



*The
Pharmaceutical Monopoly
Enforcement Agenda*

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Essential Action

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essentialaction.org/access



Access to medicines

- ✧ Generic competition has fueled a revolution in HIV/AIDS treatment
 - ✧ 98+% cost reduction over ten years:
From \$10,000 to near \$100
 - ✧ Treatment program scale-up
 - ✧ 3 million globally on ART



Competition

- ✧ Price drops average 40-80% with first generic entry, continue to fall with time
- ✧ Competition between branded and generic, also between generics firms
- ✧ Competition key to implementing vision of access to medicines for all



A global monopoly enforcement agenda

- ✧ Many new measures worldwide protect patent and copyright monopolies under guise of fighting counterfeits and “piracy.”
 - ✧ See Susan Sell, “The Global IP Upward Ratchet.”
 - ✧ See Kevin Outterson, “Import Safety Rules.”
 - ✧ See Essential Action, “Survey.”
- ✧ *Anti-Counterfeiting Trade Agreement (ACTA), European seizures, US legislation & exec branch initiatives, Kenya & Uganda legislation, WCO, Universal Postal Union, CACP, plus writings of Roger Bate*
- ✧ *ACTA objective: “Establish, among nations committed to strong IPR protection, a common standard for IPR enforcement to combat global infringements of IPR particularly in the context of counterfeiting and piracy.”*



A global monopoly enforcement agenda

- ✧ Many titular anti-counterfeiting initiatives focus in fact on private rights enforcement, not public interests such as safety
- ✧ Many additional initiatives more accurately titled “IPR enforcement.” TRIPS-plus.
 - ✧ FTAs, PSI, Int Property Academies
- ✧ Some non-spurious anti-counterfeiting initiatives risk incorporating enforcement agenda, shortchanging other public health investments
 - ✧ WHO IMPACT (joint venture with IFPMA)
- ✧ In each case, this enforcement agenda comes with serious public health costs

Source of "counterfeits" confusion



- ✧ Private rights

- ✧ TM = counterfeiting

- ✧ TRIPS

- ✧ © = unauthorized copy
"piracy"

- ✧ Patents = infringement

- ✧ Public health

- ✧ Medicines counterfeiting =
deliberately mislabeled
(WHO)

- ✧ Definitions issue

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All "intellectual property rights."

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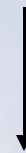
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✧ *Counterfeits endanger public health.*

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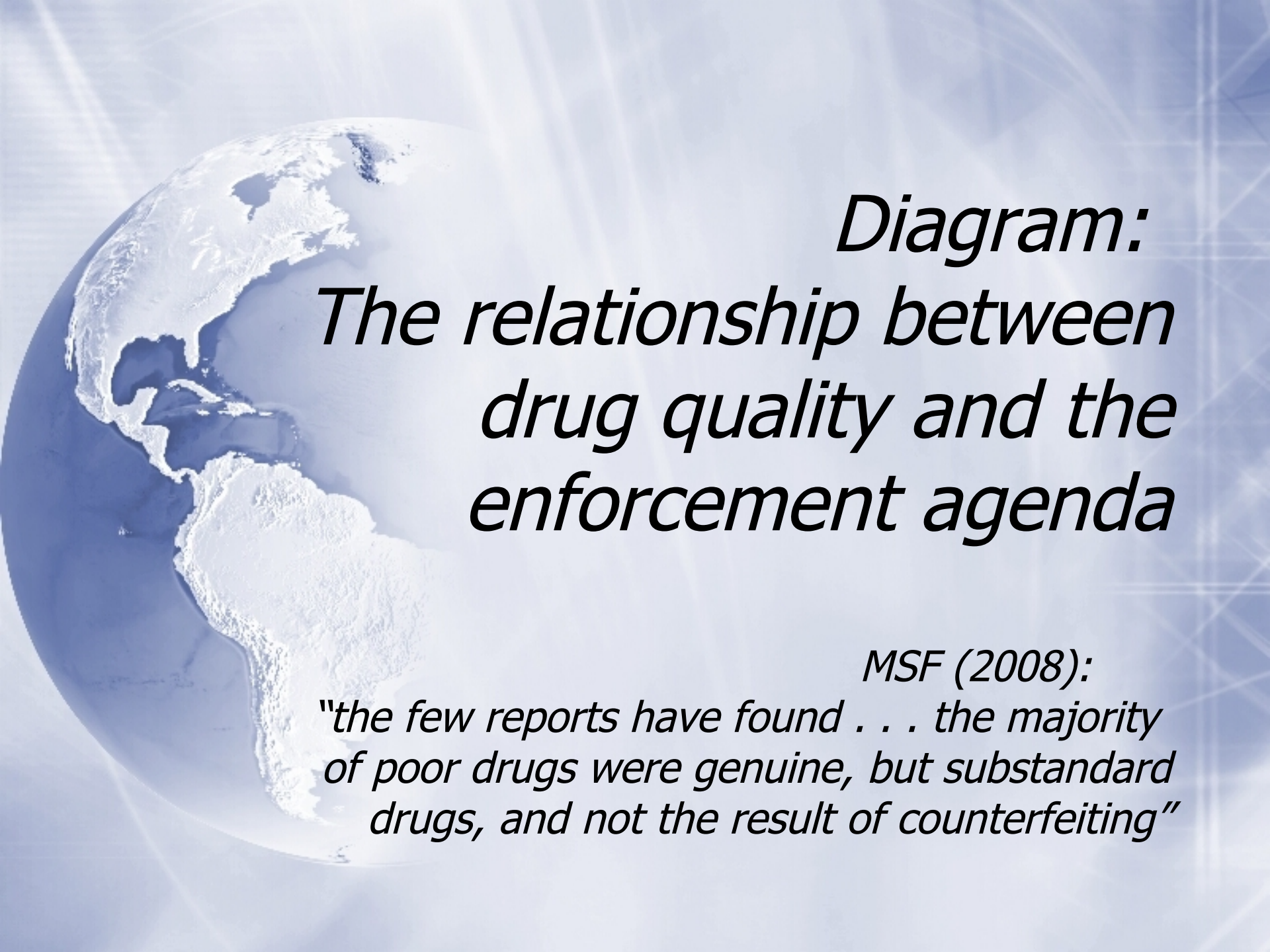


✧ Counterfeits endanger public health.



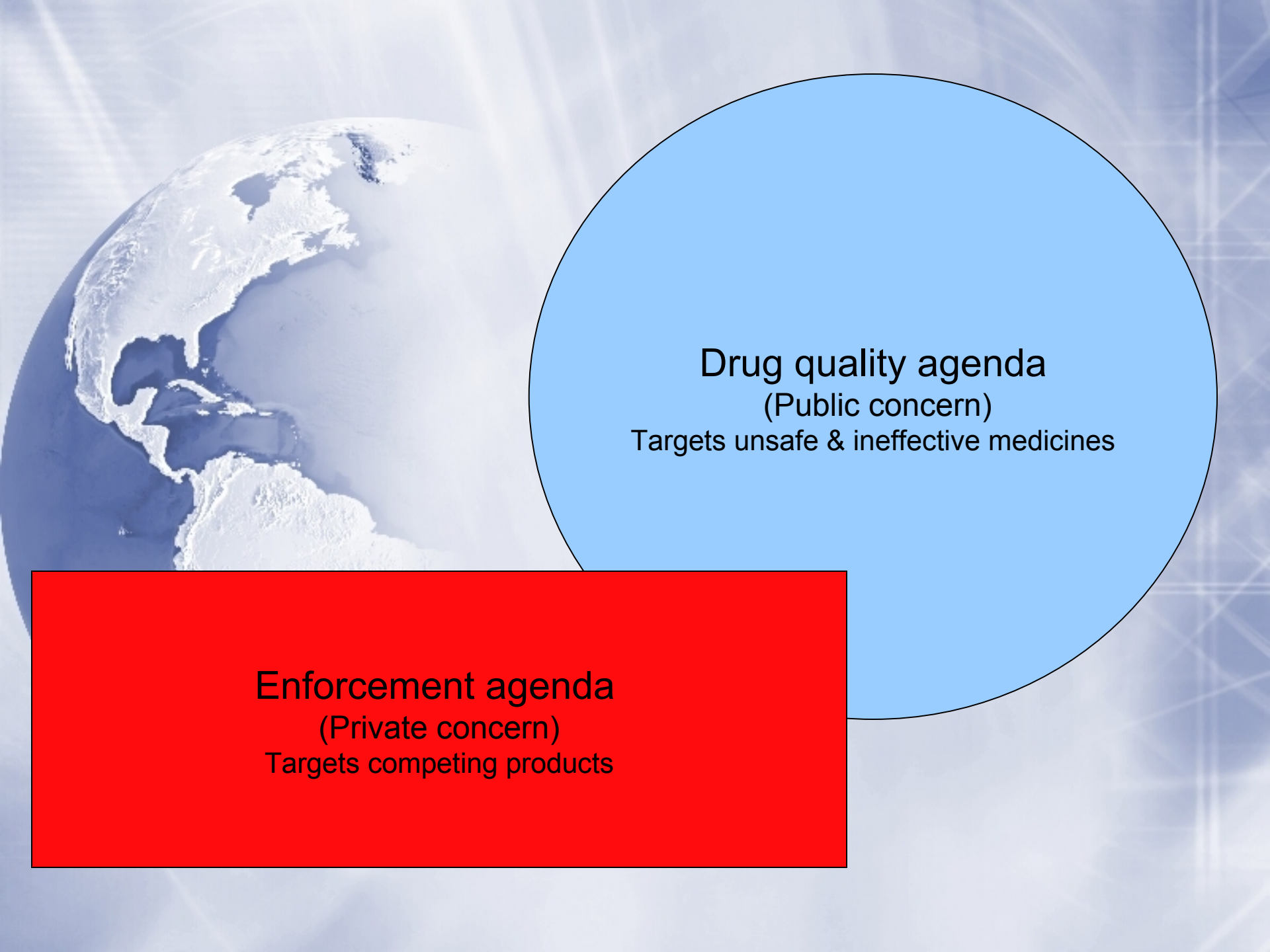
Fallacy #3: Aggressively combating alleged IPR infringements, including patents, protects public health.





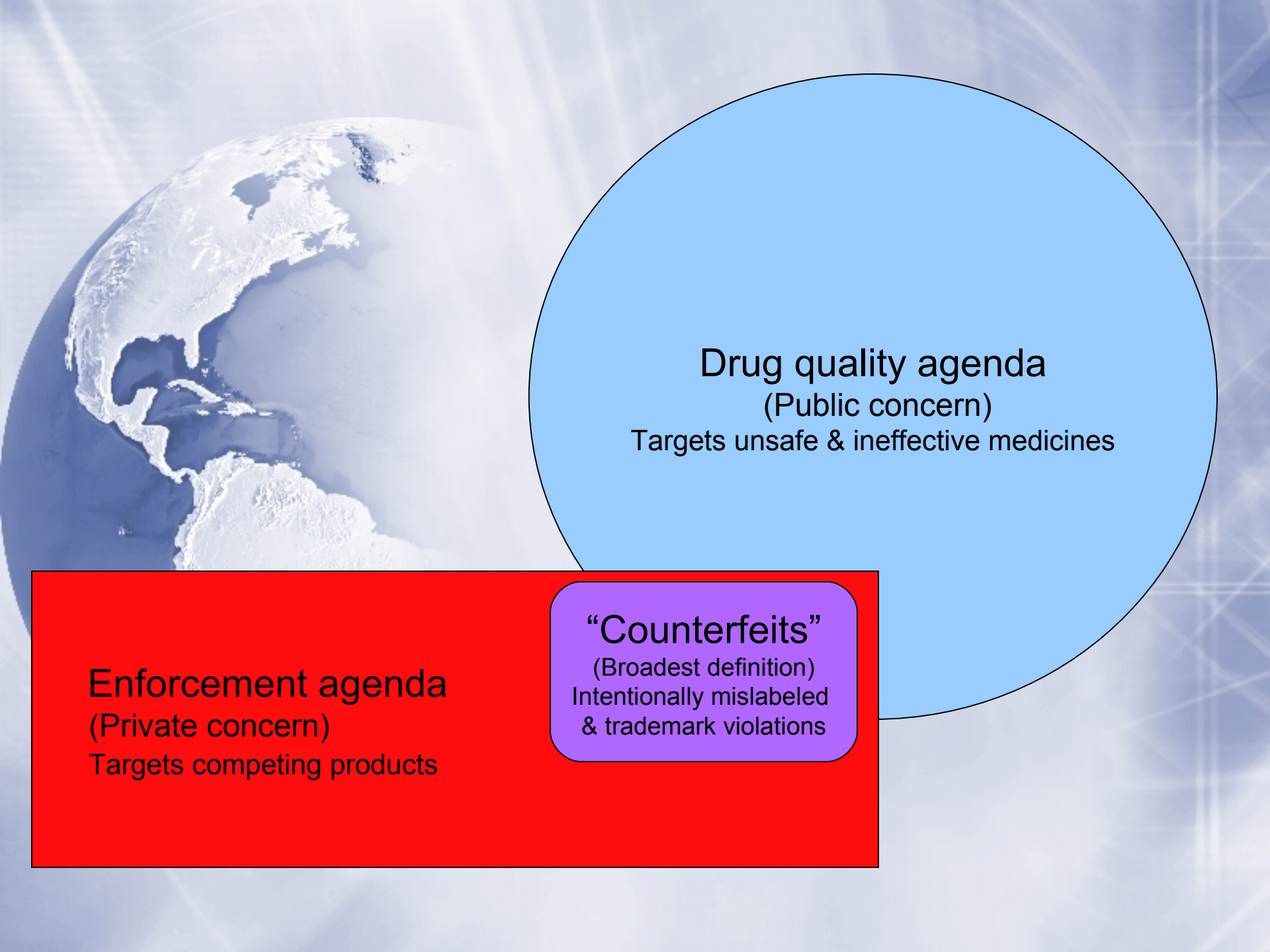
*Diagram:
The relationship between
drug quality and the
enforcement agenda*

*MSF (2008):
"the few reports have found . . . the majority
of poor drugs were genuine, but substandard
drugs, and not the result of counterfeiting"*



Drug quality agenda
(Public concern)
Targets unsafe & ineffective medicines

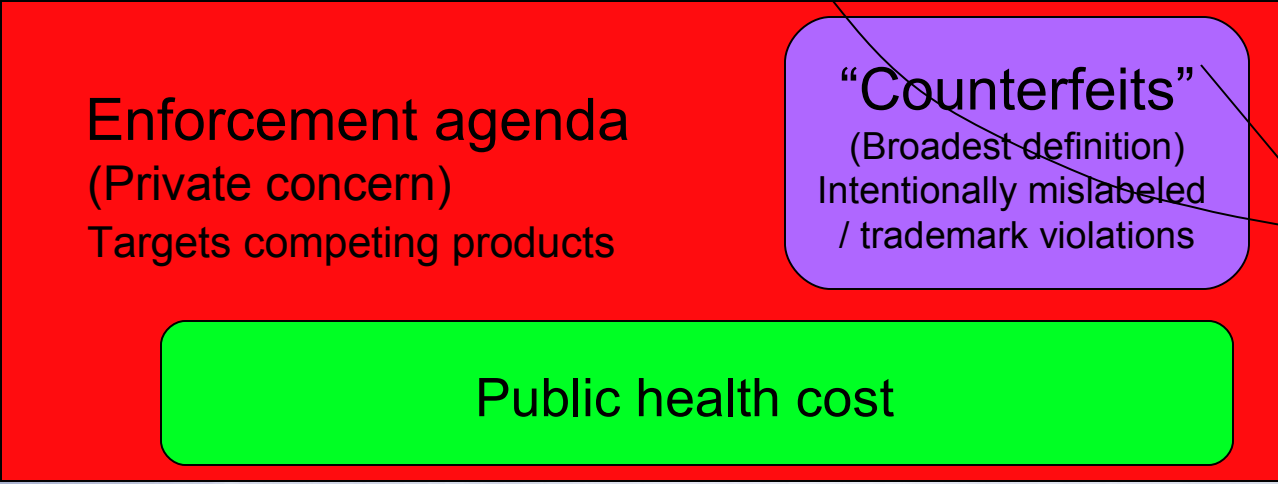
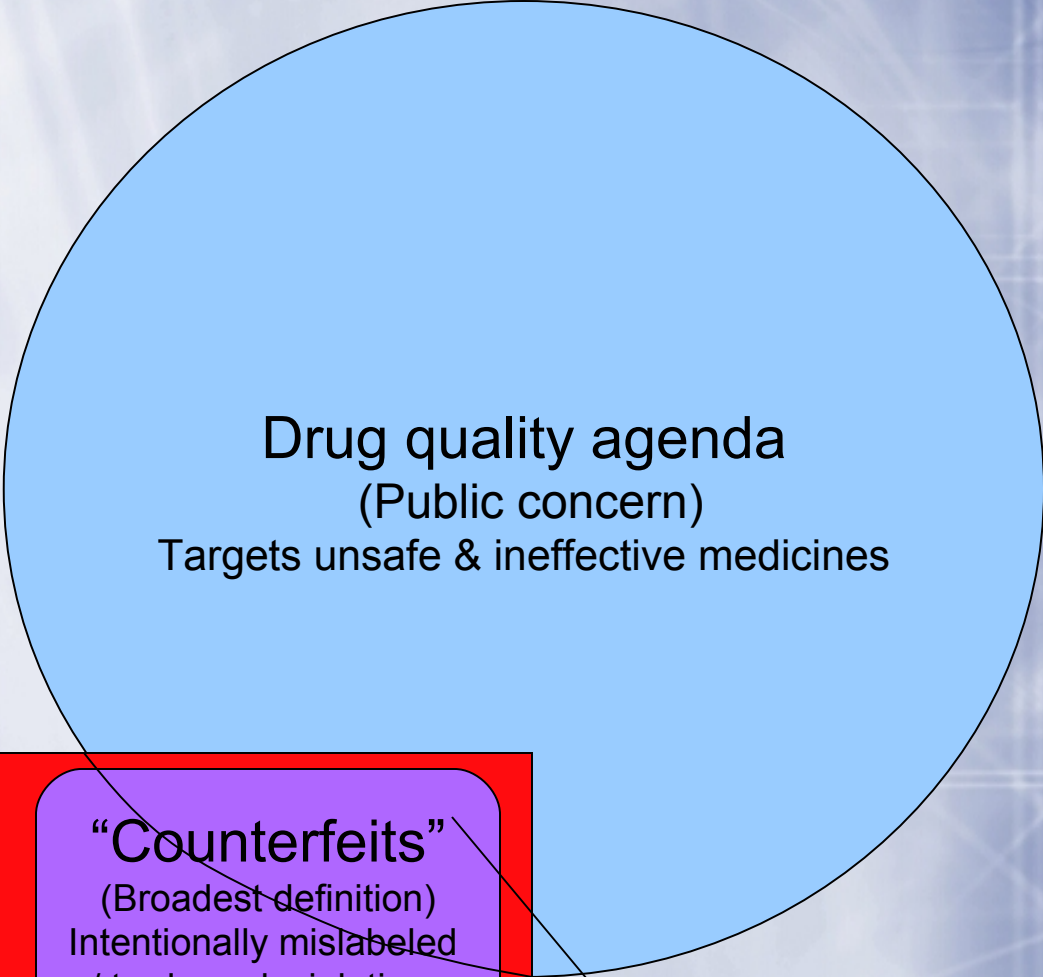
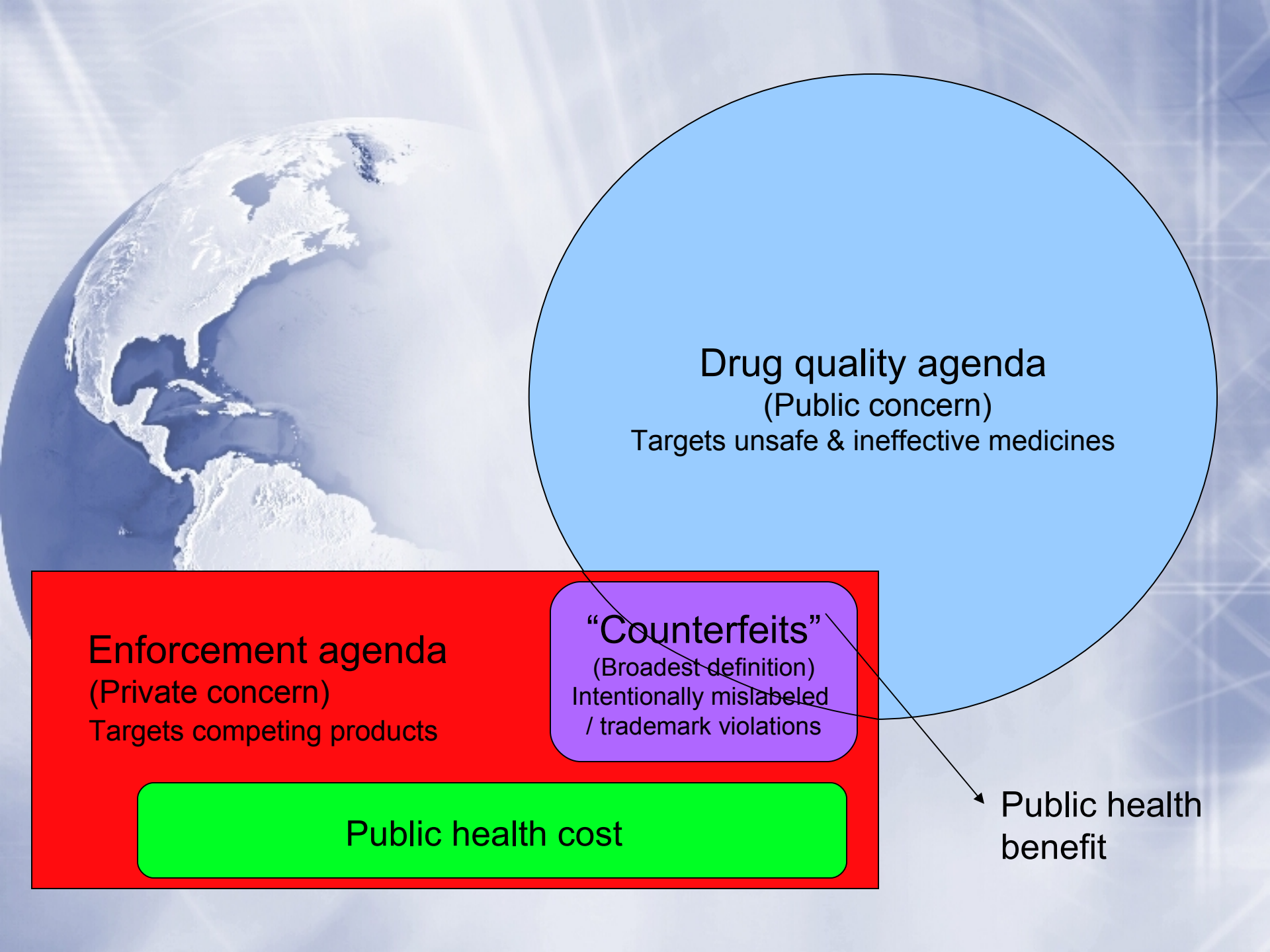
Enforcement agenda
(Private concern)
Targets competing products



Drug quality agenda
(Public concern)
Targets unsafe & ineffective medicines

Enforcement agenda
(Private concern)
Targets competing products

“Counterfeits”
(Broadest definition)
Intentionally mislabeled
& trademark violations



Public health
benefit



Enforcement agenda
(Private concern)
Targets competing products

Drug
quality
agenda
(Public concern)
Targets unsafe &
ineffective medicines


(And, problem of inadequate data)



Enforcement agenda mechanisms


- ✧ Public agency use: customs, int. orgs
 - ✧ “parties shall ensure” rather than rights holders

- ✧ Border measures, drug seizures, upon allegation of patent or TM infringement.
 - ✧ Seemingly may be initiated by firm or govt.
 - ✧ In-transit
 - ✧ 17 cases in Netherlands alone 2008



TRIPS-plus measures in the enforcement agenda

- ✧ Mandatory enforcement rights for licensees, rights management bodies (FTAs)
- ✧ Criminal penalties (“at least in cases”)
- ✧ Reduced hearing rights for alleged infringers
- ✧ Greater reporting requirements for alleged infringers
- ✧ Stronger wording on damages



A global industry IP enforcement strategy

- ✧ It's about more than adequately enforcing existing rights
 - ✧ TRIPS +, new obligations
- ✧ Seeks to change nature of patent, ©, and TM without legislative debate
 - ✧ Turn private rights into public rights
 - ✧ Seizures in place of litigation, injunctions in place of damages
 - ✧ Public enforcement in place of private vigilance



Public costs of the enforcement agenda

- ✧ Serious anti-competitive effects, health risks
- ✧ Aggressive monopoly enforcement = reduced competition, reduced access to medicines
- ✧ Prevent alleged violations, block & deter competition, rather than financial remedies after the fact
 - ✧ Very dangerous for medicines: stops legitimate generics, also chills financial incentives to market and trade in generics
- ✧ May snare non-infringing competitors in its net
 - ✧ May reduce liability of firms; increases potential for abuse



Public costs of the enforcement agenda

- ✧ Confusion

- ✧ Seeks to confuse public, reduce confidence in generics

- ✧ Opportunity cost

- ✧ Shifts public health investments and resources to industry-influenced priorities

- ✧ Public sector burdens

- ✧ Place cost of enforcing industry monopolies on taxpayers

- ✧ More counterfeits


- ✧ High prices drive supply and demand

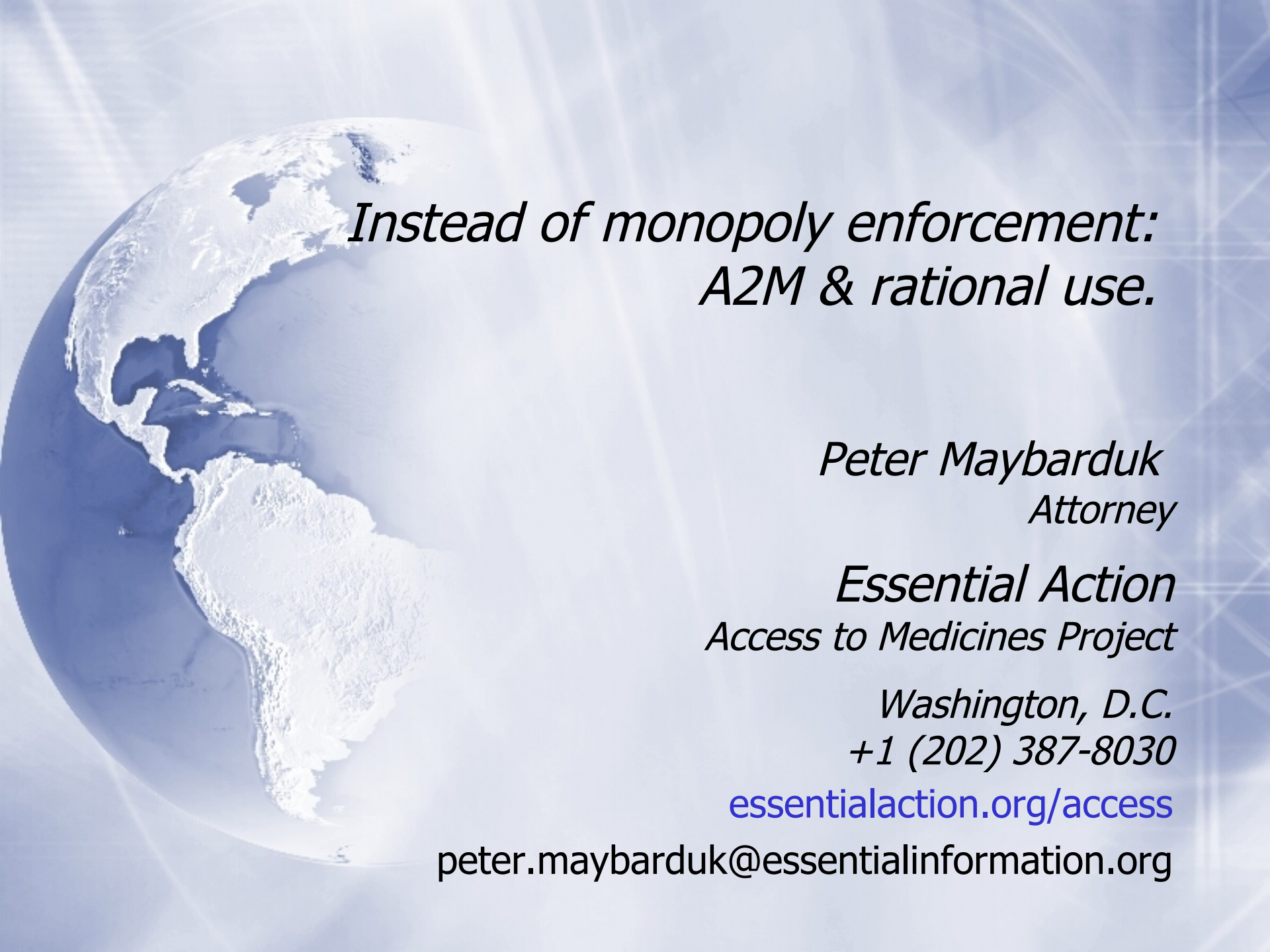


Recommendations

- ✧ Focus on **public concerns**, not private concerns: broader issue of drug quality, apply critical eye to enforcement agenda
- ✧ TACD resolution
 - ✧ **Make ACTA text public**; no negotiations until
- ✧ **Moratorium on drug seizures** for alleged patent infringement, pending EU investigation
- ✧ **Drug companies should be liable** for costs of wrongful seizures
 - ✧ Anti-abuse provisions, (waive sovereign immunity?)
- ✧ EU **investigate appropriation** of anti-counterfeiting measures by pharm. industry

Recommendations addressing drug quality

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- ✧ Concentrate on **strengthening drug regulatory authorities**: human resources, market surveillance
 - ✧ EU should commission **thorough study**, sampling-based, measuring and appropriately classifying drug quality issues
 - ✧ Discussions should use **precise terminology**: falsely labeled, substandard (contaminated, no active ingredient, too little AI, etc.)
 - ✧ Companies should be required to **disclose** knowledge of mislabeled medicines on the market
 - ✧ **Make medicines affordable**: reduced supplier incentives to counterfeit; reduced consumer need to seek out questionable, cheap alternatives



*Instead of monopoly enforcement:
A2M & rational use.*

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