson also describe costs arising from non-transparency, time delays, and uncertainty stemming from conformity assessment procedures.

Finally, measures that differ across countries can result in market segmentation. Maskus and Wilson (p. 20) cite requirements that product labels only be written in the language of the importing country, limiting opportunities for arbitrage. Roberts, et al. (p. 11) describe market-segmenting technical measures as holding the potential for "fundamentally altering the nature of competition." For example, they may transform a "small" country — that is, one that has no real ability to independently affect the world market, referred to as "market power" — into a "large" country. Technical measures may act to restrain competition — in the extreme, they may shut out foreign firms entirely, possibly allowing a local monopoly to flourish. However, market segmentation need not work to the disadvantage of all foreign suppliers. Those able to meet requirements and effectively discriminate may be able to glean greater returns through segmentation.

Who gains and loses from these arrangements? Absent a legitimate policy purpose, a "purely protective" measure would likely result in gains to the domestic industry at the expense of domestic consumers and, possibly, foreign suppliers.[76] Whether or how much foreign suppliers

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[75] Producers serving a series of smaller national markets, each with different technical requirements, may be less efficient than those serving a homogeneous global market.

[76] Domestic firms acting as agents and distributors for foreign suppliers constitute another category of potential losers. For example European firms that import and distribute U.S. products stand to lose when technical measures impede imports. Shipping and insurance firms

would "lose" from the arrangement would depend partly on the availability of alternative outlets for their products. In an otherwise competitive global market, their losses might consist of the additional transaction costs involved in shifting to a new a market, such as the initial start-up costs of establishing a new client base or the additional transportation costs of serving a market in a more remote location. If the now-protected market were still their best — or only — option, their losses would derive from the new compliance costs and any commensurate loss of sales.

Roberts, et al. (p. 11) help structure the discussion of losses from TBTs.[77] They frame the incidence of costs in terms of the "scope" of the technical measure — that is, who applies it to whom — and then illustrate the approach with four stylized cases. For the first three cases, they assume that all countries are "small" countries, implying that the actions of any one country have little or no effect on the world market. In the first case, when one importer imposes a barrier against one exporter, either can avoid the cost of the measure by finding a new trading partner. Perhaps more realistically, each would likely bear the burden of additional transactions costs, as outlined above. In the second case, when one importer imposes the barrier on all exporters, the importer alone bears the cost because the exporters can sell to other markets, unless the importer covers the cost of complying with the new measure. In the third case, if all importers (i.e., the whole world) target a specific exporter for compliance with a technical measure, the cost of the regulation is borne by the exporter alone, because other exporters can serve the market at the prevailing world-market price. In the final case, when all importers impose a regulation on all exporters, the small country assumption no longer applies. In this case, the importers and exporters share the cost burden in the form of reduced producer and consumer surplus.

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may also suffer losses from these impediments. The differential impacts on firms acting at different levels of the industry may create interesting dynamics in terms of lobbying activities.

[77] Roberts, et al., pp. 11 and 27-37, provide a thorough treatment of possible outcomes for a variety of scenarios. We address their findings in more detail in the following section.

At the beginning of this section, we broached the question of whether a technical measure that is inconsistent with the TBT Agreement might convey some non-protectionist benefit. If the answer is "no," then when calculating the net economic costs of a technical measure, we need only consider the economic effects deriving from the negative side of the ledger, e.g., compliance costs and supply shifts, the scope of the measure, and market segmentation if it occurs. This is not a simple feat, but it is still far simpler than if the answer were "yes." In the latter case, to gain the fullest perspective one would need to calculate the benefit derived from the measure net the economic costs of compliance and associated shifts in supply stemming from the measure. But again as a practical consideration, in the absence of any widely accepted method for calculating such costs empirically, the choice of approach and framework for analysis will be driven in part by the policy question ultimately to be addressed.

APPROACHES TO MODELING AND MEASUREMENT

Maskus, Otsuki, and Wilson (2001) and Beghin and Bureau (2001) provide overviews of the "state-of-the-art" in modeling and measuring the economic effects of technical measures, including TBTs.[78] Their overviews are structured differently, but cover much of the same terrain. Though not limiting their coverage to studies of TBTs *per se*, much of what they find applies to TBTs.

Maskus, et al. differentiate approaches by methodology or model type alone, whereas, Beghin and Bureau differentiate by measurement objective and methodology. Beghin and Bureau (pp. 3-4) distinguish between trade-oriented approaches and welfare-oriented approaches; the former concern themselves with trade impacts only and the latter address overall economic well-being through a larger range of effects. For example, among the trade-oriented approaches, the "price wedge" method allows estimation of the tariff equivalent of the TBT.

The trade-welfare distinction holds conceptual appeal, but is not entirely satisfying. Although some methodologies may seem to fall

[78] The authors also address SPS measures.

neatly into one category or another, the lines quickly blur. As Beghin and Bureau note, a tariff equivalent can be used as an input to a model that captures welfare effects. However, it can be argued that delineating approaches strictly on the basis of model type is equally unsatisfying, partly for the same reasons. For example, an econometrically derived parameter estimate can feed into a partial or general equilibrium model. While recognizing the merits of each of the taxonomies, we find that a methodologically based taxonomy is slightly more tractable. As such, we examine broad classes of model types, as per Maskus, et al., while paying special consideration to their potential applications, as per Beghin and Bureau.

Maskus, et al. (p.29) delineate four empirical approaches:

- "Surveys"
- "Macro-level econometric analysis"
- "Partial equilibrium (PE) models"
- "Computable general equilibrium (CGE) models"

Surveys. Surveys may vary considerably in their formality and coverage, but the basic premise of the approach is relatively clear. In general, a researcher, agency, or other entity asks questions of business executives, industry representatives, government officials, and other experts, to gather information about the effects of technical measures. Whether a particular survey is trade-oriented or welfare-oriented might depend on the list of recipients, the nature of the questions, and the use of the answers; however, most, if not all, tend to be trade oriented. Nevertheless, even a trade-oriented survey can provide inputs to a broader, welfare-oriented analysis.

OECD (2000), "An Assessment of the Costs for International Trade in Meeting Regulatory Requirements," presents findings from one of the most commonly referenced surveys. The survey covered 55 firms, associated with three industries (terminal telecommunications equipment, dairy products, and automotive components) in four countries (the United States, the United Kingdom, Germany, and Japan). The study describes its aim as investigating "the extent to which technical standards and

conformity assessment procedures impede trade," involving "an effort to collect quantitative data on the costs of compliance with technical requirements in export markets and on the extent to which these actually impede trade (p.5)." Key findings include:

- Different mandatory technical requirements existed among all study countries and within each industry, but, in general, were not perceived as large.[79]
- Companies generally found that harmonization of standards was very helpful in reducing product redesign and testing costs.
- Mutual recognition agreements of conformity assessment procedures have had a distinct and beneficial effect on costs of compliance.
- Firms have often adopted compliance strategies when considering export of their products.[80]
- Conformity assessment costs varied significantly among companies and across countries; time delays were an important indirect cost of conformity assessment.
- For many firms, meeting non-mandatory product standards was seen as at least as important as meeting mandatory technical requirements.
- Many firms have had difficulty assessing ex ante the costs of complying with foreign product requirements and assessments.
- Small firms relied more on external information sources than large firms and were less able to spread compliance costs over large output volumes, making exports less economic.

We note in passing that the last two points in particular highlight the importance of the role that NIST might play in providing support to potential U.S. exporters.

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[79] The telecommunications sector reported the greatest differences.

[80] For example, firms may incorporate features demanded by target countries into the initial product design or, initially design for the domestic market only and re-design for export as needed.

Notably, the OECD's findings on firm size, compliance strategies, and conformity assessment costs, all suggest the probable difficulty of establishing a one-size-fits-all approach to modeling and measuring the economic effects of TBTs. This conclusion increases the potential value of including survey-type elements in any attempt to determine the economic costs of TBTs. To do so would provide practical grounding and cross-checking for the validity of measures derived from other methodological approaches.

Other oft-cited surveys concerning relevant policy measures include an informal U.S. International Trade Commission survey of corporate executives, trade association officers, and government officials, located in the United States, EU, Asia, and Latin America, on the effects of technical measures in the information technology (IT) sector (USITC, 1998). Henson, et al. (2000) conducted a survey on sanitary and phytosanitary measures. The U.S. Department of Agriculture (USDA) conducted a survey of technical barriers to U.S. agricultural exports.[81]

Beghin and Bureau (pp. 13-14) find that surveys can help fill information gaps, identify "diffuse" barriers, and provide insight into real-world issues, e.g., by drawing attention to the regulations that firms really care about, as compared to those that economic modelers might otherwise latch onto. But, they question the ability of surveys to quantify barriers, "the firms consulted are likely to be biased if there is a perception that the agency conducting the survey will use the information for policy purposes," (p. 14). Although this may be the case, the OECD survey responses do not support the hypothesis. Many exporters reported relatively modest compliance costs in the course of the survey. Hence, at least for this survey, there was little evidence of an upward bias in cost estimates or complaints concerning the detrimental effects of foreign technical measures.

Econometric analyses. Econometric models typically seek to explain trade flows in terms of a set of "exogenous" variables, explicitly or

[81] Demonstrating how one approach can naturally contribute to the development of another, Roberts, et al. draw from the USDA survey to produce a typology for their analytical framework.

implicitly including policies and practices, such as technical measures. Maskus, et al. offer a single "econometric" category, whereas Beghin and Bureau identify two distinct empirical categories, inventory- and gravity-based, noting that inventory-based approaches, e.g., simple tallies of technical measures, need not be analyzed using "econometric" methods, but can provide proxy variables for econometric approaches. Gravity-based models, which are actually a distinct type of econometric approach, derive from the formula for Newton's "Law of Universal Gravitation," substituting the trade flows between two locations for the attractive force between two objects; the economic size of each location for the masses of the two objects; the distance between locations for the distance between objects.[82]

Maskus, et al. provide detailed descriptions of two econometric studies that are, in fact, inventory-based: Swann, et al. (1996) and Moenius (1999). The latter is also gravity-based. Both studies relate trade flows to a country's stock, or inventory, of "standards," as internally delimited. Per Maskus, et al. (pp. 32-33), Swann, et al. regress U.K. trade flow data on counts of national "idiosyncratic" and international standards recognized by the United Kingdom and Germany. They find that U.K. national standards tend to raise both U.K. imports and exports. According to Maskus, et al. (pp. 33-35), Moenius uses count data from 12 countries and 471 industries to estimate the effects of country-specific and shared standards, finding that shared standards affect trade volumes positively and that country-specific standards have much more complex effects.

Econometric approaches can provide insight into the broad relationships between technical measures and trade flows. However, among other shortcomings, the use of simple "count data" or tallies of standards is questionable; in particular, it is impossible to distinguish between important and unimportant standards. Beghin and Bureau (p. 11) note, "…the number of standards or the number of pages of domestic regulations is a poor proxy for the trade restrictiveness of

[82] For a more thorough description of this technique, see Beghin and Bureau, pp. 14-15.

the whole regulatory regime."[83] These problems are not necessarily inherent to the econometric approach, but to the execution of the approach. At least theoretically, various weightings and other refinements are possible.[84]

Partial equilibrium approaches. Partial equilibrium (PE) approaches incorporate various effects from both sides of the aforementioned "ledger," to assess the net effects of particular technical measures on trade and welfare more generally. Maskus, et al. address PE approaches in a single category. They include studies that draw from other micro-economic approaches discussed separately in Beghin and Bureau, such as the "price-wedge" method. Paralleling the relationship between inventory-based assessments and econometric approaches, price-wedge and other micro-economic methods may stand alone or could be used as building blocks for PE models.[85] In particular, the price-wedge method attempts to quantify a technical measure as a tariff equivalent, which can then be used in a PE model along with other market parameters, to help capture the broader effects of the TBT. Although we also treat PE approaches under a single heading, we examine price and other related measurement considerations separately.

PE approaches "rely on microeconomic representations of supply and demand and are used most often to assess the effects of a particular policy on equilibrium, i.e., on the changes in price, quantity, and welfare" (Beghin and Bureau, p. 20). In this arena, the policy — the

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[83] Beghin and Bureau, p. 16, evaluate gravity-based approaches separately, among the caveats, "they attribute departures of trade from what the model can explain to a mix of national effects, including NTBs, while the model is unlikely to be able to explain correctly all trade flows even in the absence of domestic regulations…" Sensitivity to model assumptions may be especially problematic in detailed product studies. Nevertheless, Beghin and Bureau describe gravity-based modeling, coupled with proxy variables from survey- or inventory-based methods, as a "promising area of research." Deardorff and Stern discuss other "important drawbacks," p. 19.

[84] Beghin and Bureau, p. 16, cite, Otsuki, Wilson, and Sewadeh (2000), as making use of the "level" of European aflatoxin standards to estimate the effects on African exports.

[85] Similarly, these methods may also inform computable general equilibrium (CGE) approaches.

technical regulation, standard, or conformity assessment procedure — is often modeled as either a tariff equivalent, estimated by calculating the "wedge" between the price of the imported good and a comparable domestic product, or a direct compliance cost. PE approaches are "partial" in the sense that they look comprehensively at the effects of technical measures on a specific sector or sectors, but not on an economy in its totality. In so doing, they permit a considerable amount of operational and institutional detail, but do not capture the full range of interactions across the economy.

Although lacking quantification, Roberts, et al. (pp. 26-27) offer a particularly accessible framework for drawing together many if not all of the concepts from both the positive and negative sides of the analytical ledger. Their framework includes three "different but combinable components":

- The *regulatory protection* component, which accounts for gains accruing to the domestic sector;[86]
- The *supply-shift* component, which accounts for the effects of imports on domestic supply, e.g., the benefits of mitigating supply-based externalities, and the costs of enforcing border compliance;[87]
- The *demand-shift* component, which accounts for the effects on domestic demand, e.g., the benefits of improving the flow of information from suppliers to consumers.

The authors apply the framework to several scenarios derived from the stylized cases introduced previously. In these scenarios, countries are deemed "small" or "large," and said to be with or without alternative sources and outlets for their products. Having already addressed the conceptual aspects of this framework in the foregoing

[86] A "purely protective" measure is a special case, lacking any technical justification. This component is most closely akin to an ordinary tariff or quota, for which the only clear policy purpose is to shelter and support a domestic industry.

[87] This component could also include the costs of monopolization in the case of market restructuring.

section, here we focus here on computational aspects, especially with regard to the protective element.

Modeling the protective element requires some estimate of either the tariff equivalent or the compliance cost. Beghin and Bureau, Deardorff and Stern, and others, address complications in calculating price wedges and interpreting them as tariff equivalents. For example, Krissoff, Calvin, and Gray (1997) calculate the differences between import and domestic prices for selected varieties of apples in U.S. export markets; these differences may, in fact, arise from technical measures, but they may also arise from differences in quality. The authors try to account for this possibility, by choosing like varieties, but identical matches are not always possible. This problem may be greater in more highly differentiated product markets.

Choosing the "right" prices for comparative purposes entails many other complications. Deardorff and Stern devote considerable attention to selecting price data and offer practical guidance, in a "cook book" of formulas for calculating NTBs, some of which they tailor specifically to measuring TBTs. Indeed, in the case of a TBT, which the authors deem among the most difficult NTBs to quantify, they suggest "trying to extract credible assessments of their costs from experts in the affected industries," as the first line of assault, only failing that, they provide suggestions on applying price-based approaches to measuring barriers (p. 73). The authors argue that the most appropriate prices to use in measuring NTBs generally are the domestic and invoice prices of the imported good (pp. 13-14):[88]

- The price on the domestic market of the imported good itself;

[88] Actually the authors argue that the absolutely purest price-based measures of an NTB would compare the price that would prevail without the NTB and the price that would prevail domestically with the NTB if the price paid to suppliers were to remain unchanged, p. 13.

- The invoice price of the imported good as paid by the domestic importer to the foreign exporter, inclusive of transportation costs but excluding tariffs.[89]

However, TBTs may require special consideration.[90] For example, the invoice price may already include cost increases incurred by exporting manufacturers in meeting the importing country's technical requirements so that the price wedge might understate the true effect. Prices may also embody other TBT-related effects, beyond the simple protective element, e.g., the supply or demand shift, as relevant to the particular case at hand (Deardorff and Stern, pp. 7-8). Moreover, prices may be different for many other reasons, some of which may bear opposite implications for exporters' well-being. For example, if markets are segmented and exporters can price discriminate, the wedge between an international price and a domestic market price may reflect rents accruing to exporters (Beghin and Bureau, p. 9).

Framing a policy in terms of compliance costs presents other challenges. Again, as a practical matter, the data may be hard to come by. Firms may be reluctant to share proprietary information and when they do, their reports may be susceptible to bias.[91] Additionally, costs must be carefully articulated to distinguish between "one-time" and "recurring" phenomena, with particular attention to their functional effects. Other temporal aspects cannot be incorporated in a static model, but may be essential to understanding the effects of a technical measure on a market. Baldwin (2001, p. 63) reproduces a graphic that shows the relationship between cost and time, where cost initially rises dramatically and then settles to a much lower steady state that is still somewhat higher than the pre-policy level.

In addition to the complexities of addressing the protective element of the framework, further complications arise in addressing the

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[89] This is commonly referred to as the "c.i.f." price, standing for cost, insurance, and freight.

[90] Deardorff and Stern provide more precise guidance on prices and applications, including various adjustments for transportation and other costs, in an appendix devoted to formulas.

[91] See the earlier discussion of survey-based approaches.

supply and demand shift elements, not least of which are establishing credible bases for estimating the functions themselves and predicting their structural responses.[92] Absent significant effects in either of these dimensions, authors have tended to apply existing, off-the-shelf elasticity estimates, to arrive at quantity responses to the protective element and derive welfare implications.

Challenges notwithstanding, a number of authors have productively applied PE approaches to gain insight into the workings of NTBs generally and sometimes TBTs specifically. Maskus, et al. (pp. 35-36) cite two examples in addition to the Krissoff, et al. apple study: Thilmany and Barret (1997) on the implications of technical regulations for U.S. exports of dairy products to other NAFTA countries; and Paarlberg and Lee (1998) on the case of U.S. tariff protection against beef imports that may transmit foot-to-mouth disease. Beghin and Bureau and Roberts, et al. cite several others.

Computable general equilibrium approaches. CGE approaches also hold the potential for drawing together protective, supply, and demand effects from both sides of the ledger and, additionally, capturing interactions across all sectors of an economy. However, they typically lack the capacity to handle the details that may be crucial to understanding the effects of TBTs on specific industries. Maskus, et al. (p. 37) offer the following comments on CGE's:

> …their measures of standards are necessarily heavily aggregated and cannot capture the complexities of codes as they exist at the detailed sectoral level. In that sense CGE studies incorporate crude specifications of standards into complex theoretical specifications, generating interesting predictions about how liberalization of technical barriers to trade could alter competitive prospects and rationalize industry. As policy guides, they are only suggestive.

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[92] Maskus, et al. provide more insight to these issues in a discussion of the problems of measurement, pp. 38-44.

Maskus, et al. (pp. 37-38) describe two examples: Gasiorek, et al. (1992) and Harrison et al. (1996). Per Maskus, et al., Gasiorek, et al. model two scenarios assuming that harmonizing "standards" in the EU will reduce trade costs by 2.5%. They show large impacts on EU production and trade, especially and not surprisingly in the increasing-returns-to-scale sectors. Harrison, et al. extend the approach, in part, by adding an information-induced demand shift element.

While CGE models hold conceptual appeal, particularly in so much as they can be used to shed light on broader economy-wide policy implications, they lack sufficient capacity to accommodate detail for an industry-based, case study analysis.

SUMMARY AND CONCLUSIONS

Having reviewed the literature on modeling and measuring the effects of technical measures, we turn next to the development of a methodological framework for NIST to use in assessing the costs of particular TBTs to U.S. exporters. Although few of the cited economic studies define TBTs strictly in terms of a measure's consistency with WTO commitments, or define technical regulations, standards, or conformity assessment procedures precisely in terms of the vocabulary of TBT Agreement, they nevertheless provide insight to the task at hand. For example, the OECD report cites many potential trade impediments that are not apparently discriminatory, but its findings on firm size, compliance strategies, and conformity assessment bear directly on the analysis of TBTs. The findings strongly suggest the necessity of developing a flexible approach that can support a considerable amount of institutional and operational detail.

Based on our reading of the literature, we have chosen to develop a PE-based methodology, as we believe it, coupled with information gleaned from our assessments of the pharmaceutical and automotive products sectors, can provide the most insight into the effects of particular TBTs on U.S. exporters in the selected industries. Although a PE model cannot speak directly to the broader economy-wide effects of TBTs, as might a CGE or macro-level econometric model, together with our

industry-level assessments, it can provide a credible starting point without the loss of operational and institutional detail that the other approaches necessarily entail. More to the point, they –a PE-based methodology teamed with case studies – can yield considerable practical guidance of direct value to NIST in performing its assigned role in the realm of TBTs.

Table 5.1 provides a capsule summary of the discussion of the literature in this section.

Table 5.1: Approaches to Modeling and Measuring TBTs

Categories from Maskus et at (2001)	Examples	Comments	Related categories from Beghin and Bureau (2001)
Survey	OECD (2000); USITC (1998); USDA (1996)	Trade-oriented; may fill information gaps, but quantification is susceptible to respondent bias	Survey-based approaches
Econometric	Swann, et al. (1996); Moenius (1999); Otsuki et al (2000)	Trade-oriented; may provide insight to broad relationships between technical measures and trade, but count data are problematic	Inventory-based approaches; gravity-based approaches
Partial equilibrium (PE)	Thilmany and Barret (1997); Paarlberg and Lee (1998); Krissoff, Calvin, and Gray (1997); Roberts, et al. (1999); Deardorff and Stern (1997)	May be welfare oriented, depending on use; draws together various effects of TBTs and assesses trade and welfare implication in detail, but data availability and interpretation pose practical difficulties	Price-wedge, risk-based, and stylized micro-economic approaches; sectoral or multi-market models
Computable general equilibrium (CGE)	Gasiorek, et al. (1992); Harrison, et al. (1996)	May be welfare oriented, depending on use; provides insight to aggregate-level economy-wide effects, but lacks ability to capture policy-specific details; data also pose practical difficulties	Price-wedge and other micro-based approaches may generate inputs to CGE models

Sources: Maskus, et al. (2001); Beghin and Bureau (2001).

Notes: OECD (2000) is cited elsewhere as OECD (1999). The correspondence between the Maskus, et al. and Beghin and Bureau categories is uneasy. For example, inventory-based approaches need not be econometric approaches, but can provide inputs to econometric approaches. Similarly, price-wedge and other micro-economic methods are not PE approaches *per se*, but can provide inputs and insight to PE models; they can also contribute to CGE models.

VI. A METHODOLOGY FOR MEASURING THE ECONOMIC EFFECTS OF TBTS

The discussions of definitions, industry conditions, and economic models in the preceding chapters provide the necessary foundation for constructing a practical method – or "framework" – for assessing some of the economic costs arising from particular TBTs. In this chapter, we develop and implement an initial framework, one that involves some compromise in pursuit of tractability and broad applicability. It requires relatively little data and can be applied across wide-ranging industries and TBTs, be they rooted in conformity assessment (CA) procedures, process rules, or product restrictions. However, while offering flexibility, it is intended for evaluating the effects of specific instances of TBTs on U.S. exporters, not TBTs in aggregate or economy wide. Moreover, the framework bounds the exporters' costs, by estimating the losses associated with a "worst case scenario," but it does not provide point estimates.

Framed in terms of the methodologies presented in Chapter V, we develop and implement a partial equilibrium (PE) model. PE models can be used to evaluate the effects of technical measures on economic activities in one industry or in relation to one market, such as specific automotive components or pharmaceutical products, without explicitly linking the effects to activities in other industries. In reality, an impediment to exports in one industry may have second order effects on other industries, e.g., barriers to pharmaceutical exports may reduce the demand for certain chemicals. But estimating such general equilibrium effects requires a much less tractable methodology, in most cases provides little additional understanding of the industry of primary interest, and conceivably runs the risk of obscuring operational and institutional detail. By contrast, our framework requires only relatively simple calculations, using information on prices, quantities, and compliance costs, and some insight into how manufacturers respond to changes in market prices.[93]

[93] This type of responsiveness is commonly referred to as the "price elasticity" of supply.

Further, as discussed in Chapter V, there are two approaches to modeling and measuring TBTs, one is welfare-oriented and the other is trade-oriented. Welfare-oriented approaches seek to quantify the effects of technical measures on overall economic well being, by accounting for their impact on all market participants, i.e., all producers and consumers. Such an approach would calculate the measure's net effect across all participants. The corresponding economic metric would be "net welfare loss." A welfare-oriented approach might also consider the distribution of gains and losses among participants, known as the "incidence" of the measure.

Here, in this framework, we take a trade-oriented view, focusing on the economic effects of TBTs on U.S exporters in particular industries in terms of the "additional" costs they face. In this sense, "additional" is defined as the differential element or the part of the TBT's cost that applies only to producers residing outside the TBT-imposing market.[94] As such, our metric is the "loss to U.S. exporters," evaluated at the industry level.[95] We do not address the effects of the TBT on producers and consumers in importing markets or on other non-U.S. market participants. We also limit the analysis to the "negative side of the ledger," that is, we do not calculate any of the potential market benefits that a TBT could generate.[96]

Indeed, more than just focusing on the negative, our approach provides an upper bound estimate of the losses to U.S. exporters. It does so by evaluating the economic effects of a worst-case scenario in which those exporters have no market power or alternative outlets for

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[94] In some cases, producers within the TBT-imposing market may also incur compliance or other TBT-related costs.

[95] We measure losses in present discounted value terms. Were the associated costs of eliminating or preventing the TBT known, e.g. the resources used by federal agencies, trade association, etc., this figure could be used to calculate a cost-benefit ratio.

[96] In the literature on TBTs, as noted in Chapter V, some authors point out that regulations and standards that serve as TBTs may provide some of the benefits associated with regulations and standards in general. Absent any attempt at quantification, our initial qualitative assessments of the pharmaceutical and automotive sectors offer little or no evidence that TBTs provide benefits that less trade-distorting technical measures could not otherwise provide.

their products. Our approach corresponds most closely to the scenario that Roberts et al. describe, in which all importers target a particular "small" exporter. In this scenario, U.S. firms bear the full burden of the TBT, facing a choice between the less costly of two options: (1) complying with the TBT and absorbing all the direct costs associated with compliance, such as the costs of developing and implementing a new CA procedure or (2) pulling out of or declining to enter the TBT-imposing market. Exporters will only choose the first option if the "intrinsic" value of the export market – the value prior to the imposition of the TBT – exceeds the costs of complying with the TBT. Otherwise, they will "opt out."[97]

The value the approach developed in this chapter provides is a higher degree of specificity in ascribing costs arising from TBTs than one normally sees in most calculations of such costs. We value the export market net of production, marketing, and distribution costs. A gross calculation of export revenue or shipments, as commonly reported in the press, would tend to overstate the value of the market and, in some instances, might falsely indicate "compliance" as the preferred option.[98]

This chapter proceeds in three parts. We begin with an overview of the key determinants of additional cost to U.S. exporters by considering the types of costs that a TBT might impose, the scope of the measure, and the market position or "size" of importers and exporters. Next, we develop a framework for evaluating the worst-case scenario. The framework requires a two-part evaluation: (1) an assessment of the total cost of complying with the requirements of the TBT, which we refer

[97] In effect, the intrinsic value of the market is the *absolute* upper bound on the exporters' losses, as they will not choose to incur compliance costs that exceed the intrinsic value.

[98] The press often reports gross figures, e.g., "U.S. exporters lost $200 million in sales when Country A blocked imports of Product B." A more appropriate measure, "producer surplus," would account for and net out the costs of generating those sales. However, a gross market estimate can serve as a useful indicator of the relative size of potential losses. If the export market is large, the potential losses are likely to be greater than if the market is small. Consequently, aggregate export statistics can provide a relevant gauge of priorities for responding to existing or proposed technical measures.

to as the "cost-absorption estimate" and (2) an assessment of the loss associated with exiting or never entering the market, which we refer to as the "value-of-market estimate." Recalling that exporters can either comply or opt out, the lesser of (1) and (2) is the upper bound. We provide detailed instructions for treating one-time and recurring costs in the compliance cost calculation and for evaluating the intrinsic market value, net of production, marketing, and distribution costs. The chapter concludes with a quantitative illustration, drawn from a proposed Mexican regulation in the automotive components industry. The following, final chapter of this study suggests directions for usefully extending this initial basic framework.

KEY DETERMINANTS OF LOSSES

The economic effect of a TBT on U.S. exporters depends on at least three factors. The first is the types of costs it imposes: one-time or recurring; fixed or variable. Second is the scope of the measure, whether one or all importing nations apply it specifically or universally. The third is the extent to which traders—importers in addition to exporters—have "market power." We will begin our discussion with the last of these factors.

Market Power

The concept of market power is independent of any consideration of TBT effects. It does not necessarily denote any willful intent. Rather, it just reflects the reality that some countries and some suppliers by virtue of their size or position will affect world-market prices -- possess market power -- because of changes in the quantities they demand or supply. We make use of the conventional economic delineation of "large" and "small" traders: a large importer or exporter has market power and a small importer or exporter does not. For example, if a "large" importer demands more or less of something, the world-market price will rise or fall accordingly; its actions, absent any other trader's actions, can affect the world-market price. Similarly, if a large exporter supplies more or less of something, its actions can also affect the world-market price.

Conversely, the actions of an economically "small" trader have no such effects on the world market. For example, when a "small" importer, acting alone, implements a TBT it has no effect on the world market price because its share of the world market is so small – the world-market price remains the world-market price, regardless.[99] Similarly, when a "small" exporter responds to a TBT, its actions have no global effect. Small traders are "price takers."

The designation of "large" or "small" need not correlate to physical size, but market share may be a reasonable indicator of market power. A trader that accounts for a large share of a market, broadly or narrowly defined, may be economically "large" in that market; a trader with a small market share may be economically "small."

Cost types

The costs arising from a TBT may either be "one time" or "recurring." A single TBT affecting a product, process, or CA requirement can entail either or both types of cost. Each type of cost can affect exporters' behavior, hence losses, differently.

One-time costs are the initial costs of establishing new processes and procedures to meet technical requirements. Examples include: redesigning and retooling assembly lines for export-oriented products or developing infrastructure to support new CA procedures. These types of costs are "fixed" in the sense that they are invariant to the number of lots or size of a production run, typically up to some threshold.

Recurring costs persist over time, arising in each and every operating period. Because they recur period-by-period, we also refer to them as "periodic" costs. Some of these costs are "fixed" in each period, i.e., a lump sum for any level of output; others are "variable," i.e., repeating per lot or unit of production.[100] Indeed, a single TBT can involve a variety of recurring or periodic costs. Examples include

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[99] By implication, other traders can continue to buy and sell the item in question at the world-market price, both before and after the small trader implements the TBT. Thus, the measure has no noticeable effect on world production or consumption.

[100] The literature typically addresses the variable dimension, implicitly characterizing "recurrence" with respect to units of production, rather than time.

using more expensive materials for export-oriented production, possibly because of quality differences or foregone bulk order discounts; operating separate assembly lines for export-oriented production, entailing the loss of economies of scale; staffing and implementing new CA procedures; and holding or storing product shipments for re-inspection by the importing country.

Our methodology distinguishes between one-time and recurring costs, as they can affect behavior differently. One-time costs pose a hurdle for exporters that are seeking to enter or remain in a market.[101] Indeed, one of the most difficult aspects of measuring the economic effects of TBTs is the initial fixed-cost element. If the initial cost of complying with the TBT is so high that it blocks new entrants, we cannot observe the cost of the TBT empirically. Although we may suspect that some firms have chosen not to enter the market, we cannot be sure how many are missing or to what ultimate effect. At least in the case of a newly imposed measure we can observe firms' responses.

Although one-time costs accrue in a single period, time can be a critical determinant of their effect. A longer horizon affords greater opportunity for spreading the cost across several periods, thereby reducing the effective "height" of the hurdle. In the context of our worst-case scenario, exporters compare the costs of compliance with the intrinsic value of the market to choose a course of action, i.e., complying with the TBT or opting out. Whereas the one-time cost is invariant to the length of the horizon – it accrues up front – the market valuation will depend crucially on the number of years under consideration and the rate at which costs are discounted. If exporters assess the value of the market over a three-year horizon, the market will appear to be worth "less" than if they assess the value over a five-year horizon. In effect, they will have fewer years over which to recover the one-time cost.

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[101] In the case of an existing technical measure, they pose a hurdle for new entrants; in the case of a new measure, they pose a hurdle vis-à-vis the decision to stay in—or effectively "re-enter"—the market.

A recurring or periodic cost, whether fixed or variable, can also affect a firm's market entry or exit decision. However, once a firm has decided to enter or remain in a market in a particular period, only a variable cost will affect its marginal production and export decisions.

Figure 6.1 shows a hypothetical time-path for total costs resulting from a TBT that entails both one-time and periodic costs for a fixed level of output.[102] In the figure, exporters incur large one-time adjustment costs in the first period. By the second period, only the newly imposed recurring costs remain. The new post-TBT "steady state" total cost is higher than the pre-TBT cost, but not as high as during the initial adjustment period. To the extent that exporters face a smaller post-TBT market, any resulting loss of economies of scale might push upward their unit costs and therefore the total cost.

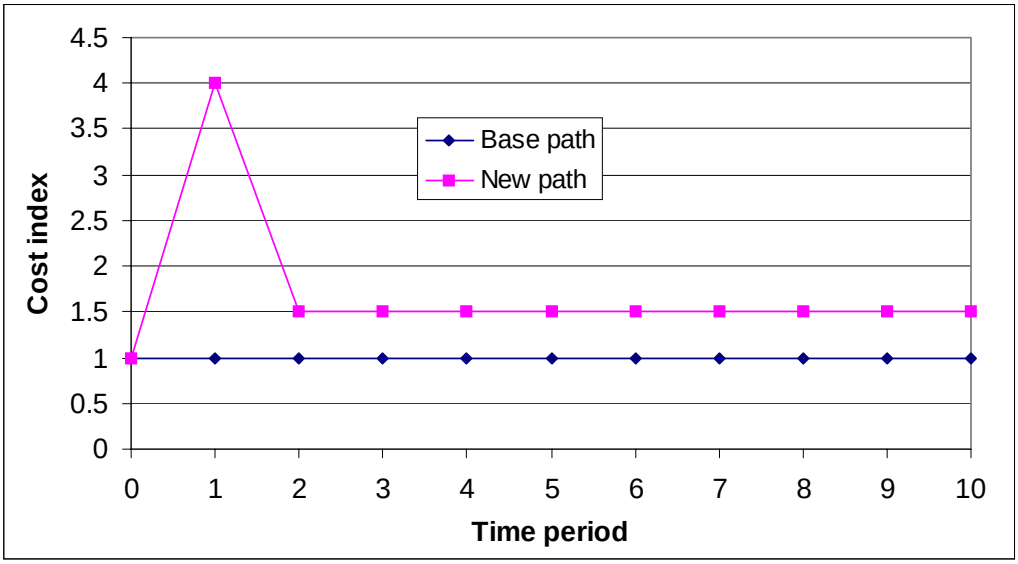

Figure 6.1-Hypothetical Time Path for One-Time and Recurring Costs

Source: Based on Baldwin (2001, p. 63)

Scope and Size

Recalling that "large" and "small" indicate market power, the case where all relevant importers apply a TBT to a single "small" exporter provides the basis for the upper bound estimation. It is our worst-case

[102] For a constant flow of production, recurring costs are constant. Baldwin (2001, p. 63) provides a similar depiction.

scenario. Roberts, Josling, and Orden (1999, pp. 11 and 25-34) describe the ways in which the scope of a technical measure and the economic size of the importer and exporter determine the magnitude and incidence of a TBT's costs.[103] Following Roberts et al.[104], an exporter only bears the full compliance cost burden of a TBT if the measure is applied selectively to the exporter alone by all importing countries — or the only relevant importers — and the exporter is small and has no other marketing options.[105] In practice, the exporter is unable to pass along the increased costs associated with the TBT to the importers who have the option of buying from other exporters. The targeted exporter either absorbs the increased cost or loses the sales — a serious decision not only for the short term but for the long as well based on the exporter's "value-of-market" estimates.

In the worst case, lacking viable alternatives, the targeted exporter can either (1) continue exporting to the TBT-imposing market, absorbing the full cost of complying with the standard, technical requirement, or CA procedure through a reduction in producer surplus ("cost absorption") or (2) pull out of the market entirely - or never enter it - and forgo sales with no prospect of replacing them elsewhere. The exporter's loss will be limited to whichever of these options imposes the lower cost. If the cost of complying with the TBT exceeds the cost of the lost exports, measured in terms of the intrinsic, pre-TBT, value of the market to the exporter, the exporter will withdraw from the market. If the costs are less, it will adapt to the TBT and continue to market some exports. Simply stated, the market must be worth more to the exporter than the cost of complying with the technical measure; if it is not, the exporter will choose to exit the market or never enter at all. The upper bound is the lesser of the two options.

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[103] Scope refers to the extent of coverage; size refers to traders' ability to affect world markets, typically through quantity and prices; and incidence refers to the allocation of costs among importers and exporters in the form of foregone consumer or producer surplus.

[104] In particular, p. 30.

[105] Alternatively, importers and exporters would share some of the costs if all importers target all exporters.

Conditions of full cost absorption lend themselves to an estimation procedure based on direct observation or reporting of actual or potential cost increases. However, if firms simply extract themselves from the market, or never choose to enter, a crude calculation of the foregone value of the market may be necessary. We discuss these two measurements separately, below.

By comparison, in framing what amounts to the best-case scenario for U.S. exporters, Roberts et al., suggest that "exporters in general should not notice the effect of the technical measure if the technical measure is imposed by only one importer, and if the world market price is not affected by the importer policy. In this case, the world market shrinks, but by an amount too small to be noticeable, as other importers will be willing to buy the displaced goods."[106] If the importer applies the TBT universally to all exporters from all countries, then its consumers bear the full cost of the measure. If the importer applies the measure selectively to only one nation's exporters, then both it and the exporters can avoid the cost by finding other trading partners.

However, it seems unlikely that many exporters, even the "smallest," will bear the full burden of a TBT, as most operate in sufficiently diffuse markets that some alternate outlets exist for their merchandise. But, as Roberts et al. suggest, shifting sales to the next best market can entail real costs for individual firms. Exporters re-orienting their marketing strategies may incur the initial costs of identifying and establishing a new client base and the higher costs of transporting merchandise to more distant locales, also suggesting a combination of one-time and recurring costs. Moreover, some exporters may appear to be "small" in relation to broadly defined markets but may be "large" in the narrower markets in which they actually operate. Even if they cannot sell their products elsewhere, they may be able to shift some of the burden of compliance to importing consumers.

On balance, it seems more likely that exporters would share part of the burden of the TBT with the importer, by absorbing some of the one-time and recurring costs or shifting some sales to the next best

[106] Roberts et al., 1999, p. 29.

market.[107] In either case, they would face something less than the full cost of the TBT. Thus, a simple cost-based or value-of-market-based estimate provides an upper bound on the economic effects of the TBT from the perspective of the exporter and should not be treated as a point estimate. That is, it is not an estimate of the costs of the TBT; rather it is an estimate of the high end of a range.

At the other extreme, it seems almost as improbable that exporters would bear none of the costs. Many firms have established ties in particular markets – linked through elaborate networks – and would rather share some of the cost than exit entirely. Even if they do exit, they would still face the aforementioned costs of shifting market venues. Moreover, some importers, like their exporting counterparts, may seem "small" in the context of broadly defined markets, but functionally "large" in more narrowly defined niche markets. As such, their actions may affect world market prices for specific items. When they impose a TBT, thereby reducing the demand for imports, prices may fall to the detriment of all niche-serving exporters.

ESTIMATING THE UPPER BOUND

While the reality most likely lies somewhere beneath it, we offer a methodology for estimating the upper bound of the costs of TBTs to U.S. exporters.[108] Here, we introduce a two-part evaluation process: first, we consider the direct cost of complying with technical regulations, standards, and CA procedures; second, we assess the net loss if exporters choose to exit or never enter a market absent a viable alternative. The upper bound is the lesser of the cost-absorption and value-of-market estimates.

In the next section, we illustrate different aspects of the methodology, drawing an example from the automotive components industry.

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[107] If the exporters still choose to service the TBT-imposing market it is because their share of the TBT burden, i.e., the cost of compliance, is less than or equal to the cost of shifting markets.

[108] Estimating the absolute lower bound is trivial, it is zero or negligible.

Cost-Absorption Estimation[109]

Developing the cost-absorption estimate requires information on the types of costs that each TBT imposes. Any TBT stemming from a CA procedure, process rule, or product restriction may entail a variety of one-time and recurring costs. Indeed, our qualitative assessments of the automotive and pharmaceutical sectors suggest that no one form of TBT is more likely than another to impose a particular type of cost. In some cases, relevant cost data can be acquired directly from interviews with firms or trade organizations. It can also be derived less directly from intermediate input prices, labor rates, prevailing values for real property and other fixed assets, and exemplary values, inferred from other appropriately analogous industries.[110] Export price or invoice data can provide further insight to the distribution of gains and losses.

Regardless of the source, the data should address questions in two basic categories, deriving from the distinction between one-time and recurring costs:

- What costs are involved in setting up new processes or procedures?
  - Research and development
  - New facilities and equipment
  - New distribution networks
  - New training
  - Others
- What costs are involved in implementing requirements?
  - Increased production costs
  - Additional personnel

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[109] The development of this framework benefited greatly from the work of Roberts et al. (1999) and Krissof et al. (1997) and from a lengthy discussion with Roberts, Krissof, and Calvin in April 2003. Any errors in designing and implementing the framework are entirely those of the authors.

[110] Absent either a direct or indirect route, it may still be possible to derive an estimate of total costs from observations of changes in export quantities and estimates of supply elasticity, where "elasticity" is a measure of the responsiveness of exports to changes in prices or, in this simple case, costs.

- Shipping delays and inventory costs
- Others

Within the second category, costs must be delineated further as fixed or variable with respect to output:

- Which of the implementing costs are fixed in each production period?
  - Minimum staff size
  - Facility overhead
  - Others
- Which of the implementing costs accrue per lot or other production unit?
  - Costlier production materials
  - Physical inspection
  - Holding or storage costs
  - Filing and other regulatory compliance fees
  - Diseconomies of smaller production runs[111]
  - Others

Ideally, we would want to know which costs are specific to the element of the technical measure that is being differentially applied to the exporter; i.e., those costs which are different or more than the costs faced by other producers. If all producers, both foreign and domestic, face the same constraints and compliance costs, implying the absence of a differential element, the measure probably is not a TBT as defined in this report.[112] The measure may be costly for U.S. exporters, but it may still be WTO consistent.

Our assessments of the variable cost effects of TBTs are founded on a simple PE export supply model in which a differential between the world-market and "autarky" prices (the market-clearing price in the absence of the opportunity to trade) of a particular item induces competitive firms to produce more of the item than they would if they

[111] Diseconomies *decline* with increased output.

[112] If all importers apply a measure to all exporters, but do not apply the measure domestically, the measure would qualify as a "TBT," but the exporters would likely share the costs with domestic consumers.

were serving only the domestic market.[113] The difference in prices arises from an inherent difference in market conditions – e.g., the firms in the home market may be relatively more efficient in the production of the item than other firms.

Figures 6.2a and 6.2b illustrate the basic export supply mechanism, *absent* a TBT. The autarky price (Pa) is the price that would prevail in the would-be exporters' home market (Figure 6.2a) if the market were shut off from trade. When the market is open for trade, both the firms that produce the item and the consumers that buy it face the prevailing—higher—world price (Pw) for this particular good. When the world price exceeds what would be the autarky price, domestic consumers typically purchase less of the item, but firms produce more. The difference between the quantity that consumers purchase, at the world-market price, and the amount that firms produce is the industry's "excess" supply. The excess forms the basis of the export supply (ES) curve in Figure 6.2b.

In Figure 6.2a, the market-clearing autarky price, Pa, is $4 and the corresponding quantity purchased by domestic consumers and produced by domestic suppliers is 3 units. When the home market opens up to trade, producers and consumers face a world-market price of $6. The autarky price is less than the world-market price because of the aforementioned differences in market conditions. At that $6 price, consumers purchase 1 unit and firms produce 5 units, exporting the 4-unit "excess." Were Pw only $4, firms in the home market would produce just enough to satisfy domestic demand; were Pw less than $4, they would produce too little to satisfy domestic demand, resulting in imports. In any case, they would be operating competitively and incurring zero economic profits.

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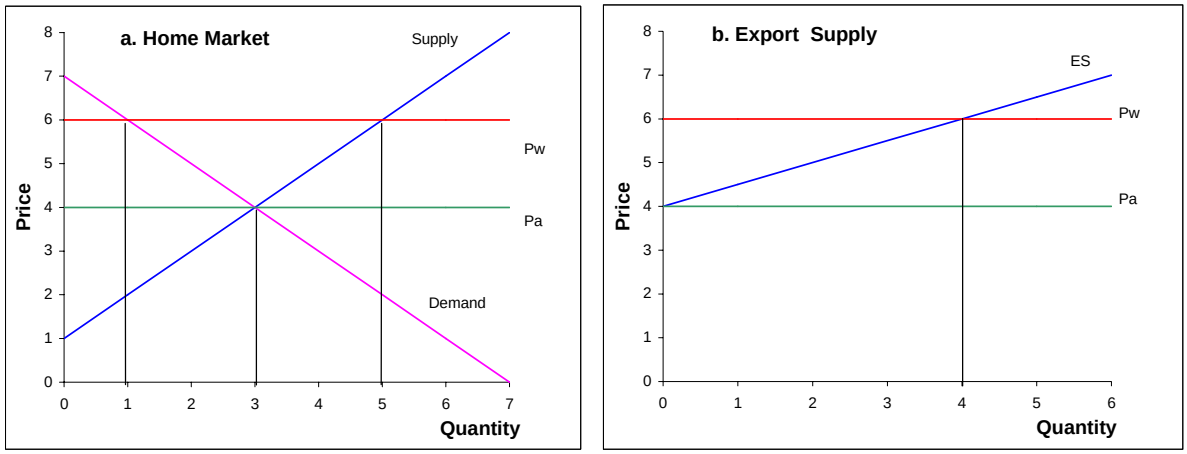
[113] We can assess the fixed and variable cost implications separately because we assume that the fixed costs apply only to export-oriented production, that is, they do not affect the underlying domestic supply function.



Figures 6.2a and 6.2b-Deriving Export Supply

Figure 6.2b shows the relationship between Pw and export supply. As noted, if Pw were equal to Pa, none of the good would be supplied by the domestic producers for export. When Pw is $6, the export supply response by domestic producers yields four units of the good for trade.

To incorporate a TBT into the basic export supply model, illustrated in Figures 6.2a and 6.2b, and assess the variable cost component of the "cost-absorption estimate," we need information on the unit costs occasioned by the TBT and one of two additional inputs: (1) the actual or expected change in export quantity due to the TBT or (2) an estimate of the elasticity—or responsiveness—of export supply with respect to price or cost. The latter might, for example, be an estimate derived from a prior study of the industry. In a simple model, with a linear export supply curve, horizontal export demand, and full cost absorption, the imposition of an additional unit cost will have the same effect on exporters as an equal reduction in unit price. The two are functionally equivalent. Given the equivalence, the treatment below will represent such effects solely in terms of unit price, again as a means to broaden tractability and applicability of the measurement tool.

In our worst-case scenario, the U.S. exporting industry, as a collective "price taker," would face a horizontal export demand curve. (Figure 6.3 depicts the effect of the variable cost component arising from a TBT in each production period.) Although the TBT would not effect a literal change in the world-market price, U.S. exporters would

be forced to absorb the additional unit cost to remain in the market, because the TBT-imposing importers could purchase the regulated item at no additional cost from other suppliers (recall that the TBT, in our worst-case scenario, discriminates against U.S. exporters vis-à-vis all other relevant suppliers). However, in a linear model, the economic effects of a unit cost increase, resulting in an inward shift in the supply curve, and a unit price decrease, resulting in a downward shift in the demand curve, are mathematically equivalent.[114]

For simplicity we assume:

- Linear upward sloping export supply[115]
- Horizontal export demand, such that $P_w' = P_w - c$ where P_w' is the new *effective* world price facing U.S. exporters, P_w is the initial world price facing U.S. exporters, and c is the recurring variable cost of complying with the TBT.

Given these assumption, the *effective* price drops from P_w to $P_w' = P_w - c$; exports therefore decline from Q to Q'. If all firms in the home market were identical, each would reduce its output by the same amount to effect the move down the industry's export supply curve in response to the cost increase. In reality, however, some firms are likely to be less efficient than others, in which case some might reduce their production more than others or even exit the market. By whatever adjustment mechanism, the competitive industry would continue to operate along its export supply curve at zero economic profit. For comparative purposes, the figure also shows the equivalent inward shift in the export supply curve, as the dashed line ES'.

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[114] In geometric terms, as illustrated in figure 6.3, the former requires estimation of the area of a parallelogram (D) and triangle (B); the latter requires estimation of a rectangle (A) and triangle (B). The areas of the parallelogram and rectangle are equal.

[115] The linearity assumption may lead us to misstate the potential costs of the TBT. If, for example, the supply curve were highly inelastic at the market equilibrium – that is, were it much steeper in the region of the equilibrium – the potential costs to U.S. exporters would be greater.

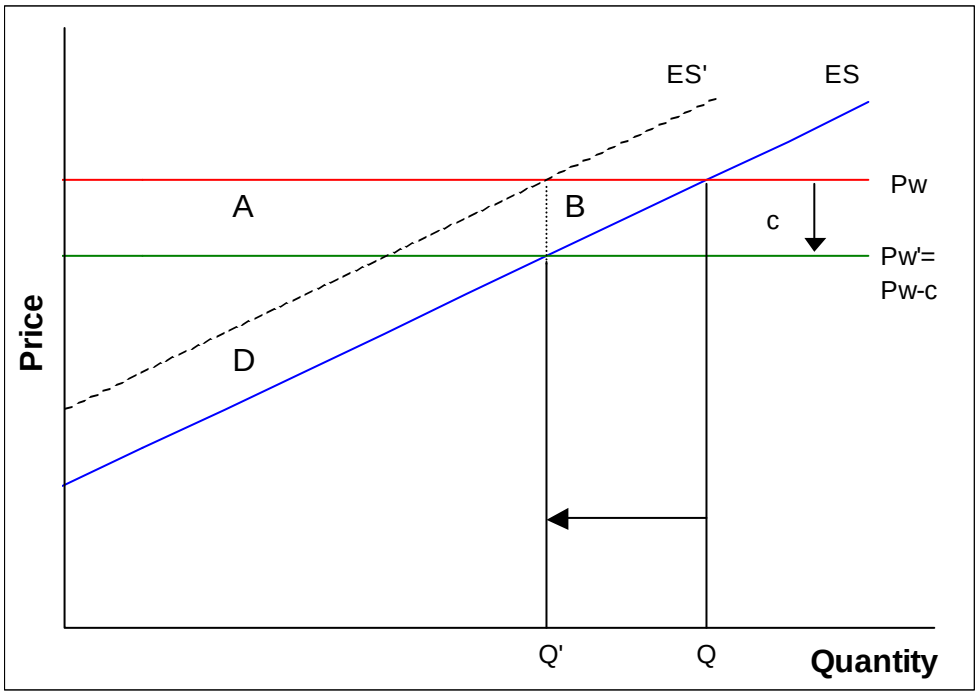

Figure 6.3-Illustrating Variable Cost Effects

Source: Based on Roberts et al. (1999).

The net effect of the additional cost, c, is the area A+B. (For a linear export supply function, the area B is a triangle of length Q-Q' and height c.) This area, A+B, is a measure of lost producer surplus. Were we to depict the variable cost effect of the TBT as a supply shift, the relevant area would be D+B.

Recalling that A+B – or equivalently, D+B – only depicts the variable cost effect of the measure, limited to a single period, the total cost of the TBT would consist of the sum of (1) any one-time costs, such as re-tooling costs, and (2) the present value of any costs that recur in future periods, both "fixed" with respect to output, such as minimum staffing and other overhead costs, and "variable," as figure 6.3 depicts, summed to time, T. Stated mathematically:

$$TC = FC^{I} + SUM_{t=0,T}\{[FC^{P}_{t} + c_{t}(Q_{t}-Q_{t}')/2 + c_{t}Q_{t}']/(1 + r)^{t}\} \quad (1)$$

where TC is the total cost of the TBT, valued at the time of implementation (t=1), FC^{I} is the one-time or *initial* fixed cost, FC^{P}_{t} is

the *recurring* or *periodic* fixed cost, c_t is the *recurring* or *periodic* variable cost as described above and shown in figure 6.3, and r is the rate at which future costs are discounted to the present period when summed over the entire period from the first period, t=1, to time t=T.

If export price data and data concerning the cost of complying with the TBT are available, they can be used to assess the distribution or incidence of costs, i.e., the extent to which exporters share cost increases with consumers in importing countries through higher prices. If exporters are able to raise their invoice prices, contrary to the foregoing example, they cannot claim to absorb the full cost of the technical measure. However, in that case, the exporters' costs must also be assessed in terms of the effect of the price increase on the quantity of import demand. Typically, as prices rise, consumers reduce their purchases.[116] So, the exporter may be able to pass some costs on to consumers in importing countries but will likely sell less of its products because of it. By combining quantity, price, and cost data we can estimate the effects of the measure on the firm's bottom line.

Value-of-Market Estimation

The value-of-market assessment considers the losses to U.S. exporters when they choose to exit a market – or never enter it – rather than absorb the compliance costs. For a new TBT resulting in market exit, the approach requires information on the quantity of U.S. exports and the price of exports pre-TBT. It is important to note, however, that an estimate of the gross value of the market, measured as total foregone export revenue, or P_w*Q, would likely overstate the cost of opting out. Rather, as discussed above, we are interested in the exporters' losses net of production, distribution, and marketing costs. Thus, the assessment also requires information on the shape and position of the industry's export supply curve.

The exercise is more difficult when it involves existing measures that have already led to a decision to forego market entry. As a

[116] The degree of consumers' price response is generally measured in terms of the price elasticity of demand: the percentage change in quantity demanded for a given percentage change in price.

practical matter, we can try to estimate the cost by looking at the size of the TBT-affected market, positing a plausible U.S. share -- were there no TBT -- based on U.S. exports to other analogous markets, and then evaluating the associated producer surplus.

Here, as illustrated in Figure 6.4, we also assume that the export supply curve is linear and upward sloping. In addition, for purposes of tractability and given the frequent lack of otherwise requisite data, we now consider not the "true" export supply curve (ES) but rather base our calculation on an export supply curve intercepting the y-axis at zero (the dotted line). In a simple excess supply framework this assumption lacks internal consistency, as the excess supply curve should start from the exporting country's autarky price, Pa. However, in this case, by assuming the supply curve intercepts the y-axis at 0, we in essence assume that the marginal cost of the first export unit is negligible.

While not ideal, how does the approach perform as a measurement device? For the market depicted in Figure 6.4, the "true" periodic loss, were exporters to opt out of the TBT-imposing market, would be the area A+B+D, where D is the triangle formed by ES, Pw', and the vertical axis. The estimated loss would include the addition of the triangular wedge between the supply curve, ES, and the dashed line lying beneath the ES curve. For any particular market the overstatement would depend on the actual location of the y-intercept. Thus, even though a zero-intercept would tend to overstate the actual loss, it still offers an improvement over total revenue as a measure of market loss. For purposes of this analysis, we describe the estimate as the largest possible loss-of-market cost that may be inflicted by the TBT on U.S. exporters.[117]

[117] More accurately, it is the largest possible cost assuming a linear export supply function. As previously noted, were the supply curve highly inelastic at the market equilibrium, the cost could be substantially higher.

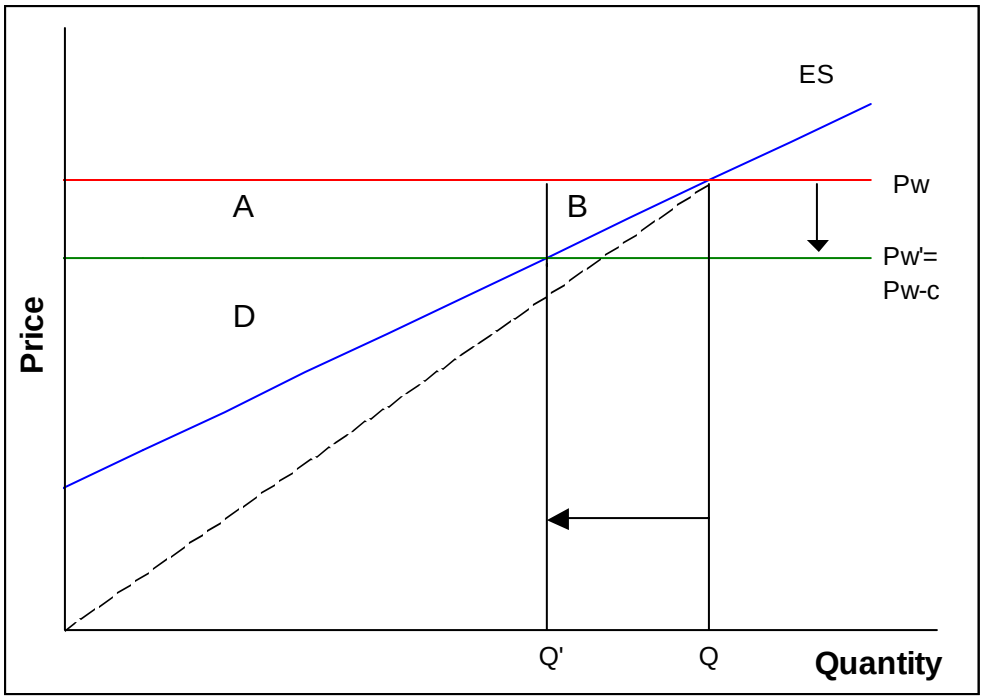

Figure 6.4-Over-Estimating Recurring Losses

With all of the aforementioned simplifying assumptions in place, the "value-of-market estimate" for each production period is $P_w*Q/2$. In present discount value terms, the value of the market over a finite horizon, T, is:

$$VM = SUM_{t=0,T} [(P_{wt}*Q_t/2)/(1 + r)^t] \quad (2)$$

where Q_t is the export quantity and P_{wt} is the world price in the absence of the imposition of the TBT.

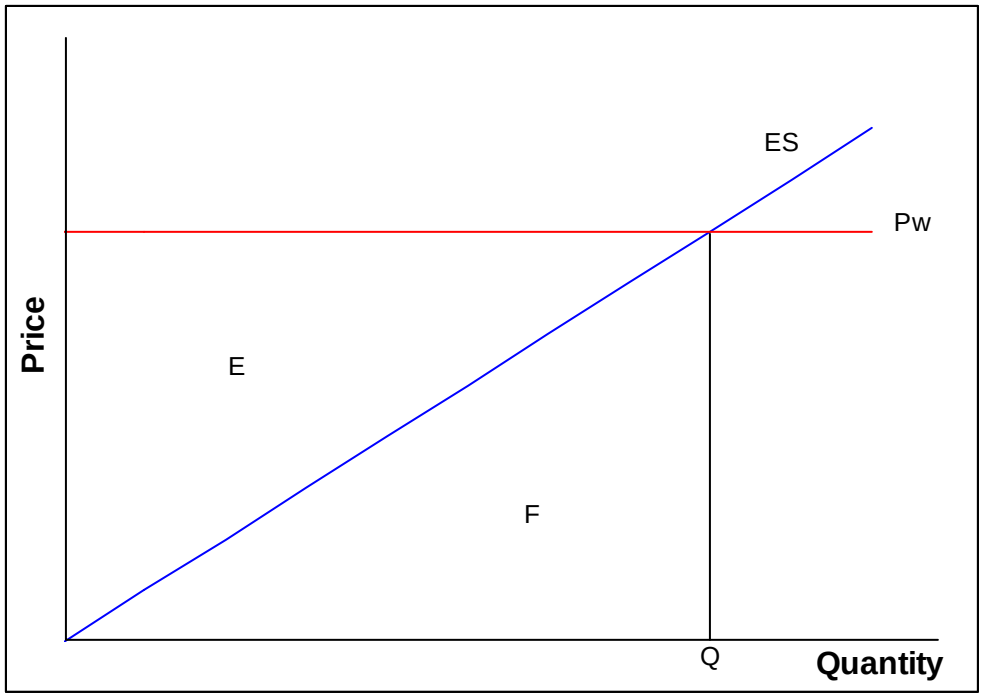

Figure 6.5-Measuring the Effects of Exiting the Market

Figure 6.5 depicts the approach graphically, for a given period, t. It shows the largest possible loss, assuming a linear supply curve, for a particular production period, as the area, E, under P_w and above the export supply curve, ES. This loss, accumulated over time and discounted to the present, measures the overall cost of the market loss in a limited set of circumstances: if (1) exiting firms have not previously dedicated any fixed resources to producing exports for the TBT-imposing market which could now be put to use elsewhere; or (2) non-entering firms would not have dedicated any fixed resources to export production for the TBT-imposing market; and (3) as above, there are no periodic lump-sum costs.

In Figure 6.5, we assume either type of firm (exiting or non-entering) would be using excess capacity to produce for the export market without any modification, i.e., the strict form of the excess supply model of export. However, if exiting firms can redirect any of their fixed export-oriented resources to other uses in other markets or can sell them, the estimate should be made net of the redirection or market substitution value. If non-entering firms avoid incurring fixed

start-up costs that would have been necessary had they begun to export, the avoided costs should be deducted.

To illustrate, suppose a firm foregoes $100,000 in present and future profits when it exits a TBT-impeded market but can sell its production line for $10,000. Its overall loss, net of the re-sale value, would be $90,000. Similarly, if a firm could have entered the market, prior to the imposition of the TBT, but would have needed to spend $10,000 on an additional production line, the overall loss must reflect the market entry cost, again yielding a net $90,000 as a result.

Summary

We have provided instructions for calculating both a "cost-absorption estimate" and a "value-of-market estimate" for any type of TBT in any given industry. Calculating the upper bound on the potential losses to U.S. exporters then requires a comparison of the two estimates. The lesser of the two estimates is the upper bound. The role of time features prominently in this comparison, particularly in the presence of a one-time cost. Were all costs recurring, neither the length of the horizon nor discount rate would affect the relative attractiveness of participating in or opting out of the market, though both would affect the final tally; however, given the existence of a one-time cost, both parameters can affect the participation decision. For example, as noted previously, a longer horizon allows more time for amortization and recovery of the initial fixed cost. Our application of the methodology, below, illustrates this point.

APPLYING THE METHODOLOGY TO AN AUTOMOTIVE COMPONENTS EXAMPLE

In 2002, the Government of Mexico considered introducing a regulation that would have set a different standard for wheels sold in Mexico's aftermarket than in other NAFTA markets.[118] The proposed

[118] The regulation would not have applied to wheels on new vehicles. Mexico, unlike its NAFTA partners, uses type approval. If a vehicle receives type approval, the vehicle may be sold in Mexico even if type approval for the specific component has not been granted. Under this system, countries do not separately certify individual components so imports of vehicles with wheels that did not conform to this regulation would not have been barred from the Mexican market.

regulation appears to have been supported by Mexican commercial interests. At the time only the three major Mexican producers of wheels manufactured models that conformed to the proposed regulation.

Arguably, the measure would have functioned as a TBT as it appeared to discriminate against foreign manufacturers. U.S. exporters to Mexico would have had to make considerable design changes to manufacturer wheels in conformity with the new regulation. Moreover, one draft version of the proposed regulation reportedly included a clause stating saying that "it (the regulation) does not apply to local manufacturers…" so as to forestall problems for smaller Mexican custom wheel manufacturers. U.S. manufacturers also argued that the proposed regulation had no legitimate basis in terms of safety or environmental considerations. Furthermore, the costs of changes in designs and manufacturing processes that would have been necessary to make wheels conform to the new regulation would have been high, potentially so high that U.S. exporters might have had to withdraw from the Mexican aftermarket had the regulation been adopted and implemented. Exporters' potential abandonment reflects both the small size of the Mexican aftermarket and the relatively high fixed costs involved in producing wheels, specifically in adjusting production methods.

Because the proposed regulation had so many aspects that indicated that it would serve as a TBT, the U.S. government took issue with the proposed regulation. The Mexican government decided not to adopt it. Consequently, U.S. exporters never incurred the costs of the proposed measure. Nevertheless, the example provides an opportunity to use the methodology to compute the upper bound of the potential costs of this regulation to U.S. exporters of aftermarket wheels.

Car owners rarely replace wheels; most vehicles are scrapped with their original wheels. Thus, the market for aftermarket steel wheels in Mexico is small. We estimate the maximum size of the market for steel replacement wheels in Mexico would be on the order of 125,000 wheels per

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Furthermore, as the Mexican automotive industry is integrated into the North American industry, assembly operations in Mexico would have continued to use the same wheels as they had in the past, wheels that would no longer be accepted for aftermarket sales under the proposed regulation.

year, assuming that on one car in eight in Mexico one wheel is replaced over a ten-year period of car ownership. (In 2000, the total number of cars registered in Mexico was 9,842,006.) According to manufacturers and retailers, the cost of a steel wheel is about $50.[119] Under this assumption, the total Mexican replacement wheel market might be as large as $6.25 million annually.

Value-of-market estimate

In value-of-market terms, $P_w*Q/2$, the loss for exiting U.S. exporters would have totaled about $3.13 million annually had U.S. exporters previously supplied the entire market of 125,000 wheels at $50 per unit.[120] Over a 3-year horizon, starting at t = 0, the loss in present discount value terms, assuming a 5 percent discount rate, would be slightly less than $9 million.

From Equation (2):

$VM = SUM_{t=0,2} [(\$50*125,000/2)/(1.05)^t]$

$VM = [(\$3,125,000)/(1.05)^0] + [(\$3,125,000)/(1.05)^1] + [(\$3,125,000)/(1.05)^2]$

$VM = \$3,125,000 + \$2,976,190 + \$2,834,467$

$VM = \$8,935,658$

However, given the circumstances of the proposed regulation, including Mexican manufacturers' support, this would likely be a substantial overstatement; Mexican manufacturers serve the aftermarket. As such, the loss to U.S. exporters would have been a fraction of the total, depending on their share of the market, e.g., for a one-third share, the 3-year loss would have amounted to just under $3 million. While apparently modest for the U.S. wheel industry in aggregate, these

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[119] Based on communications with Hayes Lemmerz and Hubcap Heaven.

[120] Given the relatively small share of production dedicated to aftermarket sales, it seems plausible that U.S. wheel manufacturers are producing for export on existing lines, requiring little or no additional 'fixed' costs in each period. In this regard, a simple periodic measure, $P_w*Q/2$, might not be unreasonable. However, the assumption of negligible marginal costs for the first unit of exports, i.e., the zero intercept, is less satisfying.

losses could be substantial if the burden fell on only a few producers which would likely be the case for the steel wheel industry where only a handful of companies are major market participants.

Cost-absorption estimate

We can also calculate the potential effects of the proposed measure had it been adopted and implemented and had U.S. producers stayed in the market, absorbing its costs.

Wheel production is a high volume, capital-intensive business. With the exception of manufacturers of customized aluminum wheels, manufacturers are primarily focused on sales to OEMs. The world's largest manufacturer of wheels, Hayes Lemmerz, manufactures tens of millions of wheels every year and has a total turnover of over $2 billion. Production lines are costly. For example, tooling costs for a single wheel type are quite expensive, on the order of $750,000 to $1,000,000 per line.[121]

At the very least, U.S. exporters would have needed to invest in tooling to produce wheels conforming to the proposed regulation. If each exporter invested $1 million in tooling, the total one-time fixed cost for four exporters, would have amounted to $4 million, quite possibly a prohibitive hurdle for a potential annual market "worth" only about $3.13 million in net terms—and a market in which local producers already had a strong presence and no need to modify their lines. Moreover, U.S. manufacturers would have had to stop and start their assembly lines to switch between the tooling needed for U.S. production and that needed specifically for the Mexican aftermarket, resulting in additional recurring operating costs. These would have been on the order of $5,000 per switch.[122]

If U.S. manufacturers had chosen to remain in the Mexican aftermarket, the cost of the TBT would have amounted to the one-time tooling costs, roughly $1 million per firm or $4 million total, assuming four U.S. firms made the investment, plus the present discounted value

[121] Based on communications with Hayes Lemmerz and Hess Engineering, Inc.

[122] Based on Communications with Hayes Lemmerz.

of any extra recurring costs, as in Equation 1. For example, if four firms switched the tooling on one line, once per year, at a cost of $5,000 per switch, the total annual switching cost—a recurring "fixed" cost—would have amounted to about $20,000 to manufacture wheels for the Mexican aftermarket.

In addition, aftermarket wheels are sold through various distribution channels, including through the service departments of the OEMs. In general, the wheel manufacturers do not maintain their own aftermarket steel wheel distribution networks. Currently, aftermarket service networks do not need to separately stock wheels for the Mexican and U.S. markets. If the regulation had been adopted, they may have had to provide separate storage, labeling, and logistics systems for delivering wheels to Mexico which would have entailed additional handling costs for each wheel exported. We assume such costs would have been on the order of one dollar per wheel.

The increase in the handling and shipping costs of exporting wheels to Mexico would result in a reduction in exports, depending on producers' responsiveness to the higher unit cost. If U.S. exporters reduced shipments by 10 percent, amounting to 12,500 unit supply reduction assuming they were previously serving the entire aftermarket, the total additional variable recurring cost would have amounted to $118,750 annually. This would consist of the $1 "surcharge" on the remaining exports and the foregone producer surplus on the lost shipments, corresponding to the rectangle, A, and the triangle, B, in figure 6.6.

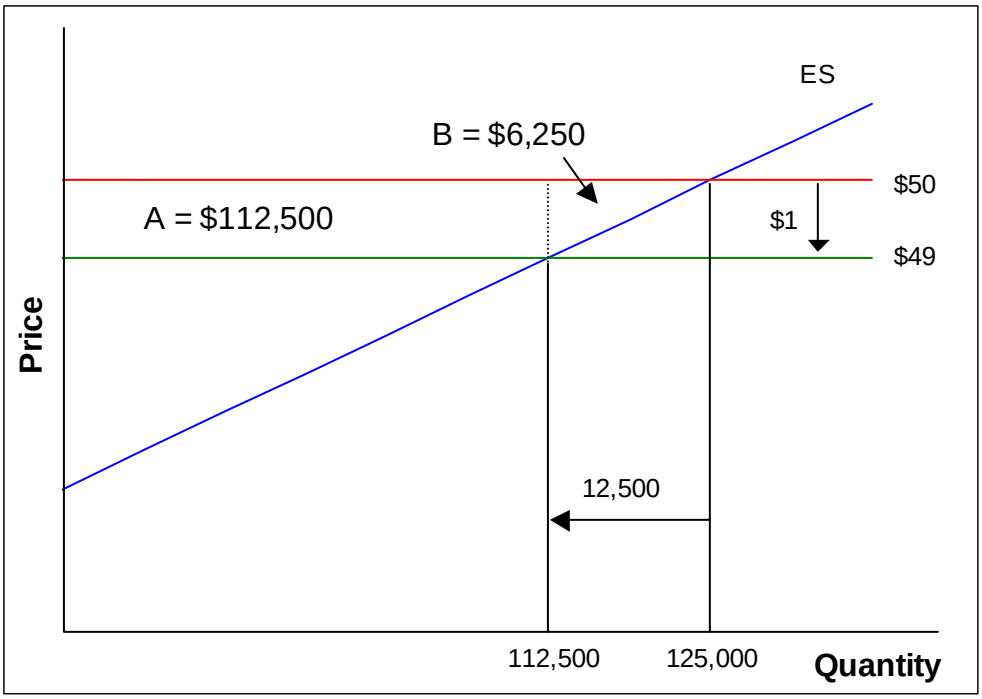

Figure 6.6-Measuring Recurring Costs in the Example

Over a 3-year horizon, the total cost, in present discount value terms, assuming a 5-percent discount rate, would have amounted to about $4.4 million, if four U.S. firms had invested in new tooling for the Mexican aftermarket and changed their lines to manufacture wheels for the Mexican aftermarket once per year.

From Equation (1);

$$TC = \$4mil + SUM_{t=0,2}\{[\$20,000 + \$1*12,500/2 + \$1*112,500]/(1.05)^t\}$$

$$TC = \$4mil + SUM_{t=0,2}\{[\$20,000 + \$118,750]/(1.05)^t\}$$

$$TC = \$4mil + \{[\$138,750]/(1.05)^0\} + \{[\$138,750]/(1.05)^1\} + \{[\$138,750]/(1.05)^2\}$$

$$TC = \$4mil + \$138,750 + \$132,143 + \$125,850$$

$$TC = \$4,396,743$$

Noting, however, that U.S. exporters share the Mexican aftermarket with Mexican wheel manufacturers, the additional variable recurring cost would have been only a portion of the $118,750 figure and the overall cost would have been less. For example, if U.S. firms served a third of

the Mexican aftermarket, the additional recurring variable cost would have amounted to less than $40,000.

Evaluating the upper-bound

Using this approach, the upper-bound cost estimate would be the lesser of the value of the market and the total compliance cost. Exporters would choose either to exit the market or absorb the compliance costs. In this example, over three years, with U.S. exporters serving the entire Mexican aftermarket, the upper bound would have been $4.4 million, the compliance cost. By implication, U.S. exporters would have chosen to stay in the market and absorb the cost of the Mexican regulation.

Recalling that the true cost of any TBT most likely lies somewhere below the upper bound, where would we expect to see the cost of the TBT in this example? Based on export data and discussions with a trade association and manufacturers, the Mexican and Canadian aftermarkets are the most important for U.S. exporters. As such, Mexico could be considered a primary destination for U.S. aftermarket wheel exports. Moreover, if four U.S. manufacturers served the Mexican aftermarket, accounting for a modest share of total sales, they might have little or no market power. Thus, we might expect to be close to the upper bound, with the possibility of some cost sharing, depending partly on the availability and technologies of non-U.S. exporters.

However, the determination of U.S. wheel manufactures' share of the Mexican aftermarket bears importantly on the calculation of the upper bound. If their share of the market were modest, then the market's value, from their perspective, would be much less than $3.13 million annually; also, in the compliance cost calculation, the variable recurring component would be much less than $118,750. For example, if the U.S. market share were a third, then the 3-year value-of-market estimate would be about $2.98 million and the total compliance cost would be about $4.17 million. On this basis, the total compliance cost would have exceeded the value of the market, suggesting that U.S. firms would have pulled out of the Mexican aftermarket rather than absorb the cost of the measure. With a one-third share of the market, the upper

bound cost of the TBT over three years would have amounted to $2.98 million.

In this application, we can also see that the choice of horizon, T = 3 years, is an important determinant of the outcome, not just in the obvious sense that the tally rises given more time for losses to accumulate, but also in the sense that the choice of the horizon may affect the apparent desirability of complying with the TBT as compared to opting out of the market.[123] Building on the one-third-market share example, a 5-year horizon would have generated a value-of-market estimate of $4.74 million as compared to the 3-year estimate of $2.98 million; however, the cost-absorption estimate would have risen to only $4.27 million. Given the additional 2-years to "amortize" or recover the initial costs of investing in new equipment, U.S. firms would have chosen to stay in the market and incur the compliance costs. Calculated over a 5-year horizon, the total loss to the exporting industry would have amounted to $4.27 million, the new upper bound. As a practical matter, the choice of horizon for any given analysis or application may depend on conditions in the market and standard industry practices, e.g., are investment decisions typically made on the basis of a 3-year, 5-year, or other horizon? Table 6.1 summarizes the results of the one-third-market share analysis.

Table 6.1: Results of One-Third-Market Share Analysis for Potential Effects of a TBT on Aftermarket Wheels Exports to Mexico

	Value of Market estimate	Cost Absorption Estimate
3-year horizon	2.98	4.17
5-year horizon	4.74	4.27

Notes: Results provided in million of dollars in present discounted value terms, using a 5 percent discount rate.

[123] As noted previously, the choice of discount rate could also affect both the total figure and the relative desirability of participating in or opting out of the export market.

SUMMARY AND CONCLUSION

In this chapter we present an initial framework for drawing together information on prices, quantities, and direct compliance costs, to assess the potential costs of TBTs to U.S. exporters. The framework is flexible in that it can be applied to almost any type of industry or TBT, but it is intended for evaluations of specific instances of TBTs, not TBTs in aggregate or economy wide. As such, it is well suited to industry-based case study analyses.

However, it is important to recognize that the framework provides an estimate of the upper bound of the potential costs to U.S. exporters, not an estimate of the potential costs per se. As such, it would be inappropriate to assert that the costs of a particular TBT would be "X" dollars, based on a framework calculation; rather, they could be no more than "X" dollars. Moreover, prudent use would require an assessment as to how far beneath the upper bound the true costs would likely lie. If the case in question approximates the circumstances of the worst-case scenario, then the true costs might be close to the upper bound. But, if they do not, e.g., if U.S. exporters possess some market power or can sell their products elsewhere, as they often can, then the true costs probably lie somewhere well beneath the upper bound.

We have tried to keep the calculations as simple as possible and the data requirements to a minimum. Nevertheless, the analysis entails some complexity, with costs accumulating differently over time and producers responding differently to them. It also requires cost and other data that may be difficult to find in some market environments. Whether this information is available will likely vary on a case-by-case basis. However, as we demonstrate in the Mexican wheel example, even when some important data are not readily available, rough approximation and sensitivity analysis can provide insights.

VII. CONCLUSIONS AND RECOMMENDATIONS

The problem of how best to craft policy with respect to the TBTs that affect U.S. exporters is clearly one whose solution rests on gaining a clearer understanding of the dimensions of the issue. The complexities of the legal, economic, and regulatory factors that arise often make it difficult to determine the appropriate occasions and courses for government actions. This begins with the very problem of identifying TBTs for what they are and coming to some reasonable estimate of the burdens they impose. The purpose of this study has been primarily to provide a clear line of reasoning as a foundation to the development and application of government actions in a variety of venues. Our course of inquiry has been to determine how best to measure the economic effects of TBTs on U.S. industries. In doing so, we have felt it necessary to answer several practical questions:

1. What data are required to determine whether a technical measure in question acts as a TBT and where are these data found?
2. How may these data be collected?
3. How can these data be used to calculate the costs to U.S. exporters of the TBT?

The information developed during the course of addressing these questions is summarized below as findings intended to assist NIST in coming to a better understanding of how to address the needs of its private sector and government agency interlocutors.

FINDINGS FROM THE RECONAISSANCE STUDY

The principal findings from this work have led to conclusions in each of the areas posed by the questions listed above. These conclusions are not intended as definitive but provide a basis for more detailed efforts.

Data: In Chapter II we developed a simple checklist to ascertain whether a measure has TBT-like characteristics. We used this checklist to structure our discussions with industry representatives in the pharmaceutical and automotive industries as well as a search through

existing records of TBT allegations (Chapters III and IV.) We also held discussions widely across agencies of the U.S. federal government.

We found that federal agencies, such as the U.S. Department of Commerce, International Trade Administration and the Office of the U.S. Trade Representative already gather a substantial amount of data, some of which is readily available in extant databases. Further, we did not find any especially helpful formal databases outside the governmental domain. This is not to say that relevant data do not exist in industry. Clearly, they do. But for the two industries we examined in the representative case studies we found no evidence of formal data gathering or collation on a comprehensive basis. That is, there were no ready-to-cull non-governmental sources. Gathering data from these industries would require either surveys of firms or direct discussions with those individuals in firms or trade associations who track TBTs on a geographic or issue area basis (See Appendix B for a listing of relevant data bases.)

These findings and others discussed below have led the project team to conclude that rather than attempt to collect new information, likely to be of the same character as the government already collects, it would be better to use existing federal databases coupled with interviews with industry and government representatives to monitor foreign technical measures that may serve as TBTs.

Collection: The project team explored in each of the two test industries studied the possibilities for collecting existing information about TBTs and their effects. This would provide one approach to making an estimate of the costs of particular TBTs in aggregate. We have concluded, based on the availability of existing data and discussions with industry representatives, that at this time independent surveys of industry and attempts to collate the responses into a new data facility are unlikely to be sufficiently fruitful to justify the requisite expenditures of government resources.

This finding stems from several considerations. The first is based on our preliminary contacts with industry. The data required to be collected are often based on, or related to, proprietary information and therefore are not likely to be forthcoming in sufficient quantity as a

result of administering objective survey instruments. This is especially likely to be true given the tendency by industry to view TBTs, their costs, and the necessary accommodations by firms on a case-specific basis rather than as a generalized phenomenon. Finally, to be useful any such survey would require a sufficient level of detail and careful definition. The resulting survey instrument would likely be viewed as a burdensome intrusion by potential respondents. Experience suggests that this would lead to low return rates.

A second consideration is that such an effort carried out by any one federal agency could potentially also lead to misunderstandings with other federal agencies. It would run the risk of being viewed as a duplication of effort or based on a confusion of roles.

Both of these considerations suggest that NIST could increase the potential value of already existing data collection efforts conducted in other agencies by providing technical guidance on the types of information necessary to identify and gauge the magnitude of alleged TBTs and providing a mechanism for assessing what this information means. Once such an ability was established and the results demonstrated the question of more general surveys of industry could be revisited. It may be that the existence of an exemplar system could demonstrate utility to individual firms as well as to industry as a whole and change the assessment of likely private sector response rates.

Calculation: This study has developed a draft methodology for quantifying costs faced by U.S. exporters when confronting alleged TBTs. The methodology is rooted in current theory and designed to be broadly applicable, minimally data intensive, and easily used and understood so that it may be widely utilized. The result is an approach geared to estimate as accurately as possible the upper bounds of the costs that could be incurred by U.S. exporters from alleged TBTs erected by importing countries. The methodology as it currently stands is designed to be applicable to the full range of potential costs stemming from specific instances of alleged TBTs, whether arising from technical regulations, standards, or conformity assessment procedures. In this report we have applied this methodology to one instance in the automotive industry. But while useful as it stands, at this stage it

represents more of a promising beginning than a final word. In particular, it would be useful to refine the methodology as well as to apply it to a number of other instances of TBT-like technical measures so as to create a range of estimates. This would be important not only for purposes of calibration and refinement but also for achieving the ultimate goal of elucidating the true costs of TBTs.

RECOMMENDATIONS FOR FURTHER RESEARCH

This project was intended as an initial exploration. Based on the results of the research conducted to date, we believe that should NIST at some later date care to build upon the foundation framed by this study, the areas we outline below would provide the greatest additional value in better understanding TBTs, the costs they entail, and the nature of effective government measures to alleviate their effects.

Recommendation 1: Consider the Experience of Other Industries

Theoretical excursions can be most helpful in illuminating the issues related to TBTs, but more data are required as well and the survey approach is unlikely to be sufficiently successful for the reasons given above. Therefore we recommend considering wider and more detailed sectoral studies of specific U.S. industries to provide a more comprehensive overview of the prevalence and types of TBTs that cause the most concern and potential costs.

The two examples included in this study form an interesting counterpoint. The automotive study does not disclose many areas where further inquiry at a more detailed level would be likely to yield more insight into this sector's TBT issues. The pharmaceutical study, on the other hand, does suggest the value of continuing a deeper probe of the question of TBTs in that sector. In addition, the project team has concluded there would be value in looking into other important U.S. export sectors to better understand the nature of TBT costs as they play across several major export groups. Such inquiry would enable more conclusive generalizations regarding TBT costs to U.S. industry and would provide better support for any findings being viewed as representative and hence more useful to USG activities and considerations. It would also be an important step for attempting to

provide an informed and authoritative estimate of aggregate costs stemming from alleged TBTs across industry.

We suggest the following industries as worthy of attention by virtue of the scale of U.S. exports, the representative character of the sectors, and the likelihood of being able to gather relevant information:

- Electronics products
- Electrical engineering products
- Mechanical engineering products

The computer sector might also be substituted for one of the suggested sectors, depending on what might be of most direct value to the relevant federal agencies.

Recommendation 2: Build Upon Foundation Methodology

We recommend refining the first draft of the methodology developed in this study to enhance its applicability to a wide range of sectors and ensure its fidelity for illuminating TBT effects within individual markets.

Part of the reason to continue with and broaden sectoral studies would be to test how well the methodology derived in this exploratory study serves its intended function of providing a guide for determining what data are necessary to answer the fundamental question of cost. This task would involve a targeted search for the data necessary to generate approximations of TBT-related costs to U.S. exporters. It would then seek to apply the basic methodology for calculating the costs of TBTs to potential TBTs in the pharmaceutical industry, automotive industry and in industries chosen for additional case studies.

In light of more application, refinements to the basic method can be sought. In particular, it would be useful to assess the value of relaxing several of the stronger assumptions that were incorporated in favor of simplicity and tractability. Further, it might be possible to incorporate more strategic aspects of the decision calculus undertaken by any selected exporter in determining how to respond to the presence of a TBT. For example, the decision to exit or decline to enter a market based on size-of-market calculations might also incorporate

considerations of future market size or the value of market presence in potentially important locales such as China.

Recommendation 3: Explore Aggregation -- Cautiously

The third recommendation is offered with a qualification. We recognize the value of exploring the possibilities for aggregation in determining overall costs to U.S. exporters of TBTs. At the same time, any attempts to do so must not come at the cost of reintroducing some of the fundamental theoretical and practical confusions this study has sought to surmount.

Exploring methods for meaningful aggregation would be integral to the activities suggested in the previous two recommendations because how to do so is as much an empirical as a theoretical issue. The value in doing so would be to gain a better approximation of the costs faced by U.S. exporters across industrial sectors. However, the methodology we presented for calculating upper bounds in the case of individual TBTs could not simply be "grossed up" to address the aggregation question. Several of the underlying assumptions of this model would become questionable to the point where the values obtained through aggregation would be less likely to yield measures of the narrowly defined effects of TBTs than does the simple, case-by-case form of the method. A well-reasoned redrafting would be required.

On the empirical side, the initial two cases, automotive and pharmaceuticals, led to two different conclusions. In the case of the former, there do appear to be grounds for claiming the existence of some TBT-like practices. The tasks of assessing where they lie and what they may cost U.S. exporters appear relatively straightforward. The pharmaceuticals industry, however, presents a richer variety of instances of alleged TBTs posing different kinds of analytical challenges. This provides two opposing guesses about what would be involved in an aggregation strategy for approximating TBT costs to U.S. exporters across sectors. Looking into other sectors would assist in refining any estimations of aggregate costs.

In addition to the quantitative dimension of aggregation, it would be useful to examine the qualitative one as well. This may be done by

follow-on research activity geared to expanding and refining the simple tables presented as Tables 3.1 and 4.3 in the body of this draft. That is, it would be useful not only to apply this framework to other sectors but to add in such dimensions as whether an alleged TBT arises from a standard or a regulation and to provide a secondary layer of definition under such broad headings as product, process, or conformity assessment TBTs.

Recommendation 4: Embody TBT Knowledge in User-friendly Software Tools

We recommend encapsulating the knowledge gained in this research in a form that will provide an infratechnology for use by NIST and other federal agencies.

An important part of this project has been to consider how better to maintain knowledge across the government of potential TBTs and their costs. We have concluded that the current situation is less one calling for extraordinary additional effort in crafting a unified data base or gathering information of a different character than is already collected, but to provide an overarching framework within which to place such information, inform its collection, and suggest avenues for utilization. In this vein, we propose creating a computer spreadsheet-based software tool based upon the existing methodology or elaborations to be further developed for calculating the bounds of possible costs stemming from any particular suspected or alleged TBT. This tool should be designed to have a user-friendly graphic user interface that will take users through a menu-driven set of steps mapping into a protocol for assessing such costs. The goal would be to provide for enhanced automaticity in assessment based on question-driven user protocols. It is entirely possible that this advance in instrumentation could in itself provide an impetus for closer coordination across the agencies of the federal government as well as more purposeful contact between government and industry on the subject of TBTs.

APPENDIX A. DEFINITIONS IN THE TBT AGREEMENT

Annex 1 of the TBT Agreement, defines technical regulation, standards, conformity assessment procedures, international body or system, and other important terms for the purposes of the TBT Agreement. The Annex does not, however, define either "TBT" or "international standard" explicitly. The Annex also provides explanatory notes for some definitions, especially those that differ from ISO definitions. From the Annex:

> The terms presented in the sixth edition of the ISO/IEC Guide 2: 1991, General Terms and Their Definitions Concerning Standardization and Related Activities, shall, when used in this Agreement, have the same meaning as given in the definitions in the said Guide taking into account that services are excluded from the coverage of this Agreement.
>
> For the purpose of this Agreement, however, the following definitions shall apply:
>
> *1. Technical regulation*
>
> Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.
>
> *Explanatory note*
>
> The definition in ISO/IEC Guide 2 is not self-contained, but based on the so-called "building block" system
>
> *2. Standard*
>
> Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal

exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.

Explanatory note

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.

3. Conformity assessment procedures

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Explanatory note

Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

4. International body or system

Body or system whose membership is open to the relevant bodies of at least all Members.

5. Regional body or system

Body or system whose membership is open to the relevant bodies of only some of the Members.

6. Central government body

Central government, its ministries and departments or any body subject to the control of the central government in respect of the activity in question.

Explanatory note:

In the case of the European Communities the provisions governing central government bodies apply. However, regional bodies or conformity assessment systems may be established within the European Communities, and in such cases would be subject to the provisions of this Agreement on regional bodies or conformity assessment systems.

7. Local government body

Government other than a central government (e.g. states, provinces, Länder, cantons, municipalities, etc.), its ministries or departments or any body subject to the control of such a government in respect of the activity in question.

8. Non-governmental body

Body other than a central government body or a local government body, including a non-governmental body which has legal power to enforce a technical regulation.

APPENDIX B. ANNOTATED BIBLIOGRAPHY ON TBTS

1. MEASUREMENT AND MODELING

1. Baldwin, Richard E.. "Regulatory Protectionism, Developing Nations and a Two-Tier World Trade System." In Quantifying the Impact of Technical Barriers to Trade: Can it be Done?, Keith E. Maskus and John S. Wilson, Eds. Ann Arbor: the University of Michigan Press, 2001.

The author covers the economics of technical barriers to trade (TBTs) and presents evidence on their importance and the various initiatives made to liberalize them. He concludes that a two-tier system of market access is likely to emerge, with developing countries occupying the second tier.

2. Beghin, John C., Bureau, Jean-Christophe, (2001), "Quantification of Sanitary, Phytosanitary, and Technical Barriers to Trade for Trade Policy Analysis", Working Paper 01-WP 291, Centre for Agricultural and Rural Development, Iowa State University.

The paper presents methodologies to model and quantify the economic effects of trade affecting sanitary, phytosanitary, and technical regulations in the agricultural and food sectors. The paper describes and evaluates various methods that have been used in the empirical estimation of the effects of NTBs. The paper explores methods that yield quantitative estimates of the impact of such barriers on equilibrium prices, trade flows, economic efficiency, and economic welfare.

3. Deardoff, Alan V., and Stern, Robert M.. "Measurement of Non-tariff Barriers", Economics Department Working Papers No. 179, OECD 1997.

The paper addresses currently available methods for quantifying non-tariff barriers (NTBs), including explicit formulas and recommendations concerning best practices. It finds that (1) the calculation of the tariff equivalent of a given NTB for a given economic indicator is complex and requires a great deal of information; (2) measures that are equivalent for one indicator will not be so for others; and (3) there is no substitute for NTB-specific expertise.

4. Gandal, Neil (2000). 'Quantifying the Trade Impact of Compatibility Standards and Barriers – An Industrial Organization Perspective". Paper prepared for the World Bank Workshop on Trade and Standards in April 2000.

The paper aims to set a research agenda for examining the effect of compatibility-based barriers to trade. The author argues that compatibility and standardization create network effects. A network effect exists when the value that consumers place on a product increases as the number of consumers who purchased identical or compatible goods increases.

5. Ganslandt, Mattias and Markusen, James R., (2000) "Standards and Related Regulations in International Trade: A Modeling Approach".

The paper describes approaches to formally modeling standards and technical regulations affecting trade. The authors only explore those models that could be used within the context of applied general

equilibrium models with real data. Simple numeric models are used to generate solutions. The authors note, however, that a practical obstacle to using these models is the lack of real data that could be used to estimate the costs and benefits of standards in terms of international trade.

6. Hilton, Francis G., and Levinson, Arik. (2000) "Measuring Environmental Compliance Costs and Economic Consequences: A Perspective from the United States". Prepared for the World Bank Conference: Quantifying the trade Effect of Standards and Regulatory Barriers: Is it Possible?

The paper explores the possibility of measuring international differences in environmental compliance costs to assess their impact on international trade and investment, based on lessons learned from compliance cost comparisons in the United States.

7. Krissoff, Barry, Linda Calvin, and Denice Gray. "Barriers to Trade in Global Apple Markets." Fruit and Tree Nuts Situation and outlook, Economic Research Service, USDA, FTS-280, August 1997: 42-51.

The authors estimate tariff rate equivalents for phytosanitary requirements facing U.S. apple exports in Japanese, South Korean, and Mexican markets. The authors find that the tariff rate equivalents of technical barriers are as large or larger than many tariff rates. The results indicate that technical barriers may have significant effects on trade.

8. Maskus, Keith E., Otsuki, Tsunehiro, and Wilson, John S., (2001). "An Empirical Framework for Analyzing Technical Regulations and Trade", Chapter 2 of the book, Quantifying the Impact of Technical Barriers to Trade: can It Be Done? The University of Michigan Press, 2001

The paper presents empirical approaches to analyzing the economic effects of technical regulations. The authors review the available empirical literature in four categories, i.e., surveys, econometric models, partial equilibrium models, and computable general equilibrium models; address measurement problems; discuss data collection; and set out a framework for econometric estimation. They also discuss potential models for performing partial- and general- equilibrium simulation analyses.

9. Maskus, Keith E., and Wilson, John S., (2001). "A Review of Past Attempts and the New Policy Context", Chapter 1 of the book, Quantifying the Impact of Technical Barriers to Trade: Can It Be Done? The University of Michigan Press, 2001.

The paper presents an analytical overview of the policy debate and methodological issues surrounding product standards and technical barriers to trade. The authors discuss motivations for performing research in this area; examine the policy context driving the need for new data and empirical evidence; and review the role of standards in international trade, discussing policy justifications for reaching voluntary standards and imposing mandatory technical regulations.

10. Mayer, Wolfgang, (1982), "The Tariff Equivalence of Import Standards", International Economic Review, Volume 23, Issue 3, pp. 723-734

The paper presents a model that generates a tariff equivalent measure of the economic effects of import standards. The author argues that there exist different combinations of tariffs and import standards, which may

be employed to grant an equivalent level of protection to the domestic industry. The model is developed under a general equilibrium framework to simulate a small open economy in which consumers buy differentiated products from both domestic and foreign producers.

11. Roberts, Donna, Timothy E. Josling, and David Orden, (1999). "A Framework for Analyzing Technical Trade Barriers in Agricultural Markets." Market and Trade Economics Division, Economic Research Services, U.S. Department of Agriculture. Technical Bulletin No. 1876.

The paper begins by looking at the rise in importance of technical trade barriers in public policy debates in general and in the agricultural sector in particular. The authors propose a definition and classification scheme to frame the discussion and evaluation of technical measures. They graphically develop an open-economy model that complements the classification scheme, to highlight the basic elements that affect the economic impacts of changes in technical trade barriers. They focus on three elements: the regulatory protection element, the supply shift element, and the demand shift element.

2. CASE STUDIES

1. International Trade Commission, November 1998 "Global Assessment of Standards Barriers to Trade in the Information Technology Industry", Working Party of the Trade Committee.

This study draws on interviews with industry representatives and government officials and literature reviews to identify technical barriers to trade in the computer hardware, software, and telecommunications equipment sectors of the information technology industry. The study identifies conformity assessment procedures as imposing the most onerous costs for exporters. It evaluates the potential effectiveness of mutual recognition agreements for reducing the costs to exporters of complying with technical regulations and also examines other potential regulatory approaches for reducing these costs.

2. OECD 2000, "An Assessment of the Costs for International Trade in Meeting Regulatory Requirements", Working Party of the Trade Committee, TD/TC/WP(99)8/FINAL.

This OECD study was conducted with the aim to investigate the extent to which technical standards and conformity assessment procedures impede trade. Quantitative data were collected on costs of compliance with differing standards and technical requirements in export markets. The study explores three sectors (telecommunications equipment, dairy products, and automotive components), in four countries (the United States, Japan, United Kingdom, and Germany). The study focused on the problems and costs imposed on firms that export to these four countries.

3. OECD 2000, "Standardization and Regulatory Reform: Selected Cases", TD/TC/WP (99) 47/Final.

Sectoral case studies can provide evidence of the strengths and weaknesses of standards, of the process through which they are developed, and the ways they are used as regulatory tools.

This report contains case studies on electrical products and electromagnetic compatibility, pressure equipment, construction

machinery, and machinery safety. The case studies focus on how standards are created, how standards are harmonized across countries, how conflicts concerning standards are resolved, and deficiencies of standard setting from an international perspective.

4. Thornsbury, Suzanne D. "Political Economy Determinants of Technical Barriers to U.S. Agricultural Exports", Paper presented at the 1999 American Agricultural Economics Association.

This paper presents econometric evidence about the economic and political determinants of questionable technical barriers. The hypothesis is that technical barriers to agricultural trade arise from combinations of scientific, economic, and political variables. The data for this econometric analysis originate from a 1996 USDA survey on the incidence of questionable technical barriers to U.S. agricultural exports across 132 countries and two regional trade blocks

APPENDIX C. RUNNING INVENTORY OF EXISTING DATABASES ON TBTS

One of the tasks for the first phase project effort is to survey and assess existing databases and information available that has been collected about instances of technical barriers to trade. This is intended as a running catalogue, designed to be updated as more information is gathered during the course of the effort.

The first iteration of this effort is presented in this appendix. It focuses on databases available on line. It should not be regarded as an exhaustive list, but an indication of some of the organized pools of data that are available over the internet. It should be noted that most of the existing databases available online do not focus individually on technical barriers to trade but on a wide range of tariff and non-tariff barriers to trade.

1. UNCTAD-TRAINS

United Nations Conference on Trade and Development has a database of tariff and non-tariff measures and of import flows on products catalogued using Harmonized Standards. This database is titled the Trade Analysis and Information System (TRAINS).

TRAINS on Internet provides an on-line access to indicators of Trade Control Measures (Tariff and Non-tariff measures) as well as imports by supplier at each Harmonized System 6-digit level for over 130 countries.

The home page of TRAINS: http://r0.unctad.org/trains/

The following is the link for initiating a search using TRAINS: http://cs.usm.my/untrains/trains.html

The UNCTAD Coding System for TRADE Control Measures has the following categories of technical measures that may be use to control trade:

8000 TECHNICAL MEASURES

8100 TECHNICAL REGULATIONS

8110 Product characteristics requirements

8120 Marking requirements

8130 Labeling requirements

8140 Packaging requirements

8150 Testing, inspection and quarantine requirements

8190 Technical regulations n.e.s.

8200 PRE-SHIPMENT INSPECTION

8300 SPECIAL CUSTOMS FORMALITIES

8900 TECHNICAL MEASURES N.E.S.

2. EU MARKET ACCESS DATABASE

This online database provides a wide range of information on market access issues such as trade flows, information on and computations of applied tariffs, tariff and non-tariff measures by country, by measure, and by product/sector. Access to the Sectoral and Trade Barriers Database is free. However, information under the Exporters Guide, Applied Tariffs, and WTO Bound Tariffs is restricted to users in the 15 Member States of the European Union.

The database is managed by Director General, Trade, European Commission.

The database on market access can be found online at the following address: http://mkaccdb.eu.int

The database on tariff and non-tariff measures can be found at the following address: http://mkaccdb.eu.int/mkdb/stb/mkstb.pl?action=search

3. PERINORM

PERINORM is the world's leading bibliographic database of standards and technical regulations from dozens of countries worldwide. Launched on CD-ROM in 1989, the content and functionality of PERINORM is constantly being improved by its original creators, AFNOR, DIN, and BSI.

Standards from different countries are added and revised documents are updated with a new CD each month. T his multilingual software (German, French, and English) is available in two versions, PERINORM Europe, or PERINORM International, depending on your data requirements.

The database is commercially available, and not for free access online.

4. UNITED STATES TRADE REPRESENTATIVE (USTR)

The National Trade Estimate

The USTR' s offices collect and compile information on tariff and non-tariff barriers to trade from their representatives and analysts covering various countries. This information is complied as the National Trade Estimate Report on Foreign Trade Barriers. The latest report was published in March 2002.

The National Trade Estimate Report on Foreign Trade Barriers for various years can be downloaded free from the following link: http://www.ustr.gov/reports/index.shtml

The "2002 National Trade Estimate Report on Foreign Trade Barriers" can be downloaded free from the following link:http://www.ustr.gov/reports/nte/2002/index.htm

5. FOREIGN AGRICULTURAL SERVICE (FAS), UNITED STATES DEPARTMENT OF AGRICULTURE

The FAS provides information on technical issues affecting US agricultural trade. This resource is available online at: http://www.fas.usda.gov/itp/ofsts/technical.HTM

The areas covered and services provided are:

a) International Standards: http://www.fas.usda.gov/itp/ofsts/intstandards.HTM
b) SPS/TBT related information: http://www.fas.usda.gov/itp/ofsts/enquirypt.HTM
c) Technical imports requirements by country: Food and Agricultural Import Regulations and Standards (FAIRS). The FAIRS *Country* Report is

a *market access report* which aims to consolidate general information on the technical requirements (i.e. food laws, labeling, import procedures, etc.) for food and agricultural imports imposed by a foreign country.
http://www.fas.usda.gov/itp/ofsts/fairs_by_country.asp

APPENDIX D. INTERVIEWEES AND CONTACTS

This appendix provides a listing of individuals interviewed or contacted by team members during the course of the project to date.

1. **Abraham, Julie:** Director Office of International Policy and Harmonization, U.S. Department of Transportation/NHTSA.

2. **Alley, Kristal:** Permanent Representative, European Office, U.S. Chamber of Commerce, Brussels.

3. **Bende, Steve:** Vice President; Scientific, Professional and Regulatory Affairs, Generic Pharmaceutical Association.

4. **Cecil, Todd**: Director of General Policy and Requirements, U.S. Pharmacopoeia.

5. **Cho, Man K.:** International Trade Specialist International Trade Administration, U.S. Department of Commerce.

6. **Claridge, Jonathan:** DG Trade, European Union.

7. **Cran, James:** Wheels Task Force, Iron and Steel Institute

8. **Damond, Joseph M.**: Assoc. Vice President, Japan & Asia-Pacific, Pharmaceutical Research and Manufacturers of America.

9. **Dresser,Bobbi:** Associate Director for International Standards and Trade, Office of International Programs, U.S. Food and Drug Administration.

10. **Feisee, Lila:** Director, Government Relations for Intellectual Property, Biotechnology Industry Organization.

11. **Finston, Susan Kling:** Assoc. Vice President, Intellectual Property and South Asian Affairs, Pharmaceutical Research and Manufacturers of America.

12. **Fitzwater, Kristie L.**: International Trade Specialist, International Trade Administration, U.S. Department of Commerce.

13. **Ford, Charles:** Minister Counselor for Commercial Affairs, U.S. Mission to the European Union.

14. **Gillerman, Gordon:** Manager Governmental Services, Underwriters Laboratories

15. **Gonzalez, Jesus:** Commercial Specialist, U.S. Commercial Service, U.S. Embassy, Mexico City.

16. **Guhl, Jennifer H.:** Director, International Trade Policy, American Electronics Association.

17. **Heck, Thomas:** Hayes Lemmerz.

18. **Hurt, William E.**: International Trade Specialist Pharmaceuticals, International Trade Administration, U.S. Department of Commerce.

19. **Jenkinson, Brian:** Deputy Head of Unit, Regulatory Coordination and Simplification; Mutual Recognition; DG General, European Union.

20. **Kennedy, Scott:** International Trade Specialist, Office of Automotive Affairs, International Trade Administration, Department of Commerce.

21. **Kyriatzis, Christos:** Administrator, DG Enterprise, European Union.

22. **Lamerigts, Dolf:** Director Technical Affairs, ACEA (European Automobile Manufacturers Association).

23. **Litman, Gary:** Vice President, Europe and Eurasia, U.S. Chamber of Commerce.

24. **Loew, Caroline:** Assistant Vice President for International Regulation, Pharmaceutical Research and Manufacturers of America.

25. **Mohr, Sylvia:** Standards Specialist, U.S. Mission to the European Union.

26. **Morrione, Marnie S.**: International Trade Specialist (Chemicals, Pharmaceuticals and Biotechnology,) International Trade Administration, U.S. Department of Commerce.

27. **Ngo, Anne:** Office for European Regional Affairs, International Trade Administration, U.S. Department of Commerce.

28. **Parris, Andrew:** International Trade Specialist, Office of Automotive Affairs, International Trade Administration, Department of Commerce.

29. **Radcliffe, Anjali A.** Assistant Vice President, European Affairs, Pharmaceutical Research and Manufacturers of America.

30. **Rios, Ivan:** Commercial Attaché, U.S. Embassy, Mexico City.

31. **Ruggieri, Caroline:** Biotechnology Industry Organization.

32. **Sene, Suzanne:** Standards Attaché, U.S. Mission to the European Union.

33. **Shaal, Gabriele:** ACEA (European Automobile Manufacturers Association).

34. **Sheinin, Eric**: Vice President, Information and Standards Development, U.S. Pharmacopoeia.

35. **Simmon, Christine:** Generic Pharmaceuticals Association (GphA).

36. **Slutsky, Bernice:** Assistant Vice President, International Regulatory Affairs, Pharmaceutical Research and Manufacturers of America.

37. **Spell, Sabine:** Communications Manager, Japan Automobile Manufacturers Association

38. **Stradtman, Jennifer:** International Trade Specialist, International Trade Administration, U.S. Department of Commerce.

39. **Troje, Suzanne:** Director, Technical Trade Barriers, U.S. Trade Representative Office.

40. **Uthus, Charles D.:** Vice President, Automotive Trade Policy Council.

41. **Walters, David:** Chief Economist, U.S. Trade Representative Office.

42. **Waelthy, Eric**: Hess Engineering.

43. **Willingham, Peg:** Assistant Vice President, Latin America & Canada, Pharmaceutical Research and Manufacturers of America.

44. **Woollett, Gillian R.**: Vice President, Science and Regulatory Affairs, Biotechnology Industry Organization.

45. **Zebroski, Shirley:** Senior Washington Representative, General Motors.

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