

**Testimony of Manon Ress on behalf of
the Union for Affordable Cancer Treatment (UACT)**

United States International Trade Commission (USITC)
hearing on "Economic Impact of Trade Agreements
Implemented Under Trade Authorities Procedure,
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The Union for Affordable Cancer Treatment (UACT), is an international network of people who share the conviction that cancer treatment and care should be available everywhere for everyone, regardless of gender, age, nationality, or financial resources. Our web page is <http://cancerunion.org>.

We are a union of people -- people affected by cancer, their family members and friends, people who take care of people with cancer, health care professionals and cancer researchers -- committed to increasing access to effective cancer treatment and care.

I myself am a stage IV HER2 positive breast cancer patient in active treatment since May 2010. I am extremely fortunate to have access to the most advanced cancer treatment available. Thanks to successful and efficient treatments, my cancer as for many cancer patients has become a chronic disease. It is costly and will be more and more costly for all of us as the price of insurance will increase to keep up with the many cancer patients living for longer and longer time.

We believe that cancer medicines and other essential medical tools, such as diagnostic tests, should be affordable. They are not, and things are getting worse.

Like many patients, caregivers, doctors, insurers... and policymakers, we are extremely concerned about the rapidly escalating cost of cancer medication.

For example, according to one large private payer of health care: the average per cycle cost of cancer drugs in 2014 was almost \$18,650. The least expensive 2014 cancer drug is \$7,400 every 4 weeks and the most expensive is \$89,000 every 6 weeks.

Appendix A to this testimony is a table and a chart based upon data on cancer drug prices compiled by Dr. Peter Bach, based upon a methodology he developed earlier for an article on cancer drug pricing in the *New England Journal of Medicine*¹ and recently updated. Dr. Bach calculates the monthly cost of new cancer drugs, at the time of the introduction of the medicine.

¹ N Engl J Med 2009;360:626-33. DOI: 10.1056/NEJMhpr0807774.

We added a calculation of the monthly price as a percentage of the average monthly per capita income, as measured by the Gross National Income (GNI), reported by the World Bank.

As you can see from the table and the graph, the initial prices for cancer drugs have increased sharply, not only in nominal and inflation adjusted terms, but as a percent of average per capita incomes.

Dr. Bach's data includes 101 cancer drugs put on the market from 1965 to 2008, and of these, just 8 had monthly prices more than average monthly incomes.

However, of the 40 new cancer drugs placed on the market from 2009 to 2014, all 40 had monthly prices higher than average monthly incomes. But it is even worse. 26 of these drugs had monthly prices that were more than twice average monthly incomes.

The median price as a percentage of income was 27 percent for the drugs put on the market from 1965 to 1999, 127 percent for the drugs put on the market from 2000 to 2008, and 231 percent, for the cancer drugs approved from 2009 to 2014. This trend should worry everyone, since everyone is paying the taxes and private insurance premiums.

Managers or private or government insurance programs often respond to high prices by narrowing the allowed uses of the expensive medicines, requiring high patient co-payments,

Rationing is not an acceptable solution, to me, and to the many persons living with cancer, who would benefit from new drugs, including those with excessive prices.

If patients lack access to government or private insurance, one response is to go without, a heartbreaking response for those affected by the cancer. 'Going without' should be seen for what it is - a form of rationing by ability to pay.

In this regard, UACT has two messages for those shaping trade policy.

First, protect the right of governments to take measures to curb expensive prices for drugs. This includes the measures necessary to facilitate a competitive supply of affordable biologic drugs, and includes addressing, and overcoming when necessary, the barriers to competition such as patents, monopolies on test data, and providing access to manufacturing know how.

In our opinion, when the prices are excessive, it is important to put the monopoly at risk, and not the patients, and trade agreements need to recognize the importance of exceptions to intellectual property rights.

More generally, there has been a failure in all the trade agreements to address the most important issue regarding innovation, and that is the funding of research and development. High drug prices have an impact on R&D spending, but only to induce a minor fraction of drug

revenues into R&D. Remember, when a pharmaceutical company spends 15 percent of revenue on R&D, they spend 85 percent on things that have nothing to do with R&D. So high prices is an expensive and harmful way to induce R&D spending.

What all of the trade agreements lack are measures to induce more R&D spending through other mechanisms, such as de-linkage from drug prices.

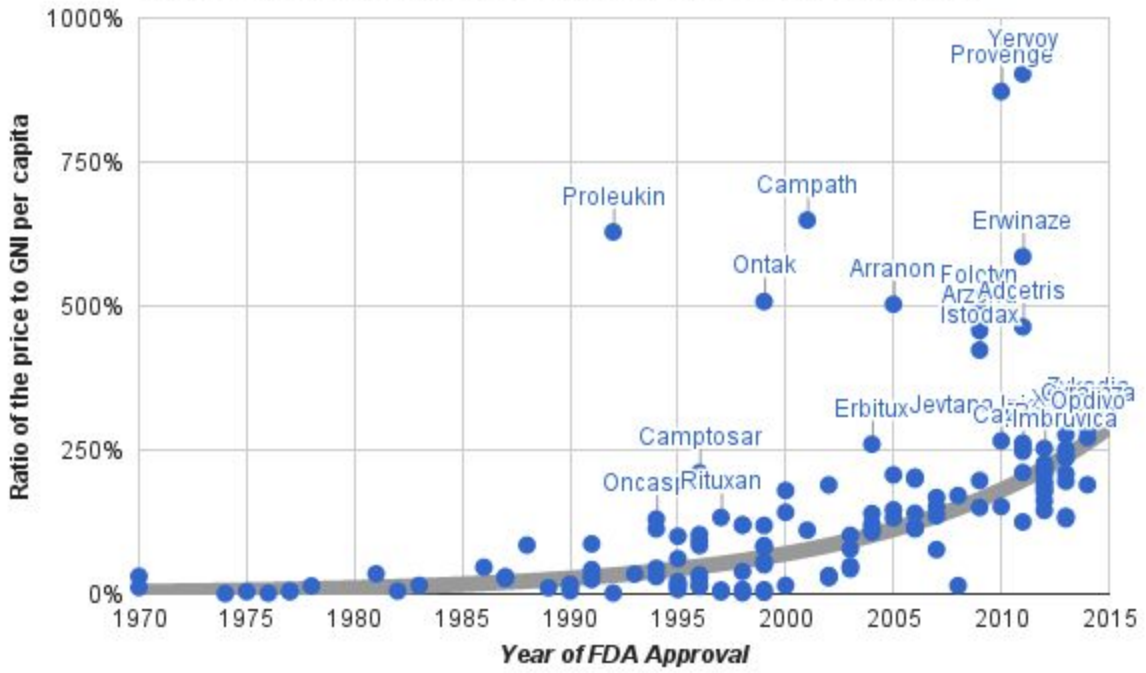
Note that in 2014, 9 of 10 new cancer drugs qualified from the Orphan Drug Tax Credit, a 50 percent subsidy for R&D that only US taxpayers subsidize. The NIH spends more than \$30 billion on research, much of it related to new drug development. What trade agreements lack are effective mechanisms or indeed any mechanism to expand public sector funding of R&D, or share the costs of subsidies like the Orphan drug tax credit.

By choosing to focus on intellectual property rights instead of research and development of new drugs, and by effectively promoting high prices instead of innovation and health, trade policy makers are elevating drug company interests over the public, including patients, taxpayers and employers.

Table 1: Counts from Annex 1, on ratio of monthly price to monthly income

(a) Years	(b) Number of cancer drugs, by year put on the market	(c) Number of drugs with monthly prices equal to or greater than 200% of monthly incomes	(d) Number of drugs with monthly prices less than 200% of monthly incomes	(e) Number of drugs with monthly prices greater than 100% of monthly incomes	(f) Median ratio of monthly prices to monthly incomes
2009-2014	40	26	14	40	231%
2000-2008	34	5	29	25	127%
1966-1999	67	3	64	11	27%

Ratio of monthly price to monthly GNI per capita



Annex 2: the U.S. has an aging population

The fact that cancer drug prices are rising is of particular concern to countries with older populations, given the rising incidence of cancer as we grow older. Table 2 reports the percent of the population ages 65 or older, for the United States and 19 countries that have regional or bilateral trade agreements with the United States, not including the yet to be approved Trans Pacific Partnership (TPP), or the yet to be negotiated TransAtlantic Trade and Investment (TTIP) agreement. Among the 19 countries, Australia and Canada have similar demographics to the United States. But the other 17 countries have younger populations, and in some cases, much younger populations. To the extent that high cancer drug prices are costs borne by employers, either directly or as taxpayers, U.S. business are less competitive in world markets, because we face a higher burden of cancer related disease.

Table 2: Percent of Population age 65 and above, United States and its partners in bilateral trade agreements

	Percent of Population age 65 and above, 2014 ²
Australia	14.7
Bahrain	2.4
Canada	15.7
Chile	10.7
Colombia	6.8
Dominican Republic	6.5
Costa Rica	8.6
El Salvador	8
Guatemala	4.8
Honduras	4.7
Nicaragua	5
Israel	11
Jordan	3.8
Korea, Rep.	12.7
Morocco	6.1
Oman	2.5
Panama	7.4
Peru	6.7
Singapore	11.1
United States	14.4

Note that due to declining fertility rates and increasing life expectancy, older people will steadily increase as a proportion of the our population. Indeed, the percentage of persons who are 65 years or older is expected to exceed 20 percent, or one in five persons, by the year 2030.³

² Source: World Bank.

³ An Aging Nation: The Older Population in the United States: Population Estimates and Projections. Current Population Reports, Issued May 2014,P25-1140. <https://www.census.gov/prod/2014pubs/p25-1140.pdf>

Annex 1: Ratio of monthly price to average monthly incomes, by year of approval

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Generic Name	BrandName	Year of FDA Approval	Ratio of monthly price to monthly GNI per capita	GNI per capita, year of approval	Monthly Medicare Price (USD, unadjusted, at time of approval)
vinblastine	Velban	1965	24%	\$3,880	\$78
thioguanine, 6-TG	Thioguanine Tabloid	1966	5%	\$4,200	\$17
hydroxyurea	Hydrea	1967	4%	\$4,380	\$14
cytarabine	Cytosar-U, TarabinePFS	1969	3%	\$5,080	\$13
procarbazine	Matulane	1969	0%	\$5,080	\$2
testolactone	Teslac	1969	42%	\$5,080	\$179
mitotane	Lysodren	1970	31%	\$5,260	\$134
plicamycin	Mithracin	1970	11%	\$5,260	\$50
mitomycin C	Mutamycin	1974	1%	\$8,000	\$5
dacarbazine	DTIC-Dome	1975	4%	\$8,530	\$29
lomustine	CeeNU	1976	1%	\$8,980	\$10
carmustine	BiCNU, BCNU	1977	4%	\$9,610	\$33
tamoxifen citrate	Nolvadex	1977	5%	\$9,610	\$44
cisplatin	Platinol	1978	14%	\$10,790	\$125
estramustine	Emcyt	1981	35%	\$14,400	\$420
streptozocin	Zanosar	1982	5%	\$14,230	\$61
etoposide, VP-16	Vepesid	1983	15%	\$14,590	\$181
interferon alfa 2a	RoferonA	1986	46%	\$19,160	\$742
daunorubicin, daunomycin	Cerubidine	1987	30%	\$21,460	\$533
doxorubicin	Adriamycin	1987	29%	\$21,460	\$521
mitoxantrone	Novantrone	1987	27%	\$21,460	\$477
ifosfamide	IFEX	1988	85%	\$23,580	\$1,667
flutamide	Eulexin	1989	11%	\$23,860	\$213
altretamine	Hexalen	1990	17%	\$24,150	\$341
idarubicin	Idamycin	1990	11%	\$24,150	\$227
levamisole	Ergamisol	1990	5%	\$24,150	\$105
carboplatin	Paraplatin	1991	42%	\$24,370	\$860
fludarabine phosphate	Fludara	1991	33%	\$24,370	\$662
pamidronate	Aredia	1991	25%	\$24,370	\$507
pentostatin	Nipent	1991	87%	\$24,370	\$1,767
aldesleukin	Proleukin	1992	629%	\$25,780	\$13,503
melphalan	Alkeran	1992	2%	\$25,780	\$35
cladribine	Leustatin, 2-CdA	1993	35%	\$26,480	\$764
asparaginase	Elspar	1994	30%	\$27,750	\$694
paclitaxel	Taxol	1994	113%	\$27,750	\$2,614
pegaspargase	Oncaspar	1994	130%	\$27,750	\$3,006
vinorelbine	Navelbine	1994	45%	\$27,750	\$1,035
anastrozole	Arimidex	1995	8%	\$29,150	\$189

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bicalutamide	Casodex	1995	13%	\$29,150	\$311
doxorubicin liposomal	Doxil, Dox-SL, Evacet, LipoDox	1995	61%	\$29,150	\$1,488
goserelin acetate	Zoladex	1995	17%	\$29,150	\$415
porfimer sodium	Photofrin	1995	21%	\$29,150	\$520
tretinoin, ATRA	Vesanoid	1995	100%	\$29,150	\$2,435
bleomycin	Blenoxane	1996	17%	\$30,380	\$421
daunorubicin liposomal	DanuoXome	1996	33%	\$30,380	\$847
etoposide phosphate	Etopophos	1996	27%	\$30,380	\$685
gemcitabine	Gemzar	1996	84%	\$30,380	\$2,129
irinotecan	Camptosar	1996	210%	\$30,380	\$5,326
nilutamide	Nilandron	1996	13%	\$30,380	\$320
topotecan	Hycamtin	1996	93%	\$30,380	\$2,344
docetaxel	Taxotere	1996	103%	\$30,380	\$2,610
letrozole	Femara	1997	7%	\$31,390	\$180
rituximab	Rituxan	1997	133%	\$31,390	\$3,475
toremifene	Fareston	1997	4%	\$31,390	\$93
BCG Live	TICE BCG	1998	2%	\$32,150	\$53
capecitabine	Xeloda	1998	39%	\$32,150	\$1,045
leuprolide acetate	Eligard, Lupron, Lupron Depot	1998	8%	\$32,150	\$206
trastuzumab	Herceptin	1998	120%	\$32,150	\$3,208
valrubicin	Valstar	1998	120%	\$32,150	\$3,209
bexarotene	Targretin	1999	84%	\$33,780	\$2,361
busulfan	Busulfex(Myleran)	1999	51%	\$33,780	\$1,427
cytarabine liposomal	DepoCyt, DepoFoam	1999	119%	\$33,780	\$3,351
denileukin	Ontak	1999	508%	\$33,780	\$14,291
epirubicin	Ellence	1999	82%	\$33,780	\$2,295
exemestane	Aromasin	1999	7%	\$33,780	\$205
methoxsalen	Uvadex	1999	3%	\$33,780	\$80
temozolomide	Temodar	1999	56%	\$33,780	\$1,574
arsenic trioxide	Trisenox	2000	180%	\$36,070	\$5,400
gemtuzumab ozogamicin	Mylotarg	2000	142%	\$36,070	\$4,262
triptorelin pamoate	TrelstarDepot	2000	15%	\$36,070	\$450
alemtuzumab	Campath	2001	649%	\$36,840	\$19,925
imatinib mesylate	Gleevec	2001	111%	\$36,840	\$3,401
fulvestrant	Faslodex	2002	30%	\$37,470	\$948
ibritumomab tiuxetan	Zevalin	2002	32%	\$37,470	\$1,000
oxaliplatin	Eloxatin	2002	189%	\$37,470	\$5,911

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zoledronic acid	Zometa	2002	28%	\$37,470	\$881
abarelix	Plenaxis depot	2003	78%	\$39,950	\$2,607
bortezomib	Velcade	2003	102%	\$39,950	\$3,392
gefitinib	Iressa	2003	48%	\$39,950	\$1,608
tositumomab	Bexxar	2003	44%	\$39,950	\$1,449
azacitidine	Vidaza, Mylosar	2004	107%	\$43,680	\$3,909
bevacizumab	Avastin	2004	122%	\$43,680	\$4,429
cetuximab	Erbitux	2004	260%	\$43,680	\$9,465
erlotinib	Tarceva	2004	115%	\$43,680	\$4,174
pemetrexed disodium	Alimta	2004	140%	\$43,680	\$5,086
lenalidomide	Revlimid	2005	207%	\$46,340	\$7,989
nelarabine	Arranon	2005	503%	\$46,340	\$19,425
paclitaxel albumin - stabilized nanoparticle formulation	Abraxane, Nanoparticle Paclitaxel	2005	146%	\$46,340	\$5,640
sorafenib	Nexavar	2005	132%	\$46,340	\$5,097
dasatinib	Sprycel	2006	113%	\$48,080	\$4,529
decitabine	Dacogen	2006	116%	\$48,080	\$4,652
panitumumab	Vectibix	2006	199%	\$48,080	\$7,991
sunitinib maleate	Sutent	2006	115%	\$48,080	\$4,590
thalidomide	Thalomid, Synovir	2006	140%	\$48,080	\$5,613
vorinostat	Zolinza	2006	203%	\$48,080	\$8,134
ixabepilone	Ixempra	2007	167%	\$48,640	\$6,781
lapatinib ditosylate	Tykerb	2007	77%	\$48,640	\$3,124
nilotinib	Tasigna	2007	151%	\$48,640	\$6,140
temsirolimus	Torisel	2007	136%	\$48,640	\$5,497
degarelix	Firmagon	2008	14%	\$49,330	\$595
bendamustine HCL	Treanda	2008	171%	\$49,330	\$7,026
everolimus	Afinitor	2009	197%	\$48,050	\$7,885
pralatrexate injection	Folotyn	2009	493%	\$48,050	\$19,732
pazopanib	Votrient	2009	150%	\$48,050	\$6,013
romidepsin	Istodax	2009	424%	\$48,050	\$16,958
ofatumumab	Arzerra	2009	457%	\$48,050	\$18,315
cabazitaxel	Jevtana Injection	2010	266%	\$48,950	\$10,842
sipuleucel-T	Provenge	2010	872%	\$48,950	\$35,588
eribulin mesylate	Halaven	2010	152%	\$48,950	\$6,193
ipilimumab	Yervoy	2011	903%	\$50,450	\$37,956
vandetanib	Caprelsa	2011	248%	\$50,450	\$10,413
abiraterone acetate	Zytiga	2011	125%	\$50,450	\$5,259
vemurafenib tablets	Zelboraf	2011	256%	\$50,450	\$10,767

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brentuximab vedotin	Adcetris	2011	464%	\$50,450	\$19,495
crizotinib	Xalkori	2011	262%	\$50,450	\$11,011
asparaginase Erwinia chrysanthemi	Erwinaze	2011	586%	\$50,450	\$24,622
ruxolitinib phosphate	Jakafi	2011	211%	\$50,450	\$8,865
axitinib	Inlyta	2012	212%	\$52,540	\$9,291
vismodegib	Erivedge	2012	195%	\$52,540	\$8,546
ziv-aflibercept	Zaltrap	2012	253%	\$52,540	\$11,063
enzalutamide	Xtandi	2012	162%	\$52,540	\$7,078
bosutinib	Bosulif	2012	189%	\$52,540	\$8,287
regorafenib	Stivarga	2012	220%	\$52,540	\$9,620
omacetaxine mepesuccinate	Synribo	2012	145%	\$52,540	\$6,357
cabozantinib	Cometriq	2012	227%	\$52,540	\$9,921
ponatinib	Iclusig	2012	208%	\$52,540	\$9,104
carfilzomib	Kyprolis	2012	182%	\$52,540	\$7,959
pertuzumab	Perjeta	2012	177%	\$52,540	\$7,758
ado-trastuzumab emtansine	Kadcyla	2013	236%	\$54,070	\$10,635
pomalidomide	Pomalyst	2013	252%	\$54,070	\$11,336
trametinib	Mekinist	2013	196%	\$54,070	\$8,812
dabrafenib	Tafinlar	2013	209%	\$54,070	\$9,411
Ra 223	Xofigo	2013	276%	\$54,070	\$12,455
ibrutinib	Imbruvica	2013	242%	\$54,070	\$10,900
obinutuzumab	Gazyva	2013	130%	\$54,070	\$5,878
afatanib	Gilotrif	2013	135%	\$54,070	\$6,071
ceritinib	Zykadia	2014	297%	\$55,200	\$13,672
ramucirumab	Cyramza	2014	288%	\$55,200	\$13,256
pembrolizumab	Keytruda	2014	190%	\$55,200	\$8,725
blinatumomab	Blinicyto	2014	1397%	\$55,200	\$64,260
nivolumab	Opdivo	2014	272%	\$55,200	\$12,500

Data Sources: GNI per capita is from the World Bank. Monthly cancer drug prices provided by Dr. Peter Bach, Center for Health Policy & Outcomes, Memorial Sloan-Kettering Cancer Center. <https://www.mskcc.org/research-areas/programs-centers/health-policy-outcomes/cost-drugs>. See also: Bach PB. Limits on Medicare's ability to control rising spending on cancer drugs. N Engl J Med. 2009 Feb 5;360(6):626-33.